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Editorial

"UNSUNG HEROES"– The facts revealed from the files

By Kamal Pratap Singh

Corresponding Author: kamal9871@gmail.com

In the article "UNSUNG HEROES: the rise of Shantha Biotech, talk with Prof. Ramareddy Guntaka – the scientific brain behind the unparalleled success", published in October 2019 issue of Biotech Express Magazine, I tried to present the facts that how a big biotech company was built and made to run through the perspective of a scientist. When 82 years old Dr. Ramareddy V Guntaka approached me to do a story, I felt curious and went ahead to know more about the genesis of India's first big biotech firm – the Shantha Biotech Ltd. and the pivotal role he played.

Dr Guntaka's CV tells us that he is a Professor(-Tenured), in Department of Molecular Sciences, College of Medicine, University of Tennessee Health Science Center, Memphis. He worked as Scientific Advisor to Cancer Research Center, Columbia, to Shantha Biotechnics Pvt. Ltd., Hyderabad (1993-2000) and to Sudershan Biotech Ltd., Hyderabad (1999-present). He worked as Asst. Research Microbiologist in University of California during 1973-75 in the laboratory of JM Bishop and HE Varmus, who later got Nobel Prize in 1989. He talked extensively how Dr Varaprasad Reddy (VR, the founder of Shantha Biotech) ditched him and finally advised public-spirited scientists like him to be less naïve.

"Success has many fathers", the proverb says. It implies that while there can only be one biological father, there will be several claimants who falsely claim that they fathered the child. In the matters concerning commercialization of scientific research, it is normally a team work that brings out a product. It is difficult for outsiders/others to ascertain which team member did which aspect of the research.

So I tried to approach Dr Varaprasad and record his version before publishing the article. Though many mails were sent to him, we could not get

any reply from his side due to organizational problems at his end. I could not talk to him directly as most of the time he was travelling. After months of waiting, I have published the interview of Prof Guntaka in October 2019 issue of Biotech Express. After the publication, it came to the notice of Dr Varaprasad and he called me and let me know the facts and I got the complete picture, thus the points to recollect are:

1) Dr. Guntaka repeatedly claimed in his interview that Dr Varaprasad had not acknowledged his contribution in initial days of Shantha Biotech and cornered all the credit to himself. The fact is - Dr Varaprasad always described himself as an engineer and never claimed that he was a Biotech scientist who designed the vaccines. As an entrepreneur, he projected his scientists in high esteem and though Dr. Guntaka's association with Shantha lasted only for a few years out of 27 years of Shantha's journey, he hailed him and his service to the cause on many occasions. This can be found in 5 books published by Government of India, Ministry of Science and other publishing houses and his own autobiography along with several public speeches, Dr Varaprasad mentioned Dr Guntaka's name and described his contribution.

2) The fact remains that though Dr. Guntaka's role was pioneer in Shantha's scientific journey in initial days, his role ended with cloning and the rest of the work to make it full product by scaling up, downstream processing, validation to the commercial stage; clearing several scientific screening committees like RCGM, GEAC, DCGI for pre-clinical and clinical studies was handled by many others.

3) In his interview Dr. Guntaka said that he got only a small amount of remuneration, less than originally understood (?). After sales of Shanvac-B started, Shantha paid him 1.5% on sales for two years, and finally settled his account by paying a lump sum of Rs. 70 lakhs (in 1999) for which Dr. Guntaka agreed.

4) Regarding Hepatitis-C vaccine, Dr. Guntaka made a commitment to Shantha to develop it but shifted to Deccan College after a while. Though in his interview Dr. Guntaka claimed that he did not receive a penny, Shantha Biotech reimbursed his scientific expenses for the process.

5) Regarding 5% of shares, Dr Varaprasad agreed that he indeed offered Dr. Guntaka, when he first met him as compensation to his future co-operation for the product. Citing patriotism, Dr. Guntaka rejected his offer, and Dr Varaprasad mentioned this on various platforms and forums. So, there was no written agreement and the issue was not raised in board meetings too. After some time, Dr. Guntaka asked Dr Varaprasad to let his nephew Dr. Kodandaram Reddy to buy the stock in the company for $42,000. Shantha made him a director and he continued in that position for 16 long years until Sanofi took major stock in Shantha.

After getting the complete picture, I understood that things are not as straight as they look. Dr Varaprasad's acknowledgement of Dr. Guntaka's contribution and payments made through company can be ascertained by looking into the books and accounts. But in the absence of written agreement, what transpired between two persons can never be claimed or crosschecked. The writer wishes to end this view of story/article for further analysis and publication, without paying further attention in this regard.

Editorial in News

Prof Ashok Pandey felicitated at 54th Annual Day of CSIR-IITR

Photo: Prof Alok Dhawan, Director, CSIR-IITR,(Left) Prof Ashok Pandey, Distinguished Scientist CSIR-IITR(middle) and Prof P Balram(Right).

Professor Pandey is currently Distinguished Scientist at CSIR-Indian Institute for Toxicology Research, Lucknow, India and Honorary Executive Director at the Centre for Energy and Environmental Sustainability- India.

Formerly, he was Eminent Scientist at the Center of Innovative and Applied Bioprocessing, Mohali and Chief Scientist & Head of Biotechnology Division at CSIR's National Institute for Interdisciplinary Science and Technology at Trivandrum. His major research and technological development interests are in industrial and environmental biotechnology, which span over biomass to fuels & chemicals, waste to wealth/energy, industrial enzymes, solid-state fermentation, etc.

Professor Pandey has ~ 1275 publications/communications, which include 16 patents, 63 books, 650 papers and book chapters, etc with h index of 91 and >36,000 citations (Goggle scholar). He has transferred several technologies to industries and has done industrial consultancy for about a dozen projects for Indian/international industries.

Prof Pandey is Editor-in-chief of Bioresource Technology, Honorary Executive Advisors of Journal of Water Sustainability and Journal of Energy and Environmental Sustainability, Subject editor of Proceedings of National Academy of Sciences (India) and editorial board member of several international and Indian journals.

Living legend award instituted on the name of Prof Ashok Pandey

International Bioprocessing Association (France) together with Henan Agriculture University China has instituted a living legend category award in the name of Prof Ashok Pandey. Award is known as Pandey award and has been conferred to four people (one from Australia, one from India and two from China) in its first edition. These were conferred on 3rd November 2019 at Zhengzhou China. Dr P Binod from CSIR-NIIST received it from India.

IFIBiop networking forum results from the round table organised during the meeting ICBF-2004 (International Congres in Bioprocesses in Food industrues) which was held in Clermont-Ferrand, France. It aim is the organisation of an efficient and structured networking in the field of biochemical and food engineering.

It covers the following topics :

• Food and Raw Materials Characterization and Properties: Equilibrium properties: aw, pH, antioxidant, Transport, Rheological, Chemical, Sensory & Nutritional properties, etc...

• Biocatalysis and Food Biotechnology: Microbiology of food, GMO foods, Predictive microbiology (risk assessment), Microorganisms detection, Enzyme and biocatalysis improvement, etc...

• Bioprocess engineering for Food and Feed products Development: Rational process development, Reactor design, Downstream processing, Waste and by-products treatment (environmental care), Food preservation (oxidative stability, antimicrobials…), Food packaging, Life cycle assessment, Sensors, etc...

• Bioprocess engineering for bioindustries: environmental engineering, biofuels, bioremediation, white and green biotechs, etc...

It allows partners to keep in touch to look for the networking for scientific projects, the exchange of students and faculties. This platform is opened to everyone wishing to contribute and participate on the above topics.

NEWS IN FOCUS

Govt issues draft notification to bring all medical devices under single regulatory framework

To ensure that all imported as well locally made medical devices meet certain quality standards, the health ministry has proposed to regulate all such equipment used on human beings or animals. The union health ministry has come out with the draft notification, making it mandatory for all the devices to get certified by the Central Drugs Standard Control organisation (CDSCO), India's drug regulatory authority.

According to the draft notification dated Oct 18, "In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings or animals as drugs with effect from the 1st day of December, 2019," the draft notification reads.

At present, only 23 medical devices are regulated under the Drugs and Cosmetics (D&C) Act.

According to the draft notification, while certification by the regulatory authority will be on voluntary basis up to 18 months from date of notification, thereafter it will be made mandatory.

The country's top advisory body on drugs, the Drugs Technical Advisory Board (DTAB), had in April recommended that all medical devices should be notified as drugs under the existing Drugs and Cosmetics Act.

ET had first reported about the government's agenda to bring medical devices under regulation. The government decided to update its review process in the wake of recent case of Johnson & Johnson (J&J) hip implants which left many people permanently disabled due to the faulty device.

As part of the draft notification, "all devices, including instruments, apparatus, appliances and implants, whether used alone or in combination for various purposes like diagnosis, prevention, monitoring, treatment, alleviation of any disease, investigation, replacement or modification or support of the anatomy among others", will be regulated under the legislation. Such medical devices also include those which are used for the purpose of supporting or sustaining life, disinfection of medical devices and control of conception.

Rajiv Nath, Forum Coordinator, AiMeD "What's missing in covering note is assured road map to a separate medical devices law with a defined transition period and in a phased manner, in addition to the voluntary registration as a temporary measure under the current Drugs Act".

The stakeholders have been given a month to respond to the draft notification.

The manufacturers, importers will have to upload information about their devices on the "Online System for Medical Devices" established by CDSCO for this purpose. Once the information is uploaded a registration number will be generated which the manufacturers will have to put on the label of the medical device. The manufacturers will also have to have certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of their medical device.

The importers will also have to also obtain free sale certificate from country of origin before they enter the Indian market.

Once notification comes into effect, the Central Drugs Standard Control organisation (CDSCO) will be the nodal authority to investigate quality, safety related failure, complaints and can suspend the registration based on the outcome of investigation. Currently there is no mechanism for reporting the malfunctioning of non-notified medical devices. Once notified, there will be an effective product recall system, inspection of manufacturing sites by CDSCO.

India's Lupin targets generic potential of biotech drugs

India's third-largest drugmaker by sales, Lupin, has diversified into biosimilars -- cheaper versions of expensive biotech drugs -- in a bid to stimulate growth amid a slowdown in recent years.

Lupin plans to supplement its traditional

business in generics and specialty drugs with biosimilars slated for launch in Japan, Europe and other markets by the end of the year, Lupin Biotech President Cyrus Karkaria told the Nikkei Asian Review.

The market for biosimilars is now dominated by bigger players, such as Switzerland-based Novartis and American groups Amgen and Pfizer, as well as South Korea's Celltrion. The entry of a major Indian drugmaker will heat up competition.

More than 100 Indian biopharmaceutical companies are engaged in the manufacturing and marketing of biosimilars, consultancy Frost & Sullivan estimates.

Lupin suffered another setback in December when the FDA raised concerns about its Mandideep facility in the Indian state of Madhya Pradesh. The plant is now subject to regulatory or administrative action, and the FDA may withhold approval of any pending applications that list the facility. The company announced on May 15 that net profit after exceptional items increased to 6 billion rupees ($85.4 million) for the year ended in March, but that was only one-fourth the level of two years ago.

HDFC Securities analyst Amey Chalke feels that while a number of Indian companies have a head start in biosimilars, Lupin took a different route: first establishing itself in the U.S. with legacy products as regulators sorted out rules for the relatively new biotech sector. "What [Lupin] is also trying to do now is to build niche products that have fewer potential competitors," Chalke said.

Transasia - Erba group to enter the Rs. 300 crore molecular diagnostics space in India

Transasia Bio-Medicals Ltd., India's leading IVD Company today announced that it will soon be foraying into the Rs. 300 crore Indian molecular diagnostics space.

It unveiled the MX 16, a fully automated nucleic acid extractor, at the 50th Union World Conference on Lung Health and TB in Hyderabad. The MX 16 has been developed by Erba Molecular, a UK subsidiary of the Transasia-Erba group.

The new system will offer an easy-to-use and lower priced molecular TB test in India, with the goal of replacing traditional smear microscopy.

The system will be particularly beneficial to India, which has the highest burden of TB and drug-resistant TB: one in four TB patient globally are in India. Also, 89% of affected individuals in India are in the productive age group 15-69, which makes it a critical national health issue to be addressed.

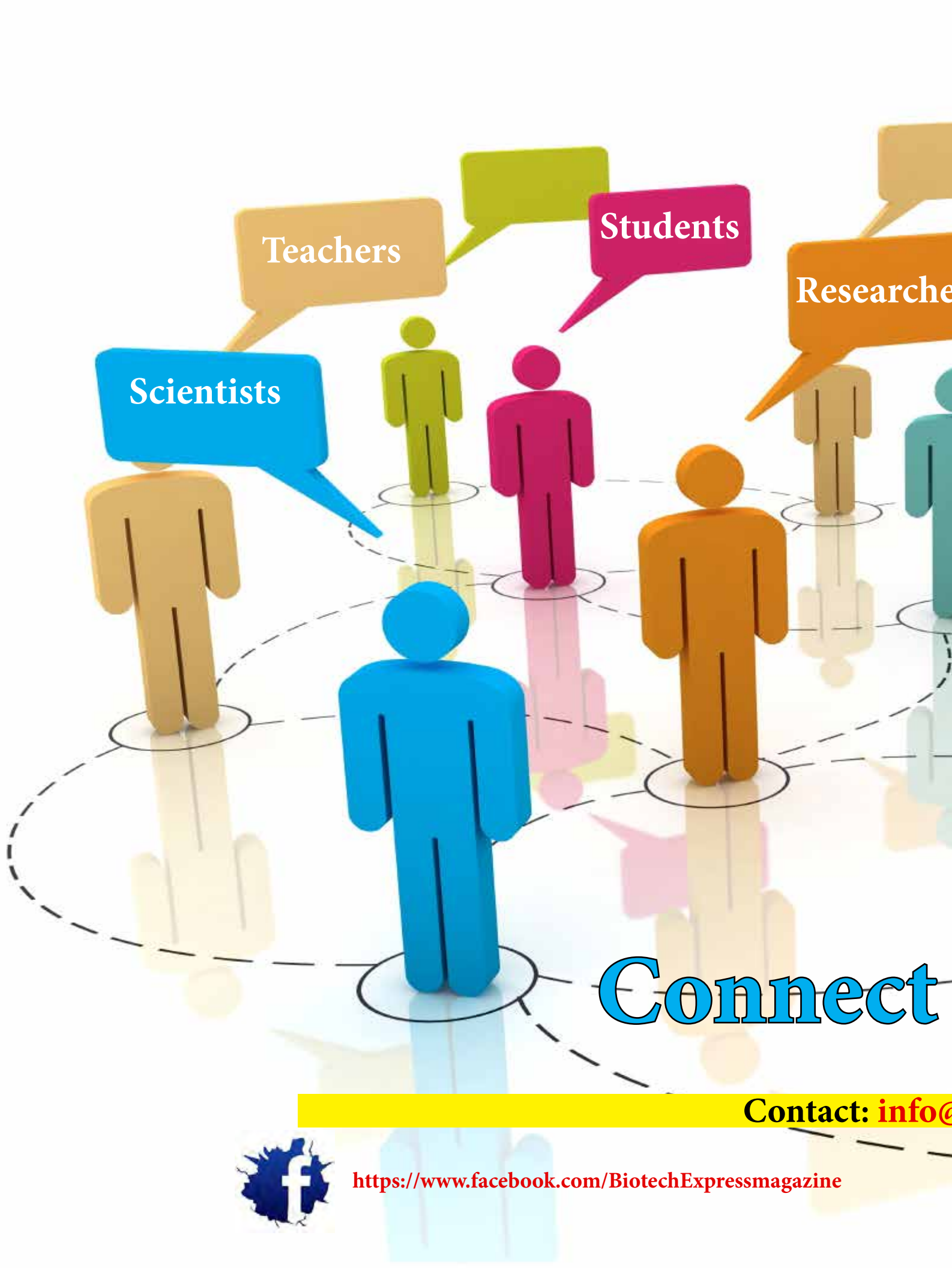
Though TB incidence in India has been declining at 1.7% annually since 2016, it is estimated that it needs to fall by 10% annually to reach the Government's 2025 goal of ending TB in the country. Currently a significant number of TB patients remain undiagnosed for long and out of those diagnosed, only 65% of cases in India are treated.

About Transasia Bio-Medicals Ltd.:

Founded in 1979, Transasia Bio-Medicals Ltd., India's Leading In-vitro Diagnostic Company offers products and solutions in Biochemistry, Hematology, Coagulation, ESR, Immunology, Urinalysis, Critical Care, Diabetes Management, Microbiology and Molecular Diagnostics. It provides doctors and patients with reliable, affordable and innovative diagnostic systems, with 70,000+ installations across India. It has a network of 300 service engineers, 400+ sales and marketing team, 24 zonal offices and 350+ distributors. It is the first Indian company to manufacture and export blood analyzers and reagents, in the 1990s.

Transasia's indigenous research has resulted in development of state of the art, 'Make in India' products and technologies, enabling its products to be among the best in the world. All along its journey spanning four decades, Transasia has been recognized for its commitment to healthcare. It has been conferred 'The Economic Times Best Brands 2019' award, 'India Medical Device - Export Company of the Year' and the 'Global Growth Company-2014' award by the World Economic Forum among many others.

Headquartered in Mumbai, Transasia is a part of the Transasia-Erba group which has footprint across USA, UK, Germany, Czech Republic, France, Italy, Russia and Turkey through various acquisitions and serves millions across 100 countries. Its' production sites in India, Czech Republic and US and R&D centres in France, UK, India and Czech Republic form a hub for world class, indigenous research and manufacturing. Do visit www.erbamannheim.com for details.



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PRESS RELEASE

Government of India
Ministry of Science and Technology

Department of Biotechnology Monthly Cabinet Summary September-2019

1. **Important policy decisions taken and major achievements during the month:**

a. **Launch of UMMID - Unique Methods of Management and treatment of Inherited Disorders & Inauguration of NIDAN - National Inherited Diseases Administration Kendra Network**

Dr. Harsh Vardhan, Hon'ble Union Minister for Science & Technology, Earth Sciences and Health & Family Welfare launched UMMID (Unique Methods of Management and treatment of Inherited Disorders) Initiative and inaugurated NIDAN (National Inherited Diseases Administration) Kendras on 23rd September 2019.

The whole initiative is based on the concept of 'Prevention is better than Cure'. The aim is (i) to establish NIDAN Kendras to provide counseling, prenatal testing and diagnosis, management, and multidisciplinary care in Government Hospitals wherein the influx of patients is more, (ii) to produce skilled clinicians in Human Genetics, and (iii) to undertake screening of pregnant women and new born babies for inherited genetic diseases in hospitals at aspirational districts; five NIDAN Kendras have been established to provide comprehensive clinical care. 7 training center have been setup and seven aspirational districts are being covered.

b. **Nobel Prize Series -2019**

The Department of Biotechnology (DBT), Ministry of Science and Technology and Nobel Media AB, Sweden in partnership with Government of Punjab organised third edition of the Nobel Prize Series -2019 from 11th -13th September, 2019 at National Agri-Food Biotechnology Institute (NABI), Mohali, Punjab Agriculture University (PAU), Ludhiana, Punjab and at Delhi. Theme of the event was "Teaching and Learning". More than 2500 students and research scholars got opportunity to get enlighten as well as more than 900 additional teachers and young faculties about unique activities of understanding Science and impact of Nobel Prize on science & society.

The occasion also marked the Nobel Prize Museum's world premiere of a new travelling exhibition "For the Greatest Benefit to Humankind," demonstrating contribution of Nobel Laureates. The exhibition will be open for public till second week of October, 2019.

c. **Indo-EU Cooperation**

DBT in partnership with European Commission (EC) announced a co-funding call under 'HORIZON 2020' for the year 2019-2020. Researchers and innovators from universities, research organisations and enterprises from India can team up with European partners in the calls for proposals published by the EC under this announcement.

DBT has agreed to participate in priority areas focusing majorly on Health, Demographic Change and Wellbeing, Food Security, Sustainable Agriculture and Forestry, Marine (Societal Challenge 2); Secure, Clean & Efficient Energy (Societal

Challenge 3) and Nanotechnologies, advanced materials, biotechnologies and advanced manufacturing and processing (NMBP)

d. Indo-Australian collaboration

Under the Indo-Australian collaboration, joint working group meeting of the DBT along with Department of Science & Technology (DST) and the Department of Industry, Innovation & Science (DIIS), Australia was held at Canberra, Australia on 6th September 2019. The agenda of the meeting was to firm up discussions to continue the collaboration in various areas through Research funding and exchange of students for capacity building. Delegates from Science and Commercialization Policy Division along with Trade & International Policy & Innovation Strategy, Australia as well as from DBT and Industry, Innovation & Science, India and DST, India were present.

e. An Inter Ministerial Committee Meeting to consider and finalize the documents on Biological Data Storage, Access and Sharing Policy of India was held on **16th September, 2019** in DBT, New Delhi under the Chairpersonship of Dr. Renu Swarup, Secretary, DBT.

f. There have been **59 research publications** and **10 patents** filed by the Autonomous Institutes of the Department.

2. Autonomous Institutions of the Department of Biotechnology- at Annexure I

3. Public Sector Undertaking (PSU) of the Department of Biotechnology – Annexure II

4. Important policy matters held up on account of prolonged inter ministerial consultations: N/A

5. Compliance of Cabinet/Cabinet Committee decisions: N/A

No. of COS decisions pending for compliance	Proposed action plan/timelines for compliance of COS decisions	Remarks
-	-	-

6. No. of cases of 'sanction for prosecution' pending for more than three months: Nil

7. Particulars of cases in which there has been a departure from the Transaction of Business

8. Rules or established policy of the Government: N/A

9. Status of implementation of e-governance:

Total No. of active files: **6938**	Total No. of e-files generated during August:**258**

10. Status of Public Grievances:

No. of Public Grievances redressed during	No. of Public Grievances pending at the end

month: **24**	of the month: **56**

11. **Information on the specific steps taken by the Ministry/ Department for utilization of the Space, Technology based tools and application in Governance and Development:** NIL

12. **Confirmation that the incumbency details of all posts in the Ministry/Department and its organizations falling under the purview of the ACC have been updated on AVMS:** It is confirmed that the incumbency details of all the posts in the Ministry/Department (both Autonomous institutes and PSUs under DBT) falling under the purview of the ACC have been updated on AVMS.

13. **Status regarding compliance of the directions of ACC. A paragraph on Cases in which the ACC directions have not been compiled with distinct heading:** It is also confirmed that the directions of ACC are complied with.

14. **Status of cases where recommendations from PESB have been received but the proposals are yet to be submitted to the ACC Secretariat:** It is stated that the same may be treated as 'Nil'

15. **Status of Government e- Marketplace (GeM):** Procurement made through GeM for the month of September, 2019 is NIL.

NEWS: Govt & Industry

Abbott's COO Robert B. Ford identified as New CEO after Miles White

Published: Nov 13, 2019

Illinois-based Abbott will have a new chief executive officer in 2020. Miles D. White will step down from his role as CEO following 21 years with the company. He will be succeeded by another long-time Abbott veteran, Robert B. Ford, who has been with the company for 23 years.

White will turn over the reins of the company on March 31, 2020. He has served as chairman and CEO since 1998. He will remain executive chairman of the board, the company said in its announcement. Ford is Abbott's current chief operating officer, a role he was tapped for last year. As the next CEO, he has been elected to a position on the company's board of directors. Ford will be the 13th CEO Abbott has had in its 131-year history. All of the company's CEOs have been appointed from within the ranks.

Looking back at his tenure at the helm of the company, White said one of his primary goals has been to leave Abbott "well-positioned" for the people who count on the company.

Over his tenure with Abbott, Ford has held numerous leadership roles. In addition to COO, he serves as president of the company. He has overseen Abbott's nutrition and medical device business. During his time overseeing the medical device business, Ford oversaw the integration of St. Jude Medical, Abbott's largest acquisition. Ford also led Abbott's diabetes care business unit and oversaw the launch of FreeStyle Libre, a sensor-based glucose monitoring system. Additionally, White oversaw the spinout of two successful companies, Hospira, which was acquired by Pfizer in 2015 and AbbVie, which markets the world's most popular drug, Humira, which was gained through the 2001 acquisition of BASF's Knoll pharmaceutical business.

"It is a tremendous honor to have the opportunity to lead Abbott," Ford said in a statement. "I thank Miles for his mentorship, and I look forward to working with my colleagues to do what Abbott people do best – anticipate where science, medicine and technology are going and innovate to best serve our customers, shareholders and communities."

Allergan's Forest Labs Pays $750 Million to Settle Class Action Suit over Alzheimer's Drug

Published: Oct 28, 2019

Allergan's subsidiaries, Forest Laboratories LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd. paid a total of $750 to settle a class action lawsuit over its Alzheimer's drug Namenda. Actavis, which later changed its name to Allergan, acquired Forest in June 2014.

The case was set to face trial on October 28, 2019.

The plaintiffs in the case alleged that Forest intentionally attempted to delay and impair generic competition of its immediate-release formulation of Namenda. The allegations included an illegal agreement with generic competitor Mylan, and then organizing a "'hard switch' product hop from immediate-release Namenda to extended-release Namenda XR. As a result of Forest's conduct, purchasers were injured because from the loss of earlier, unconstrained, lower priced generic competition."

Allergan and Forest attempted to have the case dismissed, but that was denied on September 13, 2016. Allergan did not admit to any wrongdoing when it finalized the settlement. It expects to take a pre-tax GAAP charge of $750 million in its third-quarter 2019 earnings.

In February 2014, Forest Laboratories announced plans to discontinue the sale of Namenda HCl 5mg and 10mg tablets effective August 15, 2014. It was going to continue marketing the oral Namenda and once-daily Namenda XR. Both were indicated for treatment of moderate to severe Alzheimer's disease.

At the time, Marco Taglietti, then Forest's chief medical officer and executive vice president, Drug Development and Research, stated, "Namenda XR offers important benefits, including convenient, once-daily dosing, which is particularly meaningful for this patient population and their caregivers. Our decision to focus on Namenda XR is supported by these benefits as well as the positive feedback we've received from physicians and caregivers since the launch of Namenda XR. This conversion also allows us to streamline our resources and explore innovative new compounds that may be effective for the treatment of Alzheimer's disease, including the fixed-dose combination of Namenda XR and donepezil, which is under development."

The company indicated at the time that doctors could change patients from Namenda to Namenda XR the next day without making dosage changes (titration).

It was noted in 2015 that both Dr. Reddy's Laboratory in India and Mylan had launched generic Namenda. As a result, Allergan expected a drop in Namenda sales of about $200 million.

In 2014, Namenda brought in $1.5 billion in revenue. However, the switch-over to Namenda XR reportedly involved 40% of its patients, which mitigated the generic competition to some extent. Allergan also launched an alternate, Namzaric, which combines the main ingredient from Namenda with the main ingredient from Aricept (donepezil), marketed by Eisai. Namzaric was launched in September 2016.

There was very clearly a drop in Namenda sales. In its fourth-quarter 2018 reporting, Namenda had net revenues in the fourth quarter 2018 of $1.07 million compared to $97.8 million in the same quarter in 2017. The company stated that this was caused by the patent loss of exclusivity for Namenda XR.

Since its launch in 2016, Namzaric sales have steadily grown and are expected to continue growing. Peak sales are forecast for 2025 of $574.1 million.

Amgen Invests $2.7 Billion in China's BeiGene with Plans to Develop 20 Pipeline Drugs

Published: Nov 01, 2019

Under the terms of the strategic collaboration, Amgen is paying about $2.7 billion in cash, or $174.85 per BeiGene American Depositary Share on the Nasdaq, which is a 36% premium to BeiGene's average share price over the last 30 days as of October 30. Amgen will nominate a person to BeiGene's board of directors.

Under the deal, BeiGene will commercialize Xgeva (denosumab), Kyprolis (carfilzomib) and Blincyto (blinatumomab) in China. The two companies will split profits and losses evenly. Two of them will revert to Amgen, one after five years, the other after seven years. After that commercialization period ends, BeiGene will be able to retain one product and receive royalties on China sales for another five years on the product rights it returns to Amgen.

Xgeva is used to treat bone metastases from solid tumors and multiple myeloma and launched in China in September. Kyprolis and Blincyto are currently in Phase III trials in China. Kyprolis is used to treat multiple myeloma. Blincyto is used to treat acute lymphoblastic leukemia (ALL).

The two companies will also collaborate on 20 drugs from Amgen's oncology pipeline in China and globally. BeiGene will invest up to $1.25 billion in research and development costs. Amgen will pay royalties to BeiGene on sales of any of these drugs outside of China except for AMG 510, which is being developed for solid tumors.

Amgen plans to continue to market its non-cancer drugs in China. For example, earlier this year it launched Repatha for cholesterol in China. It plans to launch several more outside of cancer in China over the next few years, including Prolia for osteoporosis.

"This strategic collaboration with BeiGene will enable Amgen to serve significantly more patients by expanding our presence in the world's most populous country," said Robert A. Bradway, Amgen's chairman and chief executive officer. "Cancer is a leading cause of death in China and will only become a more pressing public health issue as the Chinese population ages. With its extensive commercial and clinical capabilities within China and a commitment to global quality standards, BeiGene is the ideal strategic collaborator as we seek to make a meaningful difference in the lives of millions of cancer patients in China and around the world."

"For a number of years, we've had as one of our key focuses for the company

building out the business globally," David Meline, Amgen's chief financial officer, told *CNBC*. "This is an important piece that was remaining for us, and we think that will fill out that chessboard, if you will." It was noted that the deal comes amidst the Trump administration's ongoing trade war with China, and that President Trump has pressured U.S. companies to restrict investments in Chinese companies.

Appeals Court Upholds Decision in Merck and Gilead's $2.54 Billion Patent Fight

Published: Oct 31, 2019

The U.S. Court of Appeals upheld the decision to toss out a $2.54 billion patent infringement judgment leveled against Gilead Sciences. Last year, a judge overturned a decision that ordered Gilead to pay Merck 10% of the revenue earned by hepatitis C drugs due to an infringement on patents held by Merck.

But in something that Merck will likely consider a vicious Halloween trick, on Oct. 30, the appeals court upheld last year's ruling that threw out that $2.54 billion judgment. In 2018, the judge overturned the $2.54 billion verdict saying that the Merck patent should never have been granted in the first place because "it did not meet a requirement that it disclose how to make the treatment it covered without undue experimentation," *Reuters* reported this morning.

The patent dispute between the two companies has been going on for several years. In 2014, Merck acquired a company called Idenix Pharmaceuticals to boost its hepatitis C pipeline, which includes Zepatier. A few years before that, Gilead had acquired Pharmasset for $11 billion, which is where it picked up the asset that would later become Sovaldi. The two companies that were acquired had already been in patent disputes, so when the larger companies picked them up, they also picked up the legal battle.

In a separate battle over hepatitis C patents, the U.S. Supreme Court refused to hear an appeal from Merck earlier this year over a $200 million award. In 2016, Gilead Sciences had been ordered to pay Merck the money after the court ruled that patents for Harvoni and Sovaldi infringed on Merck's patents. The case advanced to the nation's highest court due to questions about the actions of a Merck patent attorney who was accused of altering patent applications.

AstraZeneca Backs $1 Billion Fund to Support China's Growing Pharma Market

Published: Nov 06, 2019

AstraZeneca is significantly expanding its footprint in China with the establishment of a global research and development center in that country, as well as the launch of a $1 billion fund aimed at supporting that nation's healthcare sector.

In total, U.K. based AstraZeneca announced three large-scale initiatives in China during the second annual China International Import Expo in Shanghai. In addition to the R&D center and the new investment fund, AstraZeneca is also establishing an artificial intelligence (AI) Innovation Center. Both the R&D center and the AI center will be located in Shanghai, the company said. AstraZeneca has had a presence in China since 1993.

The decision to heavily invest in China was due to that country's emerging presence as a "global scientific powerhouse," AstraZeneca Chief Executive Officer Pascal Soriot said in a statement. China's pharmaceutical market has grown significantly in recent years, particularly in oncology. Earlier this year, an IQVIA report projected the country's pharmaceutical market will grow to between $145 billion and $175 billion by 2022. Soriot said the company has made a decision to "follow the science" and expand its R&D presence in China and work with some of the country's leading minds to develop innovative medications aimed at treating some of the most common and most serious diseases in China.

The Healthcare Industrial Fund, which was launched with China International Capital Corporation Limited (CICC), will seek to drive innovation in China's healthcare system, AstraZeneca said in its announcement. For AstraZeneca, the Healthcare Industrial Fund is its first and largest-scale healthcare industrial fund. The target size of the fund will be $1 billion. AstraZeneca said the first steps of the fund will be to support Chinese companies, as well as partners based in the Wuxi International Life Science Innovation Campus. The fund will also provide support for international companies looking to establish a presence in China. The AI center will bolster the R&D work by capitalizing on the latest digital technologies that can accelerate the delivery of medicines. The AI center will focus on collaborations with technology companies and local start-ups to develop innovative solutions for patients, the company said.

The company signed a new licensing agreement with India-based Sun Pharmaceutical Industries to bring certain novel products into China and add to AstraZeneca's China oncology portfolio.

AstraZeneca signed licensing agreements with Ningbo Tai King Medical Technology for AZD3229, a KIT inhibitor for gastrointestinal stromal tumors; with Antengene for AZD0364, an Extracellular Receptor Kinase 1/2 inhibitor for RAS/MAPK pathway mutant cancers; and with Abbisko for AZD4547, a Fibroblast Growth Factor Receptors Inhibitor for FGFR-driven cancers.

The establishment of five regional headquarters in China. AstraZeneca will also establish local commercial innovation centers in each HQ.

Biotech Crop Area Reaches 2.5 Billion Hectares in 23 Years

October 23, 2019

High adoption of biotech crops continued in 2018, according to the ISAAA Report, *Global Status of Commercialized Biotech/GM Crops in 2018*. On the 23rd year of commercial cultivation of biotech crops, 26 countries grew 191.7 million hectares of biotech crops, bringing the accumulated biotech crop area to 2.5 billion hectares, a ~113-fold increase since 1996, the first year of commercial planting of biotech crops. This makes biotech crops the fastest crop technology adopted in recent times.

The total area of 191.7 million hectares in 2018 were grown by 26 countries, 21 developing and 5 industrial countries. Developing countries led by Brazil planted 54% of the total biotech crop area, while the industrial countries led by the USA planted the remaining 46%. An additional 44 countries imported biotech crops for food, feed, and processing, bringing the total number of countries that adopted biotech crops to 70.

Bharat Biotech's rabies vaccine relaunched under ChiroRab brand

November 13, 2019

Chiron Behring Vaccines, a part of Bharat Biotech, on Wednesday relaunched its rabies vaccine in the country under the ChiroRab brand. The company used to market the vaccine under the trade name Rabipur earlier. Bharat Biotech acquired Chiron Behring from GSK in March this year and commercial operations at the company's Ankleshwar (Gujarat) unit restarted in May.

"The new vaccine is being manufactured using the same technology (as Rabipur) at the same site, we were highly committed in expediting the manufacturing and commercialisation of ChiroRab," Bharat Biotech Chairman and MD Krishna Ella told reporters here.

"In our ongoing commitment to address the supply of shortage of rabies vaccine, we are making additional investments to increase production capacities to over 15 million dosages annually," Ella said.

Bharat Biotech also manufactures its in-house rabies vaccine, IndiRab, with an annual capacity of 12 million dosages, thus taking the total capacity of both entities to 27 million dosages per annum.

The total demand for rabies vaccine in India stands at around 40 million dosages per annum, Ella noted. According to WHO estimates, rabies is a vaccine-preventable disease that claims over 59,000 lives each year, mostly in Asia and Africa.

In India alone, around 17.4 million animal bites occur annually resulting in around 20,800 rabies deaths. MSS ANU

Alkem's Enzene Opens its First Continuous Biologics Manufacturing site

November 7, 2019

Enzene Biosciences today formally opened its first fully connected continuous Biologics manufacturing facility in Pune, India. This first-of-its-kind facility was built in half the time as compared to the conventional biologics manufacturing plants. Enzene is amongst the first movers in end-to-end connected bio manufacturing to have set up a fully automated continuous cGMP compliant manufacturing plant for mAb production.

"Some of the world's biggest drugs are biologics and Alkem laboratories Ltd. always aspired to enter the arena of biologics. With that intent, we have invested significantly into this space. Our new biologics manufacturing plant endorses our commitment to expand into the space of biotech innovations," said Mr. Sandeep Singh, the MD of Alkem Laboratories Ltd. (the 5th largest pharmaceutical company in India as per IQVIA MAT September 2019).

Enzene aims to broaden its footprint for innovative technologies through strategic global alliances and has taken first steps towards it by procuring its first European client project for cGMP manufacturing of clinical material and create minimal solid waste and carbon emission.

"High cost of manufacturing is one of the major barriers for the entry of biologics into the clinical stage of development. Enzene wishes to disrupt this cost barrier through the launch of their innovative manufacturing plant," expressed Dr. Himanshu Gadgil, Whole-Time Director and CSO at Enzene.

About Enzene Biosciences Ltd.

Enzene, a subsidiary of Alkem laboratories Ltd., is an innovation driven biotech company. Enzene's focus lies in producing biosimilars, phytopharmaceuticals and synthetic peptides while venturing into novel biologics.

FDA Approves Celgene and Acceleron's Treatment for Rare Blood Disease

Published: Nov 11, 2019

The U.S. Food and Drug Administration (FDA) approved Celgene and Acceleron Pharma's Reblozyl for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. **The approval marks the first approved treatment in the United States for this condition.**

The approval also marks the first for Acceleron, which sent shares up nearly 7% in afternoon trading. Reblozyl, an erythroid maturation agent, was approved under Fast Track Designation and the drug received Orphan Drug designation.

With the approval, Reblozyl (luspatercept-aamt) becomes a new therapeutic class for beta thalassemia patients. Reblozyl works by regulating late-stage red blood cell maturation to help patients reduce their RBC transfusion burden. The drug is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia, Celgene stressed in its Friday afternoon announcement.

Beta thalassemia is a rare, inherited blood disorder caused by a genetic defect in hemoglobin. The disease is associated with ineffective erythropoiesis, which results in the production of fewer and less healthy RBCs, often leading to severe anemia – a condition that can be debilitating and can lead to more severe complications for patients, as well as other serious health issues.

Reblozyl was approved based on data from the Phase III BELIEVE trial. The trial achieved a clinically meaningful and statistically significant improvement in the primary endpoint. Data showed that 21% of the patients who received Reblozyl achieved at least a 33% reduction in transfusions compared to 4.5% of the patients who received a placebo. The transfusion reduction meant that the patient needed fewer transfusions over 12 consecutive weeks while taking Reblozyl, the FDA said in its announcement.

The study also met key secondary endpoints, including transfusion burden reduction of at least 33% during weeks 37 to week 48. This was achieved in 19.6% of patients in the Reblozyl arm and 3.6% in the placebo arm, Celgene and Acceleron said. Other efficacy endpoints included transfusion burden reduction of more than 50% during weeks 13-24 and weeks 37-48. Also, a greater than 50% reduction in transfusion burden was observed in 7.6% of patients receiving Reblozyl versus 1.8% of placebo patients.

Common side effects for patients taking Reblozyl were headache, bone pain, joint pain, fatigue, cough, abdominal pain, diarrhea and dizziness.

FDA hold Second Clinical Hold on Solid Biosciences' DMD Gene Therapy Due to Adverse Event

After a serious adverse event was reported in a child dosed with an investigational treatment for Duchene Muscular Dystrophy, the U.S. Food and Drug Administration (FDA) has placed Solid Biosciences' Phase I/II IGNITE DMD study on clinical hold, the second in a year's time.

SGT-001 is a novel adeno-associated viral vector-mediated gene transfer under investigation for its ability to address the underlying genetic cause of DMD. SGT-001 is designed to deliver a synthetic dystrophin gene, called microdystrophin, to the body of DMD patients.

In its announcement, Solid Biosciences said a patient in its second cohort who was dosed in October experienced a serious adverse event that was deemed related to the drug. The serious adverse event was characterized by complement activation, a decrease in red blood cell count, acute kidney injury and cardio-pulmonary insufficiency, the company said. The patient was treated and is recovering and improving, Solid Biosciences added. However, as a result, the FDA placed the clinical hold on the trial. Solid Biosciences said it will work with the regulatory agency to resolve the hold and determine the next steps for the trial.

This marks the second clinical hold on the trial and the second round of adverse events-related issues in less than a year in the IGNITE DMD trial. Most recently, in a quarterly financial report earlier this year, Solid Biosciences reported that a patient treated with SGT-001 was diagnosed with a gastrointestinal infection. While it was believed that the issue was not related to the drug, it was classified as a serious adverse event. The patient also experienced a transient elevation of transaminases and a transient increase in bilirubin higher than two times the upper limit of normal. Additionally, that patient showed a transient decline in platelet count that was believed to be a non-serious adverse event related to the drug.

Last year, the FDA placed a clinical hold on the trial following the report of a serious adverse event. That hold was lifted in June 2018 after the company addressed the FDA's concerns.

Ilan Ganot, chief executive officer and co-founder of Solid Biosciences, said the company remains committed to developing a DMD treatment and continues to "believe in the differentiated construct of SGT-001 and the potential benefits it may offer to patients." Ganot said the company believes it will have a better understanding of the biological activity and potential benefit of SGT-001 in the coming weeks as it looks to resolve this clinical hold.

Golden Rice recognized as One of PMI's Most Influential Projects of the Last 50 Years

The Golden Rice humanitarian project has been recognized by Project Management Institute (PMI) as one of the Most Influential Projects of the past 50 years. It has the distinction of being the only plant-based biotech project in the list of honorees.

Golden Rice is a not-for-profit project, which means that individuals and organizations involved in its development have no financial stakes in the crop. The technology was donated by its inventors, Professors Ingo Potrykus and Peter Beyer in 2000 to aid resource-poor countries and address the global concern of Vitamin A deficiency. To date, Golden Rice has been declared safe in Australia, Canada, New Zealand, and the USA. Prof. Ingo Potrykus stated, "Hopefully in my lifetime, you, and I, will start to see Golden Rice saving the sight and lives of some of the 3.5 billion people, half the world's population, who consume rice, and often little else, every day."

The Most Influential Projects list is part of PMI's 50th anniversary celebration and aims to celebrate project work across the world and raise awareness on its positive results. For more details, read the news release in The Golden Rice Project.

Biogen's Alzheimer's Comeback

Published: Oct 25, 2019 By Mark Terry

Earlier this week, Biogen stunned everyone by announcing that analysis of a large dataset from several of its clinical trials of aducanumab in Alzheimer's patients were positive. This came after an announcement in March that the company and its collaboration partner, Tokyo-based Eisai, were basically abandoning the program after an independent data monitoring committee indicated the trials probably wouldn't hit their primary endpoint.

Reuters reports that the turnaround was built on "top secret" meetings, non-disclosure agreements and six months of researchers, regulators and statisticians churning the data on a larger dataset that included a total of 3,285 patients.

The two trials, EMERGE, which evaluated 1,638 patients, and ENGAGE, which evaluated 1,647 patients, were discontinued after the futility analysis on March 21, 2019. That analysis was based on data prior to December 26, 2018 in 1,748 patients who'd completed the 18-month trial period. The analysis found the studies were not likely to meet the primary endpoint.

After ending those studies, a larger dataset that included a total of 3,285 patients became available. Of them, 2,066 patients had completed the full 18 months of treatment. The companies analyzed the data, and found it contradicted the futility analysis.

Basically, in EMERGE, patients receiving the high dose of aducanumab were observed to have a significant reduction of clinical decline from baseline in CDR-SB scores at 78 weeks of 23% compared to placebo. They also showed a consistent decrease of clinical decline for the pre-specified secondary endpoints, including the Mini-Mental State Examination, 15% compared to placebo, the AD Assessment Scale-Cognitive Subscale 13 items of 27% compared to placebo, and the AD Cooperative Study-Activities of Daily Living Inventory Mild Cognitive Impairment Version, 40% compared to placebo.

Also, imaging of amyloid plaque deposits in EMERGE showed that the plaque burden was decreased with low and high dose aducanumab compared to placebo at 26 and 78 weeks. Biomarker data of tau levels, another abnormal protein linked to Alzheimer's disease, was also found to be reduced in the cerebrospinal fluid, which supports the clinical findings.

The findings were so surprising internally compared to what the independent data monitoring committee had concluded that Biogen did not share the new findings with their own trial investigators and oversight committee. Biogen also pulled in outside Alzheimer's experts and statisticians to analyze the new findings and discussed what they were seeing with FDA officials.

In consultation with the FDA, the company now plans to submit the drug for approval next year. The company, which had lost $18 billion in market value overnight when the programs were canceled, found that company shares rebounded 27% this week.

Apparently, Biogen worked closely with the FDA and met with them twice before deciding to move forward with a submission plan. Biogen officials told Reuters that the final decision was made immediately after the second meeting.

For the FDA "to say it's reasonable to file an application after two extensive discussions with them, formal meetings as well as a number of informal discussions, I think it's significant," Alfred Sandrock, Biogen's executive vice president, Research & Development and chief medical officer, told Reuters.

Eisai, in March, had decided to continue working on a second drug, BAN2401. Now, Eisai and Biogen hope that the aducanumab news will re-energize the BAN2401 trial. Like with the aducanumab studies, the highest doses of BAN2401 showed some encouraging data in a Phase II trial last year.

"That's why in the Phase III trial, we are only studying the highest dose," Ivan Cheung, Eisai's chief executive officer, told Reuters.

New Approaches to Alzheimer's and Tauopathies: Eikonizo Therapeutics

Published: Oct 23, 2019

One of the companies looking at tau is Cambridge, Massachusetts-based Eikonizo Therapeutics. Janice Kranz, the company's co-founder and chief executive officer took time to speak with BioSpace about the company and its approach to Alzheimer's disease and other tauopathies.

"Jacob," Kranz says, "has worked on a family of proteins called HDAC for over 10 years. He's developed a very specific PET imaging tracer that combines with HDAC6. This molecule is capable of getting into the brain, which has been a real challenge in the field, getting binders to HDAC into the brain. And he realized there were some very compelling data about how HDAC6 inhibition could stop or slow the progression of neurodegeneration for Alzheimer's and other tauopathies, diseases where tau forms the tangles, as well as amyotrophic lateral sclerosis (ALS), which is a disease of motor neurons."

Inhibiting HDAC6 prevents pathological tau phosphorylation and downstream

tangles in Alzheimer's disease. This inhibition also appears to stabilize microtubules, which has implications for ALS. The PET scans, although not diagnostic for the disease, is an imaging tool that allows the researchers to visualize in the human brain whether the drug is hitting the right target, which is HDAC6.

At this point, Eikonizo is expecting to have identified its development candidates and a backup molecule by the fourth quarter of 2020. From there it anticipates nine to 12 months to perform Investigational New Drug (IND)-enabling studies, which would allow them to get into the clinic by the fourth quarter of 2021 or first quarter of 2022.

North America Genome Editing Market Projected to Reach US$ 4,000 Mn by 2025

October 23, 2019

"The growth of the genome editing market is primarily attributed to the rise in the production of genetically modified crops and rising prevalence of the genetic diseases," according to the latest Genome Editing Market Growth Analysis Report. Overall, the market is expected to have a compound annual growth rate (CAGR) of 17.2% from 2018 to 2025. Despite rigid biosafety regulations on genome editing in the region, the emergence of markets centered on precision and regenerative medicines provides more growth opportunities for the North American genome editing market in the next couple of years.

The CRISPR segment, which dominated the genome editing market in 2017 with a share of 53.6%, is still expected to take up a significant portion of the market in 2025. Based on application, the cell line engineering segment is likewise foreseen to propel at a CAGR of 18.0%. Similarly, the genetic engineering segment will likely see a a substantial increase due to extensive researches being done on its subsegments, particularly on animal and plant genetic engineering. With the advent of CRISPR, the biotechnology and pharmaceutical companies segment is also anticipated to dominate the market in 2025 as companies benefit from drug discoveries and enhanced research and development.

Novartis' Sandoz Wins U.S. Approval for Neulasta Biosimilar

Published: Nov 05, 2019

Ziextenzo (pegfilgrastim) is a long-acting version of filgrastim and is indicated to decrease the incidence of infection in cancer patients. The infections are manifested by low white blood cell count and associated with a fever in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. A study has shown that each year in the US, more than 60,000 cancer patients are hospitalized with evidence of neutropenia, including fever or infection, with more than 4,000 deaths as a result, the company said in its announcement this morning. Sandoz said it intends to launch Ziextenzo as quickly as possible this year. The biosimilar has been available in Europe since 2018.

"The approval of Ziextenzo expands our oncology portfolio, providing physicians with a long-acting supportive oncology biosimilar option. It builds on the foundation of trust and experience we developed with our short-acting filgrastim Zarxio – the leading filgrastim by market share in the US – including consistent product supply and reliable patient services," Lynch said in a statement.

Biosimilars are something akin to generic drugs for biologics. They are always uniquely different in composition, which differentiates them from generic drugs, which are exact replicas of other drugs. They have been widely available in Europe since 2006, but the FDA was only granted the right to review and approve them when the Affordable Care Act was passed in 2010. In 2015, Sandoz won approval for the first biosimilar in the United States. Zarxio is a biosimilar version of Amgen's Neupogen.

Pliant Inks $80 Million+ Deal with Novartis on Liver Disease NASH

Published: Oct 23, 2019

South San Francisco-based Pliant Therapeutics announced it had inked a strategic collaboration and license deal with Novartis. The agreement revolves around the development and commercialization of Pliant's preclinical candidate, PLN-1474, and up to three more integrin targets for liver fibrosis associated with nonalcoholic steatohepatitis (NASH).

NASH is similar to cirrhosis of the liver but occurs in patients who drink little or no alcohol. It is a multifactorial disease, involving fibrosis, inflammation and fatty liver. It is associated with high cholesterol, obesity and type 2 diabetes.

At this time, there are no specific treatments for NASH except for lifestyle changes and various medications for the associated diseases.

PLN-1474 was discovered by Pliant. It is a small molecule selective inhibitor of integrin αVβ1. In preclinical research, PLN-1474 selectively blocked the activation of TGF-beta, which is mediated by αVβ1. This decreased the growth of fibrotic tissue within the liver. Pliant is currently running IND-enabling studies on the drug.

Under the terms of the deal, Novartis is paying $80 million to Pliant upfront as well as an undisclosed equity investment commitment. The deal is for worldwide exclusive license to PLN-1474 and up to three more candidates. Also, Novartis will fund Pliant's research and development activities related to the deal.

Pliant will handle development of PLN-1474 through Phase I. Then Novartis will take over all future development, manufacturing and commercialization activities. Pliant will be eligible for various milestone payments as well as tiered royalties from the mid-single digits to low double digits.

The NASH market is projected to be worth about $35 billion, but so far it has eluded the biopharma industry. Any number of companies, big and small, are tackling the disease, including Viking Therapeutics, Madrigal Pharmaceuticals, Intercept Pharmaceuticals, Genfit, Allergan, Gilead Sciences, Novo Nordisk and others.

Roche Terminates Myostatin Inhibitor for DMD One Year After Pfizer Did the Same

Published: Nov 08, 2019

A little more than one year after Pfizer terminated its studies of PF-06252616 as a potential treatment for Duchene Muscular Dystrophy, Swiss pharma giant Roche is following suit. The company terminated the development of RG6206 an investigational anti-myostatin adnectin protein, in ambulatory boys with DMD.

In a letter to the Duchene Muscular Dystrophy community this week, Roche announced the news about its clinical development program. Roche said its decision to terminate the DMD programs impacts both the Phase Ib/II THUNDERJET study, as well as the Phase II/III SPITFIRE study. The decision to terminate the studies was based on a pre-planned analysis of the SPITFIRE data. That analysis, Roche said, indicated that RG6206 was highly unlikely to demonstrate clinical benefit as defined by meeting the primary endpoint when compared with placebo. The primary endpoint was a change from baseline in the North Star Ambulatory Assessment. The assessment is a rating scale used to measure functional motor abilities in ambulant children with DMD. There were no safety concerns in the study, Roche said.

Roche intends to hold two global meetings with members of the DMD community to provide the stakeholders with as much information as possible. "We recognize this news is deeply disappointing for the Duchenne community, especially in view of the historical challenges in DMD drug development and the ongoing need for new treatment options to treat this devastating disease. While the science and large body of research gave us hope that RG6206 would have offered people living with DMD and their families a safe and effective treatment option, the results of the SPITFIRE study at this time led us to the difficult conclusion that this approach will not be successful," Roche said in its letter.

Last year, when Pfizer terminated its DMD studies of domagrozumab, which like RG2606 was also a monoclonal anti-myostatin antibody, Roche posted a letter addressing concerns that Pfizer's decision would impact Roche's DMD program. At the time, Roche said its work would continue and reminded members of the DMD community that clinical studies are designed in ways that are specific to the molecule being studied, which meant it wasn't possible to draw conclusions.

Duchenne muscular dystrophy is the most common and severe form of muscular dystrophy that primarily affects boys. The genetic disease causes a progressive loss of muscle strength attributable to a loss of a protein called dystrophin, which normally protects muscle fibers from breaking down. Approximately 15,000 U.S. patients are affected with Duchenne, with a total of 300,000 patients worldwide.

Data from the interim analysis of the Phase II/III SPITFIRE study will be presented at an upcoming study, the company said. Additionally, Roche is making plans to share additional data about RG6206 "in order to contribute to the broader community's efforts to develop new treatment options for people with this condition." Roche also said it and its subsidiary Genentech will continue to partner with the global Duchenne community on ongoing projects, including with World Duchenne Organization on its Psychosocial Program as well as its data-sharing initiative.

Roche to Acquire Fibrosis-Focused Promedior for Up to $1.4 Billion

Published: Nov 15, 2019

A year after Bristol-Myers Squibb walked away from acquiring Promedior and its fibrotic treatment portfolio, Swiss pharma giant Roche has stepped in to acquire the company and its pipeline for up to $1.4 billion.

At the heart of the deal is Promedior's lead product, PRM-151, which received Breakthrough Therapy Designation from the U.S. Food and Drug Administration in March for the treatment of idiopathic pulmonary fibrosis (IPF). Earlier this year, ahead of the designation, Promedior reached an agreement with the FDA for the design of a Phase III registrational study in idiopathic pulmonary fibrosis, with forced vital capacity as a primary endpoint. PRM-151 is a novel investigational anti-fibrotic immunomodulator, a recombinant form of human pentraxin-2 (PTX-2) protein.

In addition to idiopathic pulmonary fibrosis, PRM-151 has also shown promising early clinical trial data in myelofibrosis (MF) and its anti-fibrotic mechanism has therapeutic potential in other fibrotic diseases, Promedior said in its announcement.

Under the terms of the agreement, Roche will make an upfront cash payment of $390 million, plus additional contingent payments of up to $1 billion based on the achievement of certain predetermined development, regulatory and commercial milestones.

Idiopathic pulmonary fibrosis is a fatal disease caused by progressive scarring of the lungs, which makes breathing difficult

and prevents the heart, muscles and vital organs from receiving enough oxygen to work properly. The disease can advance quickly or slowly, but eventually, the lungs will harden and stop working altogether. There is no known cure for IPF. The median survival time from diagnosis is two to five years, and the five-year survival rate is approximately 20% to 40%.

In Phase II, PRM-151 demonstrated both prevention and reversal of fibrosis, Promedior said. Results from that trial demonstrated that PRM-151 is the first molecule to show significant lung function improvements on top of current therapies in IPF, the company added.

Scientists Double Sorghum Grain Yields by 200%

November 6, 2019

Scientists at the Cold Spring Harbor Laboratory (CSHL) and U.S. Department of Agriculture Agricultural Research Service (USDA ARS) have doubled the amount of grains that a sorghum plant can yield.

Led by Dr. Doreen Ware, CSHL Adjunct Professor and research scientist at USDA and colleague Dr. Zhanguo Xin, the research team identified novel genetic variations in sorghum's MSD2 gene, increasing the grain yield by 200 percent.

MSD2 comes from the gene line that boosts flower fertility by lowering the amount of jasmonic acid, a hormone that controls seed and flower development. It is regulated by MSD1, a gene discovered by Dr. Ware's team in 2018. Their research shows that manipulating either gene increases seed and flower production.

Sorghum is one of the world's most important sources of food, animal feed, and biofuel. It is considered a model crop for research because it has a high tolerance to drought, heat, and high-salt conditions.

White House Nominates MD Anderson's Stephen Hahn as Next FDA Commissioner

Published: Nov 04, 2019

Stephen Hahn, chief medical executive of the University of Texas MD Anderson Cancer Center, will be nominated as the next commissioner of the U.S. Food and Drug Administration (FDA). Hahn had been the frontrunner for the top spot at the FDA.

Late Friday, President Donald Trump put forth Hahn's name to take over the top spot of the nation's regulatory agency as the permanent replacement for Commissioner Scott Gottlieb, who retired earlier this year. Hahn's name was announced on Nov. 1, which was a deadline established by the Federal Vacancies Reform Act. Had Trump not named a new full-time commissioner, a new interim commissioner would have had to been named. The Federal Vacancies Reform Act states that a person may not serve in an acting or interim capacity for longer than 210 days.

As a radiation oncologist, Hahn specializes in treating lung cancer and sarcoma and has authored 220 peer-reviewed original research articles, the White House said in its announcement. In his role as chief medical executive, Hahn has been responsible for the day-to-day operations of the famed cancer center that includes managing more than 21,000 employees and a $5.2 billion operating budget. MD Anderson is also involved with the largest number of clinical trials in the United States, the White House said. Hahn was promoted to that role two years after joining MD Anderson as division head, department chair and professor of Radiation Oncology. Prior to MD Anderson, Hahn served as head of the radiation oncology department at the University of Pennsylvania's Perelman School of Medicine.

While Hahn is well-respected, his tenure as chief medical executive of MD Anderson was briefly entangled in accusations of racial-profiling earlier this year following the termination of some Chinese-born researchers who were accused of research espionage at the behest of China. During an MD Anderson town hall meeting following the terminations, which were part of a broader concern regarding intellectual property theft, Hahn attempted to reassure employees that racial profiling is something that the leadership at MD Anderson abhors and would not stoop to using.

Better biosensor technology created for stem cells

A team has created better biosensor technology that may help lead to safe stem cell therapies for treating Alzheimer's and Parkinson's diseases and other neurological disorders. The technology, which features a unique graphene and gold-based platform and high-tech imaging, monitors the fate of stem cells by detecting genetic material (RNA) involved in turning such cells into brain cells (neurons).

A Rutgers-led team has created better biosensor technology that may help lead to safe stem cell therapies for treating Alzheimer's and Parkinson's diseases and

other neurological disorders.

The technology, which features a unique graphene and gold-based platform and high-tech imaging, monitors the fate of stem cells by detecting genetic material (RNA) involved in turning such cells into brain cells (neurons), according to a study in the journal Nano Letters.

"A critical challenge is ensuring high sensitivity and accuracy in detecting biomarkers -- indicators such as modified genes or proteins -- within the complex stem cell microenvironment," said senior author KiBum Lee, a professor in the Department of Chemistry and Chemical Biology in the School of Arts and Sciences at Rutgers University-New Brunswick. "Our technology, which took four years to develop, has demonstrated great potential for analyzing a variety of interactions in stem cells."

The team's unique biosensing platform consists of an array of ultrathin graphene layers and gold nanostructures. The platform, combined with high-tech imaging (Raman spectroscopy), detects genes and characterizes different kinds of stem cells with greater reliability, selectivity and sensitivity than today's biosensors.

The team believes the technology can benefit a range of applications. By developing simple, rapid and accurate sensing platforms, Lee's group aims to facilitate treatment of neurological disorders through stem cell therapy.

Stem cells may become a renewable source of replacement cells and tissues to treat diseases including macular degeneration, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid arthritis, according to the National Institutes of Health.

Journal Reference:

Letao Yang, Jin-Ho Lee, Christopher Rathnam, Yannan Hou, Jeong-Woo Choi, Ki-Bum Lee. Dual-Enhanced Raman Scattering-Based Characterization of Stem Cell Differentiation Using Graphene-Plasmonic Hybrid Nanoarray. Nano Letters, 2019; DOI: 10.1021/acs.nanolett.9b03402

Critical protein that could unlock West Nile/Zika virus treatments identified

Scientists have identified a protein that is critical in controlling replication of West Nile and Zika viruses -- and could be important for developing therapies to prevent and treat those viruses.

The researchers found Z-DNA binding protein 1 (ZBP1) is a sensor that plays a significant role in triggering a robust immune response when it detects a viral infection within cells. The Georgia State study, published in the journal Frontiers in Microbiology, found ZBP1 is essential for restricting both West Nile and Zika virus replication, and that it prevents West Nile-associated encephalitis (inflammation of the brain) in mice. The absence of ZBP1 in mice leads to 100 percent mortality when infected with even a non-disease-producing strain of West Nile Virus, the study found.

"It's significant because you take a virus that has never been shown to kill anything and if you block this protein the virus will just kill everything," said Mukesh Kumar, assistant professor of biology and senior author of the study. "We discovered that when cells are infected with viruses such as Zika and West Nile, they respond by triggering necroptosis, a form of programmed cell death, via ZBP1 signaling. This inhibits viral replication and spread, allowing the immune system to clear the virus."

Kumar said the findings could present new treatment strategies for viruses that can infect the central nervous system by modulating ZBP1 expression. Subsequent research by Kumar's team will explore effectiveness against similar viruses such as Eastern Equine Encephalitis and Powassan virus.

Zika, which is spread by the Aedes mosquito that has been found as far north as Florida and Texas, can cause serious neurological diseases such as Guillain-Barre syndrome, which causes the body's immune system to attack the nervous system. Birth defects such as microcephaly, an abnormally small head and brain can result. Most people who get Zika or West Nile don't get sick thanks to the body's natural immune response and may not know they've been infected, meaning their cases probably don't get reported.

"If you try to open barriers to the brain you may be making it worse," Kumar said. "That's why we try to modulate some part of the host immune response. Manipulating a host protein already inside the genome to trigger the body's natural immune response is a better way of fighting viruses already in the brain."

Journal Reference:

Hussin A. Rothan, Komal Arora, Janhavi P. Natekar, Philip G. Strate, Margo A. Brinton, Mukesh Kumar. Z-DNA-Binding Protein 1 Is Critical for Controlling Virus Replication and Survival in West Nile Virus Encephalitis. Frontiers in Microbiology, 2019; 10 DOI: 10.3389/fmicb.2019.02089

Discovery: New biomarker for cancer stem cells

Medical researchers have discovered a new biomarker in cancer stem cells that govern cancer survival and spread, and it's raising hope that drug discovery to kill cancer stem cells could follow suit.

In the world of cancer biology, not all biomarkers are created equal. These molecules that alert doctors that an abnormal process may be underway can appear as an array of aberrant proteins, such as hormones, enzymes or signaling molecules, and vary from patient to patient. Because they are a mixed bag, no one drug exists to attack them. But now, a University of Houston College of Pharmacy associate professor has discovered a new biomarker in cancer stem cells that govern cancer survival and spread, and it's raising hope that drug discovery to kill cancer stem cells could follow suit.

"We have found a new biomarker, the protein plectin, on cancer stem cells. We believe plectin may be a more common biomarker that could lead to broadly applicable drug development," reports Gomika Udugamasooriya in Nature Scientific Reports. "Plectin is a structural protein, predominantly expressed intracellularly, but whose translocation onto the cell surface is linked to tumor invasion and metastasis."

All cancerous tumors contain a small subset of drug-resisting, self-renewing, and highly metastatic cells called tumor-initiating cells, or cancer stem cells, responsible for 90% of cancer deaths.

Udugamasooriya's process of discovering the biomarker and a drug-lead is different than conventional two-step discoveries, where researchers first find a biomarker and then develop a drug. He did both at once -- developing 400,000 potential synthetic chemical compounds (peptoids) and used them to capture the specific biomarker performing his unique, but simple two-color cell screen. From almost half a million, only three peptoids targeted cancer stem cells and not the remaining cancer cells from the same patient. When those peptoids were used to pulldown their targets, one of them was identified as plectin, proving that it is a unique biomarker for cancer stem cells.

"Our studies show both genotypic and phenotypic correlations between plectin and lung cancer stem cells, as well as association of high plectin expression with poor patient survival in lung adenocarcinoma, potentially identifying plectin as a biomarker for lung cancer stem cells," reports Udugamasooriya.

Because plectin assists in shaping cells, it is pivotal to the spread of cancer, helping cancer stem cells wend their way through the body.

Journal Reference:

Aaron C. Raymond, Boning Gao, Luc Girard, John D. Minna, D. Gomika Udugamasooriya. Unbiased peptoid combinatorial cell screen identifies plectin protein as a potential biomarker for lung cancer stem cells. Scientific Reports, 2019; 9 (1) DOI: 10.1038/s41598-019-51004-3

DNA data offers scientific look at 500 years of extramarital sex in Europe

Researchers have put DNA evidence together with long-term genealogical data to explore questions of biological fatherhood on a broad scale among people living in parts of Western Europe over the last 500 years. The study found evidence of extra-pair paternity events turned up more often in people of lower socioeconomic status who lived in densely populated cities in the 19th century.

The findings reported in Current Biology on November 14 yielded some surprises. While the number of so-called extra-pair paternity (EPP) events overall was (not surprisingly) fairly low, their frequency varied considerably among people depending on their circumstances. Specifically, evidence of EPP events turned up much more often in people of lower socioeconomic status who lived in densely populated cities in the 19th century.

"Our research shows that the chance of having extra-pair paternity events in your family history really depends on the social circumstances of your ancestors. If they lived in cities and were of the lower socioeconomic classes, the chances that there were EPP events in your family history are much higher than if they were farmers."

The evidence showed no significant difference in EPP rates between countries despite key religious differences, they report. But they varied widely with socioeconomic status and population density. The EPP rate was much lower among farmers and more well-to-do craftsmen and merchants (about 1%) than among lower class laborers and weavers (about 4%).

EPP rates also rose with population density. Putting the two together, the researchers report that the estimated EPP rates for the families varied by more than one order of magnitude, from about 0.5% among the middle to high classes and farmers living in the most sparsely populated towns to almost 6% for the low socioeconomic classes living in the most densely populated cities.

The researchers say the findings support evolutionary theories suggesting that individual incentives and opportunities for seeking or preventing extra-pair mating should depend on the social context. They also debunk the notion that EPP rates in Western society are generally high, they say, noting that the evidence puts average rates at around 1%.

Journal Reference:

Maarten H.D. Larmuseau, Pieter van den Berg, Sofie Claerhout, Francesc Calafell, Alessio Boattini, Leen Gruyters, Michiel Vandenbosch, Kelly Nivelle, Ronny Decorte, Tom Wenseleers. A Historical-Genetic Reconstruction of Human Extra-Pair Paternity. Current Biology, 2019; DOI: 10.1016/j.cub.2019.09.075

Potential new target for treatment of gout

Research team discovers alternate pathway by which MSU crystals trigger inflammation

Researchers have identified a new therapeutic target for the treatment of gout, a common type of arthritis that causes episodes of painful and stiff joints. Their study suggests that blocking a signaling molecule known as TAK1 can suppress inflammation caused by gout. The research lays the foundation for the development of potential new treatment strategies for gout.

Published in the journal Cellular and Molecular Immunology, their study suggests that blocking a signaling molecule known as TAK1 can suppress inflammation caused by gout. The research lays the foundation for the development of potential new treatment strategies that could significantly improve the quality of life of millions of people around the world who

suffer from the condition. In the United States alone, gout affects an estimated 8.3 million people, or about 4 percent of the population.

Gout is caused by high blood levels of uric acid, a natural waste product from the digestion of foods that contain purines, such as red meat, seafood, dried beans, and beer. Elevated uric acid levels can lead to the formation of monosodium uric acid (MSU) crystals that accumulate in joints. The immune system will perceive these crystals as a threat and launch an immune response against them that increases the production of interleukin-1-beta (IL-1-beta), a cytokine protein that causes inflammation and triggers the intense pain and swelling people experience during gout attacks.

"It's kind of a vicious cycle that starts with these crystals, which cause IL-1-beta to be produced, inducing inflammation and activating a lot of other proteins to produce more inflammation," said Salah-Uddin Ahmed, a professor of pharmaceutical sciences in the WSU College of Pharmacy and Pharmaceutical Sciences and senior author on the study.

One of those proteins activated by IL-1-beta -- TAK1 -- caught the interest of Ahmed's research team when their previous study suggested its key role in the regulation of IL-1-beta inflammation in rheumatoid arthritis. They designed a study to identify the molecular mechanism by which MSU crystals produce IL-1-beta inflammation and the role of TAK1 in this process. Using two different cell lines of human macrophages -- immune cells that play a key role in inflammation -- they found that MSU crystals could directly activate TAK1 and other proteins that were previously thought to be dependent on IL-1-beta signaling for activation.

"We already knew that MSU crystals activate what is known as the inflammasome pathway, which produces IL-1-beta," Ahmed said. "However, our study found that MSU crystals also use an alternate pathway that triggers inflammation through TAK1, which is a new finding related to how gout develops."

Next, they showed that the use of a chemical that inhibits, or blocks, TAK1 could completely suppress any inflammation caused by MSU crystals, both in healthy human macrophage cells and in a rodent model of gout.

Ahmed said their discovery has opened the door towards the development of new treatment strategies for gout.

One current treatment he said scientists have experimented with is Anakinra, a drug that blocks the binding of IL-1-beta to its receptor. Though it has shown promise, Ahmed said the drug is not clinically used for gout, because it is given by infusion -- which requires hospitalization; its effectiveness is limited; and it comes with a potential risk of infections when used long term. Developing TAK1 inhibitor drugs that could be taken by mouth would allow patients with gout to manage flare-ups of the disease at home.

Ahmed said their finding could also eventually be tested in other diseases that involve IL-1-beta mediated inflammation, such as multiple sclerosis, inflammatory bowel disease, and type 1 diabetes.

Journal Reference:

Anil K. Singh, Mahamudul Haque, Kayla O'Sullivan, Mukesh Chourasia, Madhu M. Ouseph, Salahuddin Ahmed. Suppression of monosodium urate crystal-induced inflammation by inhibiting TGF-β-activated kinase 1-dependent signaling: role of the ubiquitin proteasome system. Cellular & Molecular Immunology, 2019; DOI: 10.1038/s41423-019-0284-3

Potential drug targets for glioblastoma identified

Researchers at Karolinska Institutet in Sweden have identified 10 tumour-specific potential drug targets for the brain tumour glioblastoma. The results are presented in the scientific journal Cell Reports.

"We have found disease-related changes in the cells that line the tumour blood vessels, so called endothelial cells, which have long been considered a possible clinical target for cancer treatment," says Lynn Butler, assistant professor at the Department of Molecular Medicine and Surgery, Karolinska Institutet, who led the study. "Proteins only expressed in the endothelial cells of the tumour vessels could be used as targets to attack the tumour's blood supply, or for delivery of therapeutic agents, without affecting the normal brain."

There are more than 200 different cell types in the human body, each performing their own role. Understanding the differences between these cell types helps us understand how organs work and how cells change in disease. Cell identity is determined by the specific proteins expressed, which can be predicted by measuring the protein transcripts found inside the cell. For the study, the researchers analysed human brain tissue and samples of the brain tumour glioblastoma, an incurable disease with a very high mortality rate.

Existing data on transcripts from whole human brain tissue has limited usefulness when one is interested in the properties of a particular cell type, as these samples contain many different brain cell types. Now, the researchers have developed a new method to process this data and identify transcripts only expressed in certain types of brain cells. The method proved to be useful for defining cell-type properties, as well as directly comparing cell-type profiles between normal and diseased tissue. The researchers used this method to predict 10 novel glioblastoma-specific endothelial cell transcripts, which are not found in the vasculature of normal brain tissue.

"These markers could provide insights into the biology of glioblastoma and represent potential tumour-specific targets for therapy," says Lynn Butler.

Journal Reference:

Philip Dusart, Björn Mikael Hallström, Thomas Renné, Jacob Odeberg,

Mathias Uhlén, Lynn Marie Butler. A Systems-Based Map of Human Brain Cell-Type Enriched Genes and Malignancy-Associated Endothelial Changes. Cell Reports, 2019; 29 (6): 1690 DOI: 10.1016/j.celrep.2019.09.088

Scientists crack structure of a novel enzyme linked to cell growth and cancer

A research team has discovered the structure of a novel RNA-modifying enzyme, ZCCHC4, and identified the mechanism that controls how this enzyme recognizes its substrate. ZCCHC4 influences cell proliferation and has been linked to cancers. The discovery has applications in structure-based drug design against cancers.

ZCCHC4 influences cell proliferation and has been linked to cancers. It uniquely introduces one kind of RNA modification, N6-methyladenosine (m6A), into ribosomes, which are cell organelles made up of RNA molecules and protein.

Jikui Song, an associate professor of biochemistry at UC Riverside who led the study, explained ZCCHC4 controls protein synthesis and cell proliferation by introducing an m6A modification into ribosomes. ZCCHC4, he added, is overexpressed in tumors associated with hepatocellular carcinoma -- the most common type of primary liver cancer.

The m6A modification has received enormous attention in recent years due to the important role it plays in RNA metabolism and biology. How this modification is dynamically programmed and distributed in cells, however, remains poorly understood.

"The structure of ZCCHC4 provides an understanding of how this enzyme is wired to specifically act on '28S ribosomal RNA,'" Song said, noting a ribosome is assembled with differently sized subunits. 28S ribosomal RNA refers to the RNA component in the 28S ribosomal subunit. "We now understand that this enzyme is controlled by an 'autoinhibitory' mechanism that has been observed in many other cellular processes."

To crack the structure of ZCCHC4, Song's team first produced an enzymatically active and structurally rigid ZCCHC4 fragment. The researchers then coaxed this protein to crystallize. Finally, they diffracted the crystals using X-rays and analyzed the data, which led to the eventual discovery of ZCCHC4's structure.

Journal Reference:

Wendan Ren, Jiuwei Lu, Mengjiang Huang, Linfeng Gao, Dongxu Li, Gang Greg Wang, Jikui Song. Structure and regulation of ZCCHC4 in m6A-methylation of 28S rRNA. Nature Communications, 2019; 10 (1) DOI: 10.1038/s41467-019-12923-x

'Misguided and ineffectual': Publisher offers mea culpa in retraction of paper questioning link between HIV and AIDS

In 2014, the journal published a paper by a researcher in Texas, Patricia Goodson, who questioned the causal link between HIV and AIDS. In response to the predictable outcry, the journal blinked, sort of.

But rather than retract the article, as we reported back then, it decided to reclassify the work as "opinion" — an odd decision for a periodical whose mission is "to advance the scientific basis of knowledge and action for current and future public health professionals." (Both top editors at the journal, Marcia Ory and Matthew Smith, are at Texas A&M University, where Goodson holds a faculty position as professor of health and kinesiology.) It also published commentaries critical of the Goodson's article, in the hopes that readers would … ignore what she was saying.

Author protests as Elsevier retracts nine papers for fake peer review

An agriculture researcher has lost nine papers from Elsevier journals for "illegitimate reviewer reports." The researcher, Christos Damalas, is, well, irked.

The journals included Chemosphere, Crop Protection, Land Use Policy, and Science of the Total Environment, and the papers were all published in 2017 and 2018, with Damalas as corresponding author and co-authors from Iran and Pakistan. Together, the nine papers have been cited about 75 times, according to Clarivate Analytics' Web of Knowledge.

Here's a typical notice, this one from Crop Protection: This article has been retracted at the request of the Chair Editor.

After a thorough investigation, the Editor has concluded that the acceptance of this article was based upon the positive advice of two illegitimate reviewer reports. The reports were submitted from email accounts which were provided by the corresponding author as suggested reviewers during the submission of the article. Although purportedly real reviewer accounts, the Editor has concluded that these were not of appropriate, independent reviewers.

This manipulation of the peer-review process represents a clear violation of the fundamentals of peer review, our publishing policies, and publishing ethics standards. Apologies are offered to the reviewers whose identity was assumed and to the readers of the journal that this deception was not detected during the submission process.

An Elsevier spokesperson told us that an Editor of Crop Protection became suspicious of the four reviewer accounts suggested by this author for a submission (all four, non-institutional email addresses), as the Editor knew the scientists purportedly suggested as reviewers. The Editor flagged this to the other Editors and to the journal Publisher. Then Elsevier investigated all papers by this author, leading to these retractions.

Damalas was not happy with that outcome. He forwarded us a letter he sent Elsevier: I am writing this letter to you to officially appeal against decision to retract our published articles below, to which I am designated as a corresponding author: We think that the decision for retraction was absolutely unjust for our published articles for the following reasons:

1) Our articles in question do not violate any guideline of COPE for article retraction, namely, i) there is no evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or honest error (e.g. miscalculation or experimental error), ii) none of the findings have previously been published elsewhere without proper cross-referencing, permission or

justification (i.e. cases of redundant publication), iii) none of the publications have any indication of plagiarism, and iv) none of the publications reports unethical research.

2) Our articles in question were assessed by a number of reviewers, who all agreed in on the scientific merit of the articles. Literally, all reviewers agreed, indicating the high quality of our articles. This is also supported by the high number of citations that our articles have gained in the literature so far and they continue to have impact.

3) Evaluation of the appropriateness of the suggested reviewers with submission is not a responsibility of the authors.

4) Selection of the reviewers is not a responsibility of the authors.

Based on the above, I kindly request to cancel the retraction decision about the above articles and give the opportunity to the scientific community to evaluate their merit with time. On a personal basis, it will be really unfair for me, who I have helped numerous authors to publish their research, if you do not cancel your decision for the retractions.

Kindly consider my appeal and do the needful actions. If, despite our explanations, there is still any doubt about the overall merit of the above articles, we are ready to accept re-evaluation of the papers any time by any editor and by any reviewer.

Hepatitis expert out at Chicago university following misconduct finding

A researcher who is now up to six retractions has left his faculty position at the Rosalind Franklin University of Medicine and Science following a finding of research misconduct, Retraction Watch has learned.

Gulam Waris, who studies hepatitis, has reused images across multiple papers, according to a retraction notice published this week in the Journal of General Virology:

The article 'Activation of transcription factor Nrf2 by hepatitis C virus induces the cell-survival pathway' which was published in the Journal of General Virology in March 2010 has been retracted. This follows formal findings of research misconduct from the Compliance Counsel at Rosalind Franklin University. The actin immunoblot shown in Fig. 6a was found to have been reused in the following publications to represent the loading control at different experimental conditions: Waris et al. (2005) J. Virol. 79, 1569–1580 [1], Waris and Siddiqui (2005) J. Virol. 79, 9725–9734 [2], Waris et al. (2007) J. Virol. 81, 8122–8130 [3], Nasimuzzaman et al. (2007) J. Virol. 81, 10249–10257 [4], Burdette et al. (2010) J. Gen. Virol. 91, 681–690 [5], Burdette et al. (2012) J. Gen. Virol. 93, 235–246 [6], and McRae et al. (2016) J. Biol. Chem. 291, 3254–3267 [7].

Gulam Waris does not agree that the actin immunoblot was reused in other publications. Waris, who also denied reusing images when we contacted him in August following an expression of concern on the now retracted paper, is no longer working at Rosalind Franklin, according to Bret Moberg, the university's compliance counsel.

We asked Moberg to share the report of the investigation referred to by the retraction notice. He told by email that he "would like to do so in a general manner without commenting on the accuracy of the premises of that question."

The University complies with applicable federal regulations regarding allegations of research misconduct, which are codified within 42 C.F.R. Part 93. Those regulations include a confidentiality provision and, consistent with our understanding of those regulations, the University does not disclose research misconduct investigation reports except to those with a need to know or as otherwise allowed by law. For example, when necessary, the University would take steps to notify a journal when that journal had published an article that was the subject of a specific finding of research misconduct, and that notification would take place in order to permit that journal to take action it deems appropriate. Additionally, the University would take steps to notify the funding agency of research that was the subject of a specific finding of research misconduct so that the agency may take action on matters under its cognizance, as it deems appropriate.

In August, Waris told us: I did not duplicate the image and all these results are reproducible and reliable.

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BIOTECH EVENTS

Two Day Workshop
On
"Advanced Computer-Aided Drug Design and Computational Biology"

SCHRÖDINGER

18-19 December 2019,
Organized By
Department of Pharmaceutical Sciences and Natural Products
&
Schrödinger INC. USA

Theme of Workshop:
The workshop has been designed to provide the theoretical as well as hands-on approach to various advanced Computational Drug Design Techniques in lead identification and lead optimization.

Workshop Topics include:
Methods and Advances in computer aided drug design, approaches in Target selection and refinement for docking studies, identification and evaluation of Binding Pocket , docking approaches in virtual screening and Lead identification, modeling protein structures for docking and virtual screening, pharmacophore modeling and virtual screening of novel compounds, refinement of novel leads using ADME prediction, similarity and dissimilarity based methods in lead identification 3D-QSAR Modeling and Lead optimization, water thermodynamics in lead optimization, biologics design and protein engineering

About the University
The Central University of Punjab, Bathinda (Punjab), NAAC accredited 'A' grade University has been established through the Central Universities Act 2009 which received the assent of the President of India on 20th March 2009. The University is creating supporting and stimulating conditions and opportunities whereby one can learn, grow, interact and discover. The main campus is coming up on 500 acres of land near Bathinda.

About Department
Department of Pharmaceutical Sciences and Nature Products is the most renowned dept. of University with a number of research papers and projects. The dept. is currently following the latest trends and conducting a thorough research on Design, Synthesis, QSAR studies and Biological Screening of Novel Multi-target Inhibitors of Tyrosine Kinase(s) and Topoisomerase, Synthesis and isolation of Bioactive Heterocyclic Scaffolds Using Novel Green Technologies and Synthesis of Rebaudioside-A: Natural Substitute for Sugar from Stevia rebaudiana (Bertoni) and many more.

Participants
Faculty members, postdocs, Ph.D. students and research scholars (working in the area) from the Universities, Institutes, Colleges and Industries.

Registration
Registration Opening Date:-**21-10-2019**
Last date for receiving of filled ***Pre-Registration form*** via *Email at dpsnp2019@gmail.com*:- **15-11-2019**
Information to Selected Participants for submission of participation fee:- **26-11-2019**

Fee Details
Participation Fee:- Rs. 1000 (includes registration fee, certificates, participation kit, and tea for two days)-*to be submitted with* ***filled Registration form*** *after the confirmation of selection through email*: from **27-11-2019** to **02-12-2019**
Account Details:-
Punjab National Bank, Civil lines, Bathinda
Account No:- 3468000101713077
IFSC Code :-PUNB0346700
MICR CODE:- 151024005
(*Payment to be submitted only after the confirmation of selection through email*)
Last Date for Fee Submission:-**02-12-2019** (*through RTGS/NEFT-Bank detail given in registration form*)

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Trains and Bus facilities are frequently available for Bathinda. For further details please visit university site www.cup.edu.in

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Central University of Punjab, Bathinda

Convener:-
Prof. P. Ramarao
Dean, School of Basic and Applied Sciences
Pharmaceutical Sciences and Natural Products
Central University of Punjab, Bathinda

Speakers:-
Schrödinger Team

Organizing Committee
Dr. Raj Kumar
Associate Professor & Former Head

Dr. Vikas Jaitak
Assistant Professor

Dr. Pradeep Kumar
Assistant Professor

Dr. Kaki Venkat Rao
Assistant Professor

Dr. Pradeep Kumar	**Dr. Venkat**
9813774553	**9779183370**

Central University of Punjab, Bathinda

ICGCW2019

5th INDIAN CANCER GENETICS CONFERENCE & WORKSHOP

11-14th Dec 2019: Workshops – I) Genetic Counselling; II) Molecular Genetic Analysis & Functional Genomics
15th Dec 2019: 1 day Conference. *Conference theme – "To Test OR not to Test - To Act OR not to Act"*
organized by
Tata Memorial Centre & Indian Society for Cancer Genetics at ACTREC, TMC, Navi Mumbai

Why attend this workshop & conference: *The field of Clinical & Laboratory cancer genetics has witnessed major development in the last decade.* ***Onco-Genetic risk assessment*** *and management of mutation carriers is being redefined with evolving indications & methodologies for* ***NGS based genetic testing, genetic counselling and risk management of mutation carriers****. Traditionally, germline genetic testing followed detailed genetic counselling, primarily to confirm the suspected inherited cancer predisposition and to use the results for predicting future cancer risk, tailored screening / prevention and extended family testing. The scenario is rapidly changing and the main driver for germline genetic testing is now the clinical need to identify* ***actionable germline mutation*** *in BRCA1/2 or other homologous recombination repair pathway genes for* ***PARP inhibitors*** *or platinum based therapy, Mismatch Repair (MMR) genes for* ***Immune CheckPoint Blockade*** *and in few other genes for specific targeted therapies. Irrespective of the purpose of genetic test, once a mutation is identified, the patient & the family needs specialized counselling and risk management advice in addition to how the results could influence their therapy. The rapid increase in the use of germline genetic testing has overwhelmed the existing Clinical Genetic resources in the western countries, leading to the move towards* ***Mainstreaming*** *of Genetic Testing. The need for mainstreaming is even greater in developing countries with extremely limited and patchy clinical genetic resources. The oncologists need to understand the working principles of cancer genetics and their role in mainstreaming, Genetics Counsellors & Genetics Labs need to know the evolving clinical requirements and evidence while scientists need to know the unmet need for functional characterization of large number of variants. This meeting aims to bridge this gap for all stakeholders and reach consensus.*

The experience of organizers in Clinical & Laboratory Cancer Genetics: *The Cancer Genetics Unit at TMC is the apex cancer genetic referral centre in South Asia with 8300 diverse hereditary cancers families from various Indian states & neighbouring countries. The genetics lab in ACTREC performs genetic analysis for 21 genes with Sanger Sequencing, MSI, MLPA and NGS and comprehensive VUS characterization. The insight gained into the nuances of genetic counselling and genetic testing as relevant to the Indian scenario has been shared through 4 national and 2 international conferences and workshop in the field of Cancer Genetics it has conducted in the last 7 years.*

Workshop I: Cancer Genetics Counselling *(Maximum 27 participants): Principles of counselling, syndrome identification, work up, pre & post test counselling, family counselling, VUS counselling, management of mutation carriers, screening, chemoprevention & prophylactic surgery*

Workshop II: Molecular Genetics & NGS multigene Panel *(Maximum 27 participants): PCR trouble shooting, Genotyping & validation, LOH, Sanger sequencing troubleshooting, MLPA, NGS Targeted multigene panel & Bioinformatic analysis with drafting of genetic test reports*

Workshop III: Tissue Culture for Functional Genomics *(Maximum 7 participants): Establishing & characterizing cancer cell lines & EBV cell lines. Selecting appropriate cell lines, functional assays like Transformation, Invasion, Viability, Proliferation, Metastases, DNA repair etc.*

Cancer Genetics Conference (15th December 2019): Conference Theme: "To Test OR not to Test - To Act OR not to Act"
Lectures & panel discussion by experts to bring out issues related to genetic counselling, genetic testing & risk management in clinical practice

Focus on practical issues faced in the Oncology Clinics, Genetics Clinics & Genetic Testing Labs
Lectures and panel discussion using real de-identified cases

1. *Does this patient requires genetic counselling or not?*
2. *Does this patient requires genetic testing or not?*
3. *What genetic test is required for this patient – single gene, multigene NGS, MLPA, Somatic or Germline or Both?*
4. *Pitfalls in interpreting genetic test report and its consequences. How not to fall in the Valley of VUS Trap*
5. *What screening advice to give for mutation carriers with its evidence for efficacy and issues in compliance*
6. *What risk reducing surgery advice to give for mutation carriers with its evidence for efficacy & issues in compliance*

Who should attend the Conference?

Trainees & Professionals dealing with patients who need or have undergone Genetic counselling or testing

- *Oncologists (Medical, Surgical & Radiation)*
- *Clinical / Medical Geneticists*
- *Genetic Counsellors & Clinical Psychologists*
- *Radiologists, Pathologists & Translational Scientist*
- *Preventive & Community Medicine*
- *PhD/ MD/ MS/ DM/ MCh students*
- *Industry / Labs engaged in Genetic testing*

Registration Fee	Up to 30th Nov 2019		Up to 8th Dec 2019		After 8th Dec 2019 Spot Registration	
	Academia	Industry	Academia	Industry	Academia	Industry
Only Conference	2000 +18% GST INR 2360	3000 +18% GST INR 3540	2500 +18% GST INR 2950	4000 +18% GST INR 4720	3500 +18% GST INR 4130	5500 +18% GST INR 6490
Conference with Workshop	7000 +18% GST INR 8260	12000 +18% GST INR 14160	8000 +18% GST INR 9440	14000 +18% GST INR 16520	No spot registration for workshop	

Registration fee includes Handbook & all meals on 5 days. Registration link and Payment by Bank Drafts, Debit /Credit Cards or Electronic Transfer at https://tmc.gov.in/icgcw/

Limited accommodation in ACTREC campus (preference for women) and outside on first come basis. For details click here and send email request

PDF of single page abstract (+/- figures and table) can be submitted by email to icgcw.tmc@gmail.com ***Poster size****: 4 feet width x 3 feet length*
One abstract each in clinical genetics, genetic counselling and molecular genetics will be selected by a jury for Best Paper Award

"Meetings" on ACTREC website - www.actrec.gov.in **Registration Link** *https://tmc.gov.in/icgcw/*

Email icgcw.tmc@gmail.com **Phone** +91-22-27405000 ext. 5092/5529 **Mobile:** +91-8657361535

Chairman RAJIV SARIN
Organizing Secretary PRADNYA KOWTAL
Treasurer RAVINDRA REDDY

INTERNATIONAL CONFERENCE ON

ADVANCES IN BIOCHEMISTRY, BIOTECHNOLOGY AND BIOMEDICINE

8-9 February 2020 | New Delhi, India

ORGANIZED BY

INTERNATIONAL ACADEMY OF SCIENCE, TECHNOLOGY AND ENGINEERING RESEARCH

21st INDO-US Flow Cytometry Workshops

(Building Cytometry Community Since 2002)

Organized by

Live Education Task Force (LETF),
International Society for Advancement of Cytometry (ISAC),
Trust for Education and Training in Cytometry (TETC)

27th January - 7th Febuary, 2020

VENUES

1.) CSIR-National Institute of Oceanography (CSIR-NIO), Goa
"Basics of Flow Cytometry and its Applications in Oceanography"
(27th-28th Jan, 2020)

2.) M.S. Ramaiah Medical College, Bengaluru
"Clinical Applications of Flow cytometry"
(29th- 30th Jan, 2020)

3.) Panjab University, Chandigarh
"Flow Cytometry Applications in Biomedical Research"
(2nd- 5th Feb, 2020)

4.) Eternal University, Himachal Pradesh
"Basics of Flow Cytometry and its Applications in Plant Biology"
(6th- 7th Feb, 2020)

TETC
Trust for Education and Training in Cytometry

ISAC
INTERNATIONAL SOCIETY FOR ADVANCEMENT OF CYTOMETRY

National Institute of Oceanography, Goa

RAMAIAH Medical College

Panjab University

Eternal

Contact Details

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+91-9284999738

Dr. Hemant Agrawal
flowsols@gmail.com
+91-7665130114

For updates, please follow us on Facebook
https://www.facebook.com/cytoindia/
https://www.facebook.com/tetcindia/

19 - 21 December, 2019

XLIII ALL INDIA CELL BIOLOGY CONFERENCE

VENUE:
IISER Mohali

ORGANIZERS:

Sudip Mandal
Lolitika Mandal
IISER Mohali

REGISTRATION:
Registration opens:
September 1, 2019
Last Date for Registration:
October 10, 2019

CONTACT:
aicbc2019@gmail.com

SPEAKERS:

Sumantra Chattarji
NCBS, Bangalore

Anuradha Ratnaparkhi
ARI, Pune

Biman B Mandal
IIT Guwahati

Chandrima Das
SINP, Kolkata

Chetana Sachidanandan
IGIB, New Delhi

Deepa Subramanyam
NCCS, Pune

Gitanjali Yadav
NIPGR, New Delhi

Jonaki Sen
IIT, Kanpur

Kalika Prasad
IISER Thiruvananthapuram

Mousimi Mutsuddi
BHU, Varanasi

Pradyumna K Singh
NBRI, Lucknow

Puran Singh Sijwali
CCMB, Hyderabad

Rahul Roy
IISc, Bangalore

Raj Ladher
NCBS, Bangalore

Ram Kishore Yadav
IISER Mohali

Rashna Bhandari
CDFD, Hyderabad

Ravi Manjithaya
JNCASR, Bangalore

Sandhya Koushika
TIFR, Mumbai

Sanjeev Shukla
IISER Bhopal

Siddharta Jana
IACS, Kolkata

Surajit Sarkar
DU South Campus, New Delhi

www.aicbc2019.org

Indian Society of Cell Biology
Indian Institute of Science Education & Research (IISER) Mohali

MIT School of
Bioengineering Sciences & Research
Breathe Life into Engineering Career!

MIT-ADT UNIVERSITY
PUNE, INDIA

3rd International Conference on Recent Trends in Bioengineering (ICRTB 2020)

January 31 - February 01, 2020

Conference Theme Areas

- Nanobiotechnology
- Synthetic Biology
- Tissue Engineering
- Environmental Biotechnology
- Wearables & Diagnostic
- Assistive Devices
- Nanoinformatics
- Immunoinformatics
- Drug Design
- AI and Big data in Biology
- Biomedical Robotics
- Medical Image Processing

Selected thematic articles will be published as book chapter in Springer and selected high quality research papers will be considered for publication in American Scientific Publishers Advanced Science, Engineering and Medicine journal.

Please submit your Abstracts/ Papers to icrtb@mituniversity.edu.in

Talk by eminent speakers from Industry, Academia and Medical fraternity. **For more details, visit:** www.mitbio.edu.in/icrtb

Venue:

MIT ADT University
Rajbaug Campus, Next to Hadapsar,
Pune Solapur Highway, Loni Kalbhor, Pune.
Contact : 9146051841, Email : icrtb@mituniversity.edu.in

Register at www.mitbio.edu.in/icrtb

17th IAAM Annual Conference on "MICROBIOLOGY IN THE NEW MILLENIUM"

November 29 & 30, 2019

KALASALINGAM
ACADEMY OF RESEARCH & EDUCATION
(DEEMED TO BE UNIVERSITY)
Under sec. 3 of UGC Act 1956. Accredited by NAAC with "A" Grade

MNM–2019 is an initiative to provide a common platform for researchers working in the field of microbiology to share knowledge and ideas for technological advancements. This conference will bring in experts in microbiology from both academia and industry, from India and abroad. The meeting will update current knowledge on various processes involving microorganisms and their impact on human welfare and will provide a platform for sharing and gaining insights into recent innovations in microbiology and allied fields.

The Conference includes the following thrust areas:
Role of microbes in Agriculture and Environment
Food and Industrial Microbiology
Microbiota in human health and diseases
Microbial Genomics and Computational techniques in genome analysis
Microbial Proteomics and Metabolomics
Therapeutic Microbial metabolites
Designing of newer drugs and vaccines

For further information on the conference, technical programme and registration fees, please visit the conference website at: https://www.kalasalingam.ac.in/site/iaam2019

Organizing Committee
Department of Biotechnology, School of Bio and Chemical Engineering, Kalasalingam Academy of Research and Education, Krishnankoil–626126, Virudhunagar District, Tamilnadu, India

For details, please contact
Dr. V. Deepak, Assistant Professor (+91 999 400 5974)
Dr. S. Ram Kumar Pandian, Assistant Professor (+91 900 344 0063)

21st INDO-US Flow Cytometry Workshop
"Basics of Flow Cytometry and its Applications in Oceanography"

Jointly organized by

Live Education Task Force, International Society for Advancement of Cytometry (LETF-ISAC)

Trust for Education and Training in Cytometry (TETC)

CSIR-National Institute of Oceanography (CSIR-NIO)

at

CSIR-NIO, GOA

27th-28th January 2020

Workshop Highlights

Basics of Flow Cytometry
Applications of Flow Cytometry in Oceanography
Know Your Cytometer (KYC)
Quality Control and Trouble Shooting
Marine Microbial Ecology
Phytoplankton Ecology
Invertebrate Immunology
Data Analysis and Presentation

Invited Faculty

Dr. Nicole Poulton, USA
Dr. William Telford, USA
Dr. Z. Maciorowski, France
Dr. A. C. Anil, India
Dr. H. Krishnamurthy, India
Dr. Rekha Gour, India
Dr. Hemant Agrawal, India
Dr. Lidita Khandeparker, India
Dr. Dattesh Desai, India

Organizing Committee

Patron
Prof. Awtar Krishan, USA

Scientific Advisory Committee
Prof. Sunil Kumar Singh
Dr. A C Anil

Convener
Dr. Rekha Gour

Organizing Secretaries
Dr. Lidita Khandeparker
Dr. Hemant Agrawal

Members
Dr. H. Krishnamurthy
Dr. Vivek Tanvade
Dr. Dattesh Desai
Mr. Kaushal Mapari

Online Registration:

Fill the registration form and send the scanned copy together with online payment receipt to Dr. Hemant Agrawal at indiatetc@gmail.com

NEFT/RTGS Details:
Account Name: Trust for Education and Training in Cytometry
Account Number: 3712970609
IFSC Code: KKBK0000646
Bank Name: Kotak Mahindra Bank, Mumbai

	Students	Faculty	Industry
Registration fee	Rs. 2500	Rs. 5000	Rs.10000
Spot Registration	Rs. 4000	Rs. 8000	Rs.12000

Accommodation: Limited accommodation is available on campus on paid and first come first serve basis.

For further information, call or email to us

Dr. Lidita Khandeparker
klidita@nio.org; +91-8322450432
Dr. Hemant Agrawal
flowsols@gmail.com; +91-7665130114

Last date for registration: 25th December 2019

For updates, please follow us on Facebook
https://www.facebook.com/cytoindia/; https://www.facebook.com/tetcindia/

INTERNATIONAL CONFERENCE OF CARDIOVASCULAR SCIENCES-2020 (ICCS-2020)

Incorporating Annual Conferences of International Academy of Cardiovascular Sciences (IACS)-India Section & International Society of Heart Research (ISHR)-India Section

(February 21–23, 2020)

THEME

Convergence of Clinicians and Scientists for Cardiovascular Health

CO-SPONSORS

All India Institute of Medical Sciences (AIIMS), New Delhi, India
Society for Promotion and Research in Cardiovascular Sciences (SPARCS),
Academy of Cardiovascular Sciences (ACS)

ORGANIZING SECRETARY
Prof. Harvinder Popli
Off. Registrar & Dean, DPSRU

ORGANIZING SECRETARY
Prof. Nitish Naik
Department of Cardiology, AIIMS

CHAIRPERSON, LOC
Prof. Ramesh K. Goyal
Vice Chancellor, DPSRU

CHAIRPERSON, LOC
Prof. Vinay Kumar Bahl
Dean, AIIMS

VENUE

DELHI PHARMACEUTICAL SCIENCES AND RESEARCH UNIVERSITY

M.B. Road, Pushp Vihar Sector-III, Opp. Sainik Farm, New Delhi – 110 017, India
E-mail: iccsdelhi2020@gmail.com

NOTIFICATIONS

जैव प्रौद्योगिकी विभाग
Department of Biotechnology
Ministry of Science & Technology
Government of India

EUROPEAN UNION

INDIA-EU CO-FUNDING ANNOUNCEMENT FOR PROPOSALS UNDER 'HORIZON 2020' WORK PROGRAMME: 2019-2020, ON HEALTH, BIOECONOMY, CLEAN ENERGY AND BIOTECHNOLOGY

Researchers and innovators from universities, research organisations and enterprises from India can team up with European partners in the calls for proposals published by the European Commission (EC) under its Research and Innovation programme 'Horizon 2020' (2014-2020).

Through participation in 'Horizon 2020', Indian partners can benefit from access to talent, knowledge, data and infrastructures, and connect to world-leading teams, networks, value chains and address jointly global challenges. To ensure funding for successful Indian applicants, DBT and the EC have concluded a Co-Funding Mechanism (CFM) by which DBT agrees, in pre-selected calls, and subject to specific conditions and modalities, to fund the successful Indian participants that have been selected in Horizon 2020 project(s).

On 2 July 2019, the EC published the 'Horizon 2020' updated Work programmes for 2019-2020, in which the Department of Biotechnology (DBT) has agreed to participate in 30 call topics in the areas of its mandate. See in Section 1 hereunder, the full list of topics per thematic area earmarked by DBT for co-funding. The list indicates the exact Call IDs, the opening and closing date of the call; the type of action provided and the link to the full call text as published in the Horizon 2020 Funding & Tenders Portal.

The guidelines in this notice also explain various modalities of participation that the Indian applicants have to comply with in order to be eligible for funding by DBT (see hereunder Sections 2 and 3, including Annex 1 on Administrative and Financial Considerations).

All proposals should be submitted to the Horizon 2020 Funding & Tenders Portal and to DBT, including the budget requested from DBT. In the absence of this, DBT will disqualify the Indian participants from funding (see Section 4 hereunder).

At the end of the notice, information is also provided on how to access and go about 'Horizon 2020' formalities, which Indian applicants have also to comply with (Annex 2) and on How to find partners (Annex 3).

Interested participants must also ensure complete understanding about the call text itself on the Horizon 2020 Funding & Tenders Portal for the overall conditions and modalities.

Notice

DETAILS FOR "ICMR-CNMC STS EXCELLENCE AWARD"- 2019 APPLICATIONS

The ICMR- Calcutta National Medical College (CNMC) Short Term Studentship (STS) Excellence Award was instituted by CNMC Alumni Association, Kolkata in 2015. This award is conferred upon a medical undergraduate student who has been awarded ICMR-STS (2016, 2017 & 2018) and has published a paper in an indexed journal as the first author. This award aims to encourage undergraduate medical students to take up research.

The Award carries a cash award of Rs. 25,000/- and a Certificate of Honour

Last date of submission of applications is November 30th, 2019.

Eligibility and Terms & Conditions:

1 A student pursuing MBBS or/has completed MBBS AND who has been awarded ICMR-STS successfully AND published an original article as first author in an indexed peer reviewed journal based on his STS research work will be eligible to apply for this award. The journal should be indexed in MEDLINE or Science Citation Index (SCI)/Journal Citation Reports (JCR) index Clarivate Analytics only. No other indexing will be considered.

2 The application in a given format accompanied by CV and original Publication in an indexed journal (as stated in point above) may be submitted by the student.

3 Case reports/letters to editors/papers in non-peer reviewed/non-indexed journals/review articles/chapters in books/abstracts/conference proceedings or any other reports will not be entertained for this award.

4 **STS 2016, 2017 and 2018 awarded students**, who have published their paper till November, 2019 shall be eligible to apply for ICMR-CNMC STS Excellence Award-2019.

5 The student should have followed ethical norms for conduct of research and have acknowledged STS Program of ICMR in the publication.

6 The topic for research could be any kind of biomedical and health research involving either clinical, laboratory, experimental, epidemiological, qualitative, quantitative, or community based work *etc.* carried out under ICMR-STS programme.

7 Application for the award should be sent ONLY in the specified format given below.

8 The selection will be based on scientific merit only and no other considerations will be taken into account.

How to apply:

Applicants should send their duly filled and signed application only by email to stsaward@gmail.com by 30th November 2019, with the following documents (mandatory) as email attachments. No paper/hard copies will be accepted.

Kindly send the pdf of the following:

a. Filled and duly signed in application in the given format (pdf).
b. Signed and dated CV (pdf).
c. Reprint/ Original Publication in an indexed journal (as required) (pdf).

Tel: 91-11-23316742, 23736212
PABX : 23470 218, 23470274
Fax: 91-11-23316764,23739041, 23710618, 23714788

COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH
Anusandhan Bhavan 2, Rafi Marg, New Delhi - 110 001.

The Head, International S & T Affairs
Division (ISTAD), CSIR HQ

No : 22 / RRF / 2019 - ISTAD
Date : 13.11.2019

To

The Directors of All research institutes of CSIR

Subject : Raman Research Fellowships for the year 2020-2021

Sir,

Applications are invited from CSIR institutes for the award of **Raman Research Fellowships for the year 2020-2021**. The Raman Research Fellowships are granted to the CSIR researchers for carrying out research in the emerging / high priority technology areas. It is tenable at foreign institutions / R&D Centres of Excellence. The entire cost is met by CSIR HQs.

The application proforma is given at **Annexure-I**. The details regarding eligibility, terms & conditions etc. may be seen at **Annexure-II**. Applications of **upto two** eligible meritorious candidates may be forwarded to ISTAD, CSIR after thorough careful evaluation. All applications will be returned to the concerned Institute if the number of nominations exceeds two.

The candidates are required to submit **6 (six) copies** of their application form. In addition, an electronic copy of the nomination summary as per **Annexure-III** may be sent to the undersigned **(kamlesh@csir.res.in)**.

The nominated candidates are expected not only to be meritorious but also be fully aware of the national agenda in Science and CSIR's Vision. They are expected to possess general awareness about our country, its culture, history and present day socio-economic and geo-political issues.

The selection will be made through a mechanism of interview by the duly constituted Selection Committee. The interviews will be held in **CSIR HQs., New Delhi sometimes in April/May 2020**. The exact date and time of the interview will be intimated to all the eligible candidates about one month in advance.

The last date for receipt of the duly filled in applications, complete in all respects is **February 15, 2020**. Applications received after the last date will be summarily rejected.

The candidates are advised not to correspond directly but may feel free to make enquiries through ISTAG of their respective Lab/Instt.

NATIONAL INSTITUTE OF IMMUNOLOGY

(An Autonomous Research Institute of Department of Biotechnology, Govt. of India)

Career Opportunities for Scientists- Rolling Advertisement

The National Institute of Immunology, New Delhi, is a leading research Institute in India with a long-standing reputation for scientific excellence. The institute is equipped with state-of-the-art infrastructure for pursuing research in immunology and allied sciences. The Institute also imparts vigorous long-term research training leading to a Ph.D degree.

The Institute invites applications from early as well as mid-career scientists, with potential for intellectual leadership and passion for innovative research to set up independent research programmes in the areas of (but not restricted to) Immunology, Virology, Microbiology, Structural, Chemical and Molecular Biology, Immunology and Vaccines, Infectious and Autoimmune Diseases, Metabolic Disorder and Chronic diseases, Structural and Computational Biology, Genetics, Cell and Developmental Biology to address immunological problems at the expanding interface of modern biology for filling 2 positions of Staff Scientist-III and 5 positions of Staff Scientist-IV as per details given below:

Name of the post/ Number of vacancies	**Pay Level (7th CPC)**	**Qualifications and Experience**	**Upper Age Limit**	**Remarks**
Staff Scientist-III (2 Vacancies)	11	1st class M.Sc with 5 years experience or 1st class M.Tech/ MD/ MVSc/ M.Pharm/ M.Biotech with 4 years R&D experience **OR** Ph.D with 4 years postdoctoral experience in the relevant field.	40 years	1-UR 1-for Person with benchmark disability (deaf and hard of hearing)
Staff Scientist-IV (5 Vacancies)	12	1st class M.Sc with 9 years experience or Ist class M.Tech/ MD/ MVSc/ M.Pharm/ M.Biotech with 8 years R&D experience **OR** Ph.D or corresponding degree in other disciplines with original work as evidenced by patents or publications. Evidence of leadership with about 8 years of R&D experience.	50 years	2-UR 2-OBC 1-SC

NOTE: Call for applications will remain open till the vacancies are filled. The applications will be accepted throughout the year and will be scrutinized / shortlisted on quarterly basis. The last date for receipt of applications for each quarter is is March 31st, June 30th, Sept 30th, and Dec 31st.

Government of India
Ministry of Science and Technology

DEPARTMENT OF BIOTECHNOLOGY
Public Health, Food and Nutrition Division

Call for R&D Proposals on "Food fortification and newer technologies to improve bioavailability of nutrients"

Rationale: Nutritional anaemia is primarily caused due to deficiencies of micronutrients Food fortification as a strategy to address micronutrient malnutrition, has the dual advantage of being able to deliver nutrients to large segments of the population without requiring radical changes in food consumption patterns. With an aim of making food fortification more efficacious and to help to reduce the burden of micronutrient malnutrition in the country, this department **proposes to support R&D proposals in the following thrust areas of food fortification**:

1. Novel fortificants/additives that can enhance the bioavailability of fortificants.
2. Sensory, acceptability and stability studies of fortified staples in real field conditions, food interactions and methods to overcome negative nutrient-nutrient/food interactions
3. Generate data on bioavailability of bio-fortified versus fortified food.
4. Micronutrient combinations to impact anaemia, bone health, reproductive health, work productivity, immunity etc among vulnerable population groups.
5. Studies that would evaluate potential negative interactions on health in response to consumption of fortified foods.
6. Role of other micronutrient nutrients (eg, calcium, zinc, vitamins) in determining co- fortification levels with iron for staples.
7. Studies that would provide new insights, data on fortified food acceptance, consumption, enablers, deterrents from the various stake holders (farmer, miller, consumer, socio economic, behavioral and cultural interactions).

Eligibility: Applications may be submitted by public and private universities, colleges, Institutes, non-profit organizations (recognized by DSIR as a Scientific and Industrial Research Organization (SIRO)). Development of interdisciplinary collaborative research team with involvement of experts from biomedical field is encouraged.

How to apply: Applicants should submit full proposal on or before the deadline through DBT Epromis portal and submit two hard copies to **Dr. Balendra Singh,** Scientist-C, Department of Biotechnology, Block- 3, Room No. 525B, 5th floor, CGO Complex, Lodhi Road, New Delhi – 110003 and email the soft copy to email: **balendra.singh@dbt.nic.in**. The link to DBT epromis format: https://dbtepromis.nic.in/sample_forms.aspx

The deadline for submission of full proposal is 23rd November, 2019

For any queries, contact Dr. Balendra Singh, Scientist-C, Email- balendra.singh@dbt.nic.in / Dr. A.Vamsi Krishna, Scientist-E, Email- vk.addanki@nic.in

Notice

2nd ASIAN SHORT COURSE ON AGRIBIOTECHNOLOGY, BIOTECHNOLOGY REGULATION AND COMMUNICATION

December 2-6, 2019 | SEARCA, Los Baños, Laguna, Philippines

The potential of agribiotechnology to contribute to sustainable agriculture depends on R&D as well as on the integration of other factors such as effective communication, science-based national regulatory frameworks, and adequate understanding of international legal instruments. Strong collaboration among scientists, regulators, and lawyers is important so that science and regulations can co-evolve and society can benefit from modern biotechnology while risks are minimized.

The 1st Asian Short Course on Agribiotechnology, Biotechnology Regulation and Communication (ASCA) was conducted in Malaysia in 2018 with 26 participants from Malaysia, Singapore, Philippines, Turkey and Pakistan. The 2nd ASCA takes place in the Philippines on December 2-6, 2019.

This short course is designed to:

- enable participants to better understand the entire value chain related to research, development, commercialization and trade of LMOs;
- national and international legal instruments related to LMOs; and
- effective communication of agribiotechnology and biosafety regulation.

SCOPE OF THE TRAINING

1. Conceptual and laboratory experience on biotechnology: plant transformation and animal biotechnology in the laboratories, screenhouse, field and farms.
2. Hands-on training in environmental and food/feed safety assessment supported by exercises.
3. Strategic communication methods (in quad media), risk management and risk communication.
4. Role of modern biotechnology in agriculture, its impact on the economy and its current and future pipeline.
5. National and international biotech regulations and agreements (commonalities, differences, approval process).
6. Debriefing of COP14MOP9 in Egypt, its protocol, impact to national systems including gene edits, synbio, socioeconomic consideration, risk assessment and management, liability and redress, ABS.

FEES

Participants' Fees: US$1,000
Inclusive: Meeting package, local transport, accommodation, and an official dinner
Not inclusive: Travel, airfare, and other dinners
Payment methods: Please contact us for details.

REGISTRATION

Register now at:
bit.ly/ASCA2019register

CONTACTS

PANFILO DE GUZMAN
Assistant Scientist
ISAAA *SEAsia*Center
pdeguzman@isaaa.org
Tel. No. +63 49 5367933

ZABRINA J. BUGNOSEN
Administrative Coordinator
ISAAA *SEAsia*Center
zbugnosen@isaaa.org
Tel. No. +63 49 5367216

Department of Biotechnology, Vignan's Foundation for Science, Technology and Research, (Deemed to be University)

Accredited by NAAC with 'A' Grade

VIGNAN'S UNIVERSITY

Recruitment of JRF

A JRF position is available in MoEF (Ministry of Environment, Forest and Climate Change), New Delhi, supported research grant proposal entitled " Phylogenetic analysis and Barcoding of Indian Apple Snails (Ampullaridae) as a prelude to their conservation strategy" in the Department of Biotechnology, Vignan's Foundation for Science, Technology and Research (Deemed to be University), Vadlamudi 522213 A P. Candidates with M.Sc/M.Tech in Bioinformatics will be given preference. Interested candidates may submit their CV along with a note indicating their interest in doing research in Molecular Phylogeny to the email: hodbt@vignan.ac.in at the earliest.

Selected candidates will be made to enroll for a Ph.D. program in the Department of Biotechnology, VFSTR.

Contact Person: Prof.S.Krupanidhi, PI, HoD, Dept of Biotech, VFSTRU

Vignan's Foundation for Science, Technology and Research (VFSTR)

(Deemed to be University)
Vadlamudi : : Guntur – AP 522213

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Ph.D. admissions and Postdoctoral Fellowships (2019-20 Even Semester) in all branches of Engineering and Sciences

VFSTRU invites applications from M.Tech. / M.Sc., / M.Pharma. / Medical / Veterinary/Agriculture candidates with UGC NET/ GATE score for the year 2019-20 even semester. HTRA (Half Time Research Assistance) will be provided to Ph.D scholars (Full-Time) with a discrete project proposal. HTRA range from Rs. 18,000/ for Science and Humanities streams to Rs. 25,000/ P.M for Engineering streams for a period of 4 years from the date of admission or until the submission of thesis whichever is earlier.

Post Doc Fellowships in all branches of engineering and sciences will be provided for a period of two years with negotiable remuneration.

CoEs, CIF, RC and state-of-the-art lab facilities are available at VFSTRU and MoUs with reputed organizations both in India and abroad are in place to facilitate research scholars to expand their scope of research. Excellent Research culture and ambience is available to carry out the research in cutting edge technology and niche areas.

Applications are accepted yearly twice in the months of July and December.
Apply online: www.vignan.ac.in. The admission will be granted on the basis of entrance test and interview.

Dean – Admissions

Call for Nominations/ Applications for ICMR Awards & Prizes- 2019

The Indian Council of Medical Research (ICMR) invites Nominations/Applications from Indian scientists for ICMR Awards & Prizes for the year 2019 (list given below) in various fields of biomedical sciences. Last date of receipt of Nominations/Applications is 30th November, 2019

List of ICMR Awards/Prizes for the year 2019

Dr. B.R. Ambedkar Centenary Award for excellence in Biomedical Research (Biomedical Research)
Dr. Subhas Mukherjee Award (Assisted Reproductive Technology, Reproductive Biology & Endocrinology and Reproductive Health in General)
Basanti Devi Amir Chand Prize (Biomedical Sciences)
Shakuntala Amir Chand Prize (Clinical Research) - Age below 40 years (Number of prizes – four)
Amrut Mody Unichem Prize (Gastroenterology)
Dr. H.B. Dingley Memorial Award (Paediatrics) – Age below 40 years.
ICMR Kshanika Oration Award (Biomedical Sciences) – for Indian women scientists
ICMR Prize for Biomedical Research for Scientists belonging to underprivileged communities (Biomedical Sciences)
ICMR Prize for Biomedical Research conducted underdeveloped areas – (Biomedical Sciences)
ICMR Tilak Venkoba Rao Award (Psychological Medicine) - Age below 40 years
JALMA Trust Fund Oration Award (Leprosy and other mycobacterial diseases)
Major General Saheb Singh Sokhey Award (Communicable Diseases) – Age below 40 years
Smt. Kamal Satbir Award (Non-tuberculosis Chest Diseases, especially Respiratory Allergy and Chronic Obstructive Lung Diseases) - Age below 40 years
Dr. D.N. Prasad Memorial Oration Award (Pharmacology)
Dr. J.B. Srivastav Oration Award (Virology)
Dr. M.O.T. Iyengar Memorial Award (Malaria, Filariasis, Plague or Medical Entomology)
Dr. Prem Nath Wahi Award (Basic and/or Clinical Cytology and/or Preventive Oncology)
ICMR Chaturvedi Ghanshyam Das Jaigopal Memorial Award (Immunology)
ICMR Chaturvedi Kalawati Jaghmohan Das Memorial Award (Cardiovascular Diseases) – Preferably a medical person
ICMR Smt. Swaran Kanta Dingley Oration Award (Reproductive Biology)
ICMR-CNMC STS Excellence Award (for medical undergraduate student who has been awarded ICMR STS)

Address for correspondence:

The Director General, [Kind Attention: Dr. N. C. Jain, Scientist-G & Head, Division of Human Resource Planning and Development (HRD)], Indian Council of Medical Research, V. Ramalingaswami Bhawan, Ansari Nagar, Post Box No. – 4911, New Delhi-110029 Telephone: 011-26589258, email: drencejain@gmail.com

Indian Academy of Sciences, Bengaluru
Indian National Science Academy, New Delhi
The National Academy of Sciences, India, Prayagraj

Science Academies' Summer Research Fellowship Programme for Students and Teachers – 2020

Applications are invited from interested students and teachers from all universities and colleges affiliated to UGC/AICTE/MCI/Accredited Institutions of State Universities for these Fellowships. The application should include: (a) the application form in the prescribed format; (b) scanned copies of marks sheets from class X till the last examination; (c) a write-up (about 150–250 words) as to what the applicant wants to learn and achieve. Student applicants should provide the e-mail id of one of their teachers or HoD familiar with their work. The Academy will approach them for a recommendation letter in the prescribed format. The selected candidate should work with the assigned guide for two months any time during the calendar year, preferably during the summer.

Applications should be submitted by logging onto one of our websites (www.ias.ac.in; www.insaindia.res.in or www.nasi.org.in). The registration number assigned soon after online submission must be quoted in all future correspondence.

The last date for receipt of applications online is 30 November 2019.

Information of selection along with concurrence of the guide will be despatched around February–March 2020. The selected students/teachers will be provided appropriate round trip train fare and a monthly fellowship to meet their living expenses at the place of work.

Professor M R N Murthy Chairman, Joint Science Education Panel Indian Academy of Sciences, Bengaluru

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Publication: February 1 to March 31
Announcement of winners: March 31

For more information :
ngsf.in
blog@ngsf.in

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Passage No:	
Biosafety Level	1
Organism	Homo sapiens (Human)
Growth properties:	Adherent
Age:	Lot Specific
Morphology	Spindle-Shaped, fibroblast-like
Gender	Lot Specific
Volume/Vial:	5ml (2.3 million cells / 1ml)
No: of Vials	As required
Viability	≥92%
Population Doubling Capacity:	≥ 10 in complete growth medium and support differentiation
Shipped	Frozen
Storage	Liquid nitrogen or for short term storage at -80°C
Quality Assurance:	
Testing	Tested for CD73, CD90, CD105, CD34, and CD45. Primary cells display normal karyotype as assessed by G-banding of 20 metaphase cells.
Sterility Tests	Bacteria & Yeast : Negative Mycoplasma: Negative Endotoxin: Negative

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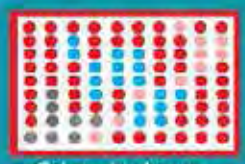
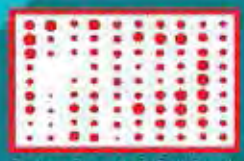


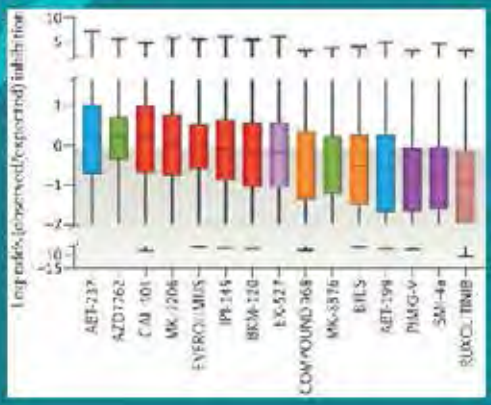
Colorimetric Assays

Turbidity Measurements

Cell Marker Expression



Colony Growth & Cell Death



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