

BIOTECH BULLETIN

Biotech Bulletin is a bi-monthly publication brought out by Biotech Consortium India Limited (BCIL), a company promoted by the Department of Biotechnology (DBT), Government of India and the All India Financial Institutions which is involved in facilitating accelerated development and commercialisation of biotechnology.

The bulletin is a useful compilation of latest clippings from newspapers, magazines and journals on relevant areas in biotechnology including healthcare, agriculture, market/ collaborations, research and development.

The publication is brought out exclusively for our **Biotech Club Members**.

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First indigenous rotavirus vaccine launched

THE HINDU
March 10, 2015

Prime Minister Narendra Modi launched the first indigenously developed and manufactured rotavirus vaccine. Every year, diarrhoea caused by rotavirus results in up to 10 lakh hospitalisations and kills nearly 80,000 children under the age of 5.

The three-dose ROTAVAC vaccine, developed through a collaboration between India and the United States, is expected to help bring about a significant reduction in

the 100,000 infant deaths caused by the rotavirus diarrhoea in India.

Mr. Modi hoped the vaccine would inspire higher levels of research, development and manufacturing in India, in not just medical science but also in other advanced areas of science and technology. He highlighted the vaccine as a successful example of collaboration between India and the U.S. in the area of medical research for the benefit of ordinary citizens.

“We have realised a dream by bringing out the first Made in India Molecule. We have also maintained

our pledge to offer ROTAVAC for \$1 to governments in low-income countries,” said Krishna Ella, Chairman and Managing Director of Bharat Biotech, which contributed towards product development and testing. A vaccine innovated in India, developed in India and to be made in India, would be a big boost to the “Make in India” initiative, said Dr. Ella.

The vaccine has been developed under an innovative public-private partnership model. It involved a partnership between the Ministry of Science and Technology, institutions of the U.S. government, various government institutions and NGOs in India, and has been supported by the Bill and Melinda Gates Foundation, a government statement said.

Harry Greenberg, Associate Dean at Stanford University, termed the project a “beautiful example of the great power of team science.” ■

Government labs developing new affordable life saving drugs

MILLENNIUM POST
April 12, 2015

The government has stepped up efforts to develop and provide new and affordable drugs for malaria, osteoporosis and diabetes to meet increasing demands, said Science and Technology Minister Harsh Vardhan. The new medicines, which are currently undergoing clinical trials, would be showcased by the Indian pharmaceutical sector soon.

“I am confident that the drug laboratories under CSIR are capable of

backing up the Swasth Bharat Mission. Our scientists are focusing on both infectious and life-style diseases. We are developing next-generation drugs, biologics, biosimilars, gene therapeutics, stem cell therapeutics, personalised medicine and multifunctional nanomedicine,” the minister said.

The drugs are being developed at Central Drug Research Institute (CDRI, Lucknow). Talking to the media persons after a visit to CDRI, he said that research and development efforts in government laboratories under the wing

of the Council of Scientific and Industrial Research (CSIR) have a track record in making drugs for kalaazar, filaria, leprosy and tuberculosis available at affordable rates to the common man.

“The pharmaceutical sector would soon be showcasing new drugs for malaria, osteoporosis and diabetes,” Vardhan said. He announced that simultaneously, the CDRI is carrying out Investigational New Drug (IND) studies on lead molecules for fracture-healing, cancers, thrombosis, malaria and hyperglycemia.

It would strive to build a new generation of enterprises in the healthcare sector, he said. He also announced that government would soon set up the Biopharma Industry Incubator (BI) under the umbrella of CDRI Lucknow.

He added that recently the IMTECH, Chandigarh has developed a clot specific streptokinase; IIM, Jammu has discovered natural product-based potential medicine for rheumatoid arthritis, IICB Kolkata has developed herbal extract for the treatment of benign prostate hyperplasia. ■

Indian researcher wins woman of the year 2015 in new south wales

THE INDIA EXPRESS
March 17, 2015

A 56-year-old Indian pancreatic cancer researcher in Australia has been named New South Wales Woman of the year 2015 for her contributions to medical research, tertiary education and the Indian community. Minoti Apte, researcher at University of New South Wales (UNSW) received the award from NSW Premier Mike Baird and Minister for Women PruGoward during a reception at NSW Parliament House recently.

“Alongside her impressive career successes, Apte is an active member of the Marathi Association of Sydney, an organisation that serves Sydney’s significant Indian population,”

said Premier Baird, adding that her achievements inspire other women to follow in her footsteps. “In winning the award I’d like to acknowledge the wonderful support of members of the Pancreatic Research Group, my current PhD students ZhihongXu and Sri Pothula and my mentors Professor Jeremy Wilson and Professor Ron Pirola,” she said. Apte, Professor of Medicine at the South Western Sydney Clinical School of the University of New South Wales, last year, was awarded the Order of Australia Medal (OAM) for her services to medical research, tertiary education and the Indian Community.

“Inequality and disadvantage for women returning to work remains a big problem in Australia and more work

needs to be done in this area. “UNSW is leading the way when it comes to family-friendly workplace arrangements and supporting women who want to balance family with pursuing a career in science, academia or medical research,” she said. Based at Ingham Institute for Applied Medical Research, she is director of the Pancreatic Research Group and is an acknowledged world-leader in alcohol-induced pancreatic injury and pancreatic cancer. She investigates pancreatic cancer at a cellular level to find out how and why the cancer is so aggressive and spreads so quickly.

Pancreatic cancer is one of the most deadly cancers with a five-year survival rate of just 6 per cent.

She was the first in the world to develop a method to isolate pancreatic stellate cells, a technique which provided a much needed research tool for studying the path that pancreatic fibrosis (scarring of the pancreas) takes.

She is currently leading pre-clinical studies that are primed to suggest new treatments for pancreatic cancer – the fifth leading cause of all cancer deaths in Australia. ■

Government asks RBI to declare biotech as priority sector

LIVE MINT
March 19, 2015

To encourage investment in research and entrepreneurial activities in the biotechnology field, the government has asked the RBI to declare it as a priority sector to make lending easy for start-ups, minister of state for science and technology said. The minister said his ministry is also working with the finance ministry to boost spending in the sector.

“We have asked the RBI to consider adding biotechnology as a priority sector

for lending, so that the start-ups can easily get loans. We are also working with the ministry of finance on this matter.” “We are also in talks with the ministry of Micro Small and Medium Enterprises to increase the credit limit given to this sector,” Chowdary said.

The minister was speaking on the sidelines of a function organised by the Biotechnology Industry Research and Assistance Council (BIRAC) — a PSU under the Department of the Biotechnology under the ministry of science and technology. Pushing for

a greater assistance under the newly announced MUDRA Bank in the union budget, the minister said that the biotechnology sector should take advantage this newly announced bank.

Micro Units Development Refinance Agency (MUDRA) Bank, with a corpus of Rs20,000 crore and credit guarantee corpus of Rs3,000 crore will help in lending money to small and medium size industries and start-ups. “I am going to establish a help desk in the ministry for assistance in this initiative,” the minister said.

He added that while other ministries saw a drop in the budget, the ministry of S&T budget has not only remained the same, but there has been a slight increase in it. Pitching to make India a country for scientific tourism, Chowdary said the efforts should be made to in the field of science to create world class laboratories which can encourage foreign scientists to come and research in India. ■

‘National biotechnology development strategy’ being drafted

THE INDIA EXPRESS
March 18, 2015

A policy to encourage life sciences education, research, and entrepreneurship, is being drafted and the government had informed it to the Lok Sabha.

The draft policy, known as National

Biotechnology Development Strategy 2, is currently under discussion with all senior experts and stakeholders for finalization before its release.

“The Department of Biotechnology, Ministry of Science and Technology is in the process of drafting a ‘National Biotechnology Department Strategy 2 for encouraging life science education,

research and entrepreneurship,” Minister of state for Science and Technology, Y S Chowdary said in a written response to a question in Lok Sabha. The strategy seeks to address a number of identified challenges in terms of tailor-made human capital for scientific research and entrepreneurship, research priorities, resources, core facilities, he said.

He added that the policy will help in creation of investment capital, intellectual property regime, technology transfer, absorption, diffusion and commercialization (of technology), setting regulation standards and accreditation, creating biotechnology partnerships between public and private sectors both nationally and globally, and public understanding of the field. ■

Government seeds stronger IP protection with agrochemicals

THE FINANCIAL EXPRESS
March 20, 2015

Signalling a policy shift that would allay the global concern that India’s intellectual property rights (IPR) regime is not strong enough, the Narendra Modi government is set to give statutory backing to “data exclusivity” (DE) for agrochemical innovations and lengthen the period of protection to five years from three now. Sources said the Cabinet would soon consider a proposal to include the stronger DE regime for agrochemicals in the Pesticides Management Bill, 2008, which is pending in the Rajya Sabha.

While the move would benefit global chemical giants like Bayer, Syngenta, BASF, Dow, Monsanto and DuPont, it is also seen as a precursor to similar exclusivity for pharmaceutical majors. The DE for agrochemicals was first granted in

India in 2007, through an executive order. This followed recommendations from a high-level inter-ministerial committee. Big Pharma has long lobbied for data exclusivity, that is, a guarantee that the valuable test and other data they submit to the regulators for marketing and pre-marketing (clinical trials) approvals for new chemical entities (NCEs) won’t be disclosed to a third party who can potentially put it to unfair commercial use. Once DE, which is arguably a TRIPS obligation and has examples in many countries including the US, Canada, China and South Korea, is granted, the regulator will be barred from not only disclosure of the data, but also from relying on the innovator data for giving approvals for copycat versions.

The US government has consistently backed this claim, and the issue repeatedly surfaced in high-level meetings between

the two countries. Local drug companies have, however, opposed data exclusivity and got the backing of various wings of the government including the health ministry, which wants to promote cheaper generic drugs. According to generic drug companies, although the demand for DE would, on the face of it, appear justified, it could be misused by the patent holders to prolong the patent life of a product.

To illustrate, after a patent on an NCE is granted, it could take eight to nine years on average for the firm to take the product (medicine or agrochemical) to the market after completion of all regulatory tests. If a new drug, for instance, is launched in the western markets in the 12th year of patent, its launch in India could get delayed further to, say, the 17th year of the patent, whose usual term is 20 years. In such cases, a five-year data protection could undermine generic ventures and the patent owner could enjoy an extended period of marketing exclusivity, the generic companies argue. However, the innovator pharma companies refute this saying drug launches in India are no longer delayed. The actual commercial exploitation of patents, they add, is for periods much shorter than 20 years.

DG Shah, secretary general, Indian Pharmaceutical Alliance, said: "We will soon write to the ministries concerned and the prime minister against the move

to introduce DE in Indian law. We will join issue with Swadeshi Jagaran Manch." A parliamentary standing committee on agriculture has favoured enhancing DE

for agrochemicals to five years, a position that the government has now supported, sources said, adding that a Cabinet note is in circulation to modify the relevant Bill. ■

Research institutes urged to develop user-friendly technologies

BUSINESS LINE
March 23, 2015

Union Minister for Science and Technology Harsh Vardhan has urged research institutes to develop cost effective and easily implementable technologies to solve people's problems. The government depends a lot on research institutes of repute to diagnose various issues that needs to be taken care of, he said on a visit to CSIR-Structural Engineering Research Centre, Chennai, one of the national laboratories under the Council

of Scientific & Industrial Research.

Prime Minister Narendra Modi has announced an ambitious Make in India programme in which thousands of components are required. "We have to develop technology that is easily transferable and easily available to people. We have to make it people-friendly," he said. It is time to start re-orienting research to find out innovative solutions to problems of the country. Some of the projects are lingering for decades because 'we may not have the fast track technology or no mechanism to

implement,' he said.

GLORIOUS PAST

"We have a glorious past to inspire us. Structures built in this country thousands of years ago are still testimony to the finest brains we have had in the field of structural engineering. We have to take inspiration from the past and look at the present day's work to make our future far brighter," he said.

"If we do not connect science with people, it is of no use. Thousands of papers are prepared by various research institutes. However, often there is no breaking news in the research," he said. The pace of projects should be speeded up. For instance, he was told that in Brazil, technology is being used to construct houses for the poor in three days. "We have to start thinking a little out of the box," he said.

Vardhan visited the Central Leather Research Institute. ■

Tribal foray into biotechnology

THE HINDU
February 24, 2015

Inspired by their success in the production of biocontrol agents and bio-fertilizers, members of the Sabari, a tribal women self-help group (SHG) of the KrishiVigyan Kendra (KVK) under Kerala Agricultural University (KAU) at Ambalavayal in the district, are planning to repeat the success story in the production of the liquid form of Pseudomonas culture,

which is easier to use.

The university is producing the liquid form of pseudomonas, a biocontrol agent used against crop diseases and as a growth promoter for plants, for the first time on a commercial scale, Reshmy Vijayaraghavan, Assistant Professor, plant pathology, KVK, who is supervising the project, says.

TECHNICAL GUIDANCE

The 10 members of the Sabari in the

Nellarachal tribal colony were guided towards the biotechnology venture by A. Radhamma Pillai, former head of the KVK during a filed visit in 2004. Later, the KVK trained them for six months in fungal and bacterial culture and packing.

The group produced 10.24 tonnes of Trichoderma, a biocontrol agent to fight quick wilt disease afflicting pepper vines, and 9.1 tonnes of pseudomonas fluorescence last year. Under a Memorandum of Understanding with the university, the group will get 35 percentage of the income.

The cost of 250 ml of liquid pseudomonas is Rs. 120, and 5 ml of it is mixed in one litre of water and used as soil drench and foliar spray. ■

Land acquired for first-ever Biotech park in J&K

PRESS INFORMATION BUREAU
March 8, 2015

The Union Minister of State (Independent Charge) of the Ministry of Development of North-Eastern Region (DoNER), MoS PMO, Personnel, Public Grievances, Pensions, Atomic Energy and Space, Dr. Jitendra Singh disclosed that approximately ten acre of land has been acquired for bringing up the first- ever Biotechnology park in the State of Jammu & Kashmir. This land was acquired by Science & Technology Department at Gaati SIDCO Phase-III Industrial Complex in district Kathua about 10 km proximal to Kathua town on the Jammu-Pathankot National Highway. Dr. Jitendra Singh had been actively following up the project and got it approved during his tenure as Union Minister for Science & Technology. The work on the project will start in the next few weeks. This will be Govt of India's second mega project to come

up in Kathua close on the heels of Keedian-Gandyal bridge sanctioned by union Surface Transport Ministry at the initiative of Dr Jitendra Singh.

Dr. Jitendra Singh informed that, he had, as Union Science & Technology Minister, simultaneously moved a proposal for a Biotech park in Srinagar as well but that project has got delayed because of certain issues related to land acquisition. Elaborating on the project, Dr. Jitendra Singh said, the Biotech park in Kathua will be brought up at a total cost of about Rs.80 crore. The work on the project will be carried out in three phases and the first phase will cost around Rs.23 crore on which the work will be completed in about 3 to 4 years, he added. The subsequent phase-II and phase-III will be carried out in quick succession thereafter, he said.

Highlighting the importance of an Industrial Biotech park in the State of Jammu & Kashmir, Dr. Jitendra Singh said, this will help catalyze development

of the region by augmenting revenues, increasing employment opportunities and promoting industrial culture as well as agricultural productivity. This will in turn contribute to overall socio-economic growth of the State, he added.

Dr. Jitendra Singh said, Indian biotechnology is one of the fastest growing areas and is expected to play a vital role in shaping the overall economy of India during the next two decades. In this context, he said, the Biotech park at Kathua will have a unique place in the economic growth of India considering the fact that exclusive variety of plant species can be cultivated here because of conducive climatic and other related factors. The Industrial Biotech park in this area would thus entail direct as well as indirect employment and income generation for the youth. The Industrial Biotech park in Jammu, Dr. Jitendra Singh said, will also promote research based entrepreneurship and development of biotech industry. Outlining some of the salient activities envisaged in the proposed Biotech park in Kathua, Dr. Jitendra Singh said, for research purposes there will be a Biotech Information Centre as well as pilot scale units for micro propagation and medicinal plants extraction. In addition, there will also be a training cell and a business support facility cell, he added ■

Abbott introduces glucose monitoring system

BIOSPECTRUM
April 3, 2015

Abbott has launched the professional version of its flash glucose monitoring system.

“Abbott has chosen India as the first country globally to launch this technology. The glucose assessment



tool will cost Rs 1,999 for 14-days, will empower doctors to help their patients manage their diabetes effectively,” said Mr Matthew Bates, R&D director, Abbott Diabetes Care, in a statement.

“The glucose monitoring system continuously measures glucose in interstitial fluid through a small filament that is inserted under the skin. It records glucose levels every 15

minutes, capturing up to 1,340 glucose readings over 14 days, thus giving the treating doctor comprehensive data for a complete glucose profile of their patient,” explained Mr Bates.

After 14 days the doctor uses a flash glucose monitoring reader to scan the sensor and download the glucose results. This data can help doctors to make more informed treatment decisions ■

Pune lab gets nod to conduct diagnosis tests

THE TIMES OF INDIA
March 17, 2015

The state health department granted permission to Golwilkar Metropolis Health Services Pvt Ltd, Pune to conduct swine flu diagnosis tests. This is the first private lab in the city which will conduct the diagnosis without sending work outside the city. The two existing private labs, which have been conducting the test, have the diagnosis facility outside the city.

“Our lab is well-equipped to carry out real-time polymerase chain reaction (PCR)-based swine flu testing. We started conducting the test in 2009, but

the state had then denied us permission. This time we applied for a permission well in advance and have received a nod from the state on March 16. People can avail of the swine flu diagnosis facility at our lab from Monday onwards,” said Awanti Golwilkar-Mehendale, chief of laboratory at the Golwilkar Metropolis Health Services Pvt Ltd.

Golwilkar-Mehendale said the lab has trained manpower at its main centre on Bhandarkar Road to take throat swabs. “The collection facility will not be available at our other centres. But our technicians can collect throat swabs from home. We will issue the test report within 24 to 48 hours. The test will cost

Rs 6,000,” she said.

The Golwilkar Metropolis Health Services Pvt Ltd will conduct the test on GeneXpert, an equipment required to carry out the test using real-time PCR technique. “All bio-safety measures are followed at our set-up,” Golwilkar-Mehendale said. The state public health department has formed regional committees comprising experts from premier virology research institutes and government-run medical colleges to scrutinize and validate the diagnostic facilities of labs that are planning to offer their facilities to conduct the test. Currently, there are five diagnostic facilities in government set-ups. Two private laboratories - SRL Diagnostics and Dr Lal Path Lab - have also been conducting the test for critically-ill patients in the state.

Doctors have been administering Oselatamvir capsules to people suspected of having contracted the infection without conducting any test which, experts think, can lead to irrational use of the drug and make the virus resistant to the

medicine over a period of time.”We decided to grant approvals to standalone private laboratories and those attached to major hospitals in Maharashtra to start swine flu testing facility simply because this will reduce the cost and make the process more competitive,” Satish Pawar, director of state public health department, had earlier told TOI. The state health department has decentralized the procedure for granting

approval to labs. “We have set up three expert committees for Mumbai, Nagpur and the rest of Maharashtra. Experts from the NIV and government-run medical colleges evaluate the laboratories on various parameters such as their technical competence, trained manpower and bio-safety issues and give their report. The final approval is given on the basis of their remarks,” said Kanchan Jagtap, joint director of the state health department.

Haffkine Institute and Kasturba hospital in Mumbai, Government Medical College, Nagpur and Government Medical College, Aurangabad and National Institute of Virology, Pune currently provide testing facility for swine flu infection in public sector. Bomi Bhote, chief executive officer of Ruby Hall Clinic, said, “We have applied for a permission. We have the requisite diagnostic facility and technical competence.” ■

Hester biosciences launches vaccines for large animals

BUSINESS LINE
March 18, 2015

Hester Biosciences Ltd, Ahmedabad based poultry vaccines maker, has laid out ambitious plans to venture into large animal vaccines and healthcare products to more than treble its annual turnover in the next two years. The company launched PPR vaccine and Goat Pox vaccine here eyeing on the upcoming opportunities in the animal healthcare industry.

“We are focusing on large animal vaccines at present as there is great potential to grow in this segment. We expect to cross Rs. 200 crore turnover by fiscal 2016-17,” said Rajiv Gandhi, CEO & MD, Hester Biosciences Ltd. Company posted net profit of Rs. 10 crore on revenue of Rs. 69 crore during 2013-14, while for the nine-month period this fiscal, it registered net profit of Rs. 10 crore on net sales of Rs. 67 crore. Currently about 90 per cent of the

company’s turnover comes from poultry.

Hester plans to invest about Rs. 25 crore for India operations to expand its current facility at Kadi having existing capacity of 4.8 billion dosages per annum. Gandhi further mentioned that the company is also exploring joint-venture partners in Africa, Middle East and South American regions to set up either a greenfield or a brownfield manufacturing facility for vaccine manufacturing.

According to Gandhi, the global animal healthcare market is estimated at around \$ 22 billion, of which Indian market size is around \$ 375 million. “India has a huge poultry and cattle population and with growing awareness, market is expected to see a multi-fold increase in years to come,” he said. Company has a product portfolio of over 47 vaccines and over 35 health products. ■

Cipla launches generic Hepatitis C drug Hepcvir

BUSINESS LINE
March 26, 2015

Cipla announced the launch of generic drug Sofosbuvir for treating chronic Hepatitis C under the brand name Hepcvir.

“Following the non-exclusive licensing agreement signed with Gilead Sciences in September last to manufacture and market chronic Hepatitis C medicines, Cipla is now all set to make the drug Sofosbuvir available to Indian patients in a week’s time,” the company said in

a statement.

“Cipla has always brought accessible and affordable medicines to fight against diseases like AIDS and Hepatitis B; hence, Cipla has made it a priority to bring Hepcvir to patients in India as well as the other developing nations,” Cipla Managing Director and Global CEO Subhanu Saxena said.

The availability of product in other markets is subject to approvals from the regulatory authorities in the respective countries, Cipla said.

“Sofosbuvir marks a new era of medicines in oral treatment of Hepatitis C, which reduce the need for injectables,” Cipla Chief Medical Officer Jaideep

Gogtay said.

In India alone, around 12-18 million patients are estimated to be infected with Hepatitis C, which is several fold

greater than those with HIV/AIDS, Cipla said.

Earlier this week, Dr. Reddy's Laboratories has entered into an

agreement with Hetero to distribute and market generic version of U.S.-firm Gilead Sciences' Hepatitis C drug under the brand Resof. ■

Cipla wins \$189 mn contract from Global Fund ARV

BUSINESS LINE
February 13, 2015

Drugmaker Cipla has been awarded a contract by the Global Fund ARV Tender to supply anti-AIDS medicines worth \$ 188.95 million.

This means that the Mumbai-based drugmaker has been selected as a 'panel

supplier' for a supplier partnership agreement. The contract is effective January 1, 2015 and will run for a period of three years, Cipla said.

And the supplies will begin from the fourth quarter of the financial year 2015, it added.

Subhanu Saxena, Cipla's Managing Director and Global Chief Executive,

said in a statement: "We are extremely proud to have won this tender from Global Fund. Cipla has been committed to the cause of HIV/AIDS for over two decades and this tender offers us a great opportunity to make HIV/AIDS treatment accessible to more than 140 countries through Global Fund."

Cipla has a long-term association with Global Fund since 2002. And last year, Cipla was one of the suppliers awarded with a long-term contract for supplying anti-malarial drugs.

The anti-retrovirals (ARV) drugs will be manufactured at Cipla's manufacturing facilities in India, which has been approved by various international regulatory agencies, it said. ■

Sun seals Ranbaxy deal, to invest \$300 mn in R&D

BUSINESS STANDARD
March 26, 2015

Sun Pharmaceutical Industries, India's largest drugmaker, announced the closure of its merger with Ranbaxy Laboratories and said the integration would deliver synergies worth \$250 million (about Rs 1,500 crore) in three years.

Announcing an operational blueprint to achieve synergies through value-creation across functions, Sun Pharma Managing Director Dilip Shanghvi told reporters that the company would invest about \$300 million (about Rs 1,800 crore) in research and development (R&D) this

year, six-seven per cent of the combined revenue.

The acquisition of Ranbaxy would not restrict the combined entity from making more large acquisitions, Shanghvi said. He, however, added his "most important focus" was winning the confidence of regulators. "We are committed to bring back confidence of the US FDA (US Food and Drug Administration). We will fix problems and create value for shareholders."

Sun Pharma's third-quarter profit was hit by costs incurred on addressing observations raised by the US FDA, following an inspection of a manufacturing plant of the company. After the merger, Ranbaxy will be

de-listed from Indian bourses and each Ranbaxy shareholder will get 0.8 share of Sun Pharma for each Ranbaxy share. In April 2014, Sun Pharma had agreed to buy Ranbaxy for \$3.2 billion in stock, along with \$ 800 million of debt.

The merger will make Sun Pharma the world's fifth-largest maker of generic drugs, after Teva, Sandoz, Actavis and Mylan. The combined entity will become the largest pharmaceutical company in India, with a market share of 9.2 per cent and sales of \$1.1 billion a year, ahead of Abbott (which has a market share of 6.5 per cent). Following announcement, the Sun Pharma stock rose 1.29 per cent to close at Rs 1053.3, while Ranbaxy shares closed at Rs 863, up by 1.63 per cent on the BSE.

Sun Pharma has said the priorities for the combined entity include achieving 100 per cent compliance in manufacturing, in line with the expectations of regulators; increasing R&D productivity to introduce new innovative products; and ensuring

MARKET/ COLLABORATIONS

strong business growth across India, the US and other markets. Israel Makov, chairman of Sun Pharma, said, "The combined entity will capitalise on the expanded global footprint and enhance our dominance as a world leader in the specialty generics landscape."

On March 23, the Competition Commission of India had given an approval to Sun Pharma and Ranbaxy

for the sale of seven brands to Emcure Pharma, to comply with the norms for a conditional nod to their merger. Sun Pharma will sell products marketed and supplied under the Tamlet brand name, while Ranbaxy will sell all products marketed and supplied under the brand names Eligard, Terlibax, Rosuvas EZ, Olanex F, Raciper L and Triolvance. This week, Sun Pharma had received the approval of the Reserve Bank of

India for the issue of equity shares of Sun to non-resident holders of the securities of Ranbaxy, as well as for the transfer of foreign investments held by Ranbaxy in its joint ventures and wholly-owned subsidiaries to Sun Pharma. Earlier this month, the Punjab and Haryana High Court had approved the merger, while the US Federal Trade Commission had approved it in January this year. ■

Intas Pharma launches biosimilar in Europe

THE HINDU
February 23, 2015

Intas Pharmaceuticals has launched its biosimilar product, filgrastim, in the European market under the brand Accofil, which is a biosimilar product of Neupogen made by Amgen. It is used in the treatment of immune system disorders such as neutropenia and is used to treat patients with advanced HIV infection.

After winning two tenders, the product has been launched in the

Netherlands and the U.K. through Intas' subsidiary Accord Healthcare. "This is only the first of many biological products that we will launch in the EU and other regulated markets over the next few years," Intas Vice Chairman Binish Chudgar said in a statement.

"The product was developed as per our original agreement with our collaborator, Apotex," Rajiv Malik, Executive Vice President, Business Development and Licensing, Intas, told this correspondent, adding that the market for size of filgrastim in Europe

was \$400 million. The global market for the product was \$1.8 billion, Mr. Malik said. He said the injectible product would be priced competitively, and had added safety and packaging features and unlike other biosimilars in the market, it would remain stable even at room temperature.

Accofil was developed at Intas' laboratories and is made at its cGMP approved facility in Ahmedabad. "The same facility will be used to make the products for the U.S. and other regulated markets. We will launch in Mexico in the next six months and Brazil and the U.S. in about a year after Sandoz launches its first biosimilar in the U.S. this year," Mr. Malik said.

Intas is a leading player in biosimilars in India having launched its first product in the domestic market in 2004. ■

First stem cell therapy reaches EU market

EUROPEAN-BIOTECHNOLOGY
February 24, 2015

Holoclar is the first treatment for the rare eye disease limbal stem cell deficiency and is based on autologous stem cells. Seven years ago, Holoclar had been designated an orphan medicinal product. The European Medicines Agency (EMA) recommended Holoclar for approval in December. "This recommendation represents a major step forward in delivering new and

innovative medicines to patients," Enrica Alteri, Head of EMA's Human Medicines Evaluation Division, said back then. Now, the European Commission has given the treatment the nod.

Holoclar was developed by Parma-based Chiesi Farmaceutici S.p.A. It is manufactured by Holostem Terapie Avanzate – a spin-off of the University of Modena and Reggio Emilia – at the Centre for Regenerative Medicine "Stefano Ferrari" of the same University. The therapy consists of living tissue

made from the patient's cornea and is grown in the lab. It is then transplanted to the affected eye, where it is capable of restoring the eyesight of patients with severe cornea damage.

"Holoclar is the very first medicinal product based on stem cells to be approved and formally registered in the Western world," commented Andrea Chiesi, Director of R&D Portfolio Management of Chiesi Farmaceutici S.p.A. and CEO of Holostem Terapie Avanzate. "This record shows that the partnership between the public and private sectors is not only possible, but is probably the best strategy for the development of stem cell-based regenerative medicine, particularly when autologous cells are used." ■

New vaccine could completely protect against HIV

FIGO
February 19, 2015

Researchers have developed a new vaccine that could completely protect people against HIV. A team at the Scripps Research Institute in California,



in the US, adopted a different approach when it came to developing this latest vaccine. Normally vaccines are designed to train the immune system to fight an infection but this variation trained the DNA of the subject to give them HIV-fighting properties.

Using monkeys, the researchers developed a technique which used gene therapy to introduce a new section of DNA inside healthy muscle cells. The researchers noted in the journal *Nature*

that the monkeys were protected from all forms of HIV for at least 34 weeks.

Speaking to the BBC, lead researcher Professor Michael Farzan said: "We are closer than any other approach to universal protection, but we still have hurdles, primarily with safety for giving it to many, many people." The research comes after the discovery of a new aggressive form of HIV in Cuba. The strain was found to have the ability to develop into AIDS in just three years. ■

Novel blood test detects intensity of peanut allergy

MARCH 1, 2015
The Pioneer

Researchers have developed a new blood test that could predict the intensity of a patient's allergic reaction to peanut consumption. Based on initial results, the researchers noted that the new test is many times more sensitive than current procedures.

"A patient who has a serious allergy and gets exposed to an allergen protein will form antibodies in their body that

should stay there for a while," said James Rusling, professor at the University of Connecticut in the US. When an allergic person eats peanuts, their immune system releases an antibody protein known as immunoglobulin E or IgE.

These antibodies fight off peanut allergen molecules by binding to them and flushing them out of the body.

But the release of the antibodies causes tissue cells in the body to produce a compound called histamine, which is involved in regulating physiological

function in the gut.

This process in turn generates a variety of allergy symptoms such as itchy skin, runny nose, coughing, or wheezing. The more antibodies that are released, the more histamine is generated, the stronger the person's allergic response.

While existing peanut allergy tests can generally measure IgE antibodies found in a blood sample, the presence of other biomolecules can distort the results and they are not always accurate, the study said. The new allergy test screens out other biomolecules and measures the presence of antibodies that bind to very specific protein fragments, called peptides, and carbohydrate residues found in peanuts.

While the trial test was limited to just a few allergic components from peanut glycoproteins, Rusling said it could be expanded to screen for more than 20, allowing for even more selective results. ■



Bengaluru scientists find drug which could cure malaria with one dose

APRIL 1, 2015
The Times of India

Three scientists from Bengaluru, who led a team of global researchers looking for an antimalarial drug, have found a fast-killing solution. After completing some tests, it'll go in for clinical trials on humans. That this drug has the potential to cure the dreaded disease in one dose makes it more attractive to healthcare providers.

The Bengaluru solution — Triamino-pyrimidine (TAP) — comes with many advantages over existing drugs. Vasan Sambandamurthy, one of the senior authors of the research paper, said: "It's a fast-killing and long-acting antimalarial clinical candidate. TAP acts exclusively on the blood stage of Plasmodium falciparum (the stage responsible for clinical symptoms) in a relevant mouse model. This candidate is equally active against causative agent Plasmodium vivax." He added, "The compound has shown good safety margins in guinea pigs and rats.

With a predicted half-life of 36 hours in humans, TAP offers potential for a single dose combination."

The rapid spread of Plasmodium falciparum, the parasite which causes malaria in humans, has left nations battling it with a weakened arsenal and coping with thousands of deaths every year. This parasite has gradually become resistant to available medication.

The World Health Organisation (WHO) estimates that 3.2 billion people in 97 countries, including India, are at risk of being infected with malaria. In 2013, WHO reported an estimated 198 million cases and the disease was responsible for an estimated 5.84 lakh deaths, including 4.53 lakh children less than five years old.

Every person infected with malaria has to deal with millions of parasites and existing drugs have a limited effect in humans. "The half-life, which isn't more than 2 hours, means it allows parasites to bounce back. Existing drugs are not fast-killing, which means that not only does a

human need more doses but each dose is capable of only killing a few parasites," he said.

Besides, a potential side-effect of existing drugs is liver damage. "This doesn't happen all the time, but the possibility does exist. Also, the parasites have become resistant to these drugs. With TAP, there are now known side-effects and the parasites are unable to develop resistance at the same pace as they do for existing drugs," he said.

TAP was discovered by a team at pharmaceutical company AstraZeneca. "The main research happened in its R&D centre in Bengaluru between 2011 and 2014, which has since been shut down. It took us three years of rigorous work by teams across the globe. Today, we confidently nominate TAPs as a clinical candidate to treat drug-resistant malaria," Vasan said. Shahul Hameed and Suresh Solapure were the two other team leaders.

Times View: The discovery of a malaria drug, yet again, highlights Bengaluru's leadership in scientific research. The promise that the new medicine can kill the virus in a single stroke and act for a long time is good news for malaria patients. While the scientists deserve compliments on working towards a remedy free of side-effects, the companies that will eventually massproduce the drug should look at making it affordable to the aamaadmi. For their part, public health administrators must renew their battle to prevent vector-borne diseases, which cause untold suffering. ■

New engineered insulin may control diabetes more efficiently

ZEE NEWS
February 15, 2015

A new engineered insulin for diabetes patients hope to improve the treatment

as insulin is critical to maintaining good health and normal blood-sugar levels.

The study conducted at Koch Institute showed that their modified insulin can circulate in the bloodstream

for at least 10 hours, and that it responds rapidly to changes in blood-sugar levels. This could eliminate the need for patients to repeatedly monitor their blood sugar levels and inject insulin throughout the day.

Daniel Anderson, the Samuel A. Goldblith Associate Professor in MIT's Department of Chemical Engineering, and a member of MIT's Koch Institute for Integrative Cancer Research and Institute for Medical Engineering and Science, said that the real challenge was to get the right amount of insulin



available when one needs it, because if one has too little insulin their blood sugar goes up, and if one have too much, it can go dangerously low.

The researchers team set out to create a new form of insulin that would not only circulate for a long time, but would be activated only when needed that is, when blood-sugar levels are too high. This would prevent patients' blood-sugar levels from becoming dangerously

low, a condition known as hypoglycemia that can lead to shock and even death.

To create this glucose-responsive insulin, the researchers first added a hydrophobic molecule called an aliphatic domain, which is a long chain of fatty molecules dangling from the insulin molecule. This helps the insulin circulate in the bloodstream longer, although the researchers do not yet know exactly why that is. One theory is that the fatty tail

may bind to albumin, a protein found in the bloodstream, sequestering the insulin and preventing it from latching onto sugar molecules.

Giving this type of insulin once a day instead of long-acting insulin could offer patients a better alternative that reduces their blood-sugar swings, which can cause health problems when they continue for years and decades, Anderson says. ■

Candy-sized heart-on-a-chip to help screen drugs

THE TELEGRAPH
March 8, 2015

An Indian bioengineer in the US has helped develop a human heart-on-a-chip, a device the size of a chocolate candy loaded with heart cells that mimic the real organ to serve as a novel tool to screen medicines. The heart-on-a-chip, unveiled through a research publication today, is being described as the world's first microphysiological system built from human heart cells arranged in the same 3-D geometry of heart tissue to beat like human hearts.

The device, developed by Anurag Mathur, a postdoctoral research fellow at the University of California, Berkeley (UCB), and his colleagues, may emerge a powerful tool for the pharmaceutical industry to screen candidate drugs more reliably than now possible through animal tests. "There's nothing in the laboratory today that comes close to mimicking the structure and function of the human heart as this device," Mathur, who studied mechanical engineering in Jodhpur before pursuing a Masters and a PhD at Columbia University, told The Telegraph. "The heart cells in our device

cluster among themselves to form 3-D heart tissue that beats at 55 to 80 beats a minute."

Mathur said the device is not intended to serve as a replacement for human hearts as it mimics only the minimal structure and function of the heart - enough to support drug screening, disease modelling, and personalised medicine, but not to function as a substitute heart. The first application of the heart-on-a-chip would be to screen new drugs for their effects on the cardiovascular system. While all candidate drug molecules currently go through rigorous experimental animal studies and human trials, the results are not always reliable.

The researchers estimate that nearly one in three drugs that have been withdrawn from the market because of safety concerns were pulled out because of their effects on the human cardiovascular system - that were not detected during animal studies. Mathur, guided by UCB professor of bioengineering Kevin Healy and collaborating with nine other researchers, first turned human skin cells into stem cells which were coaxed to turn into

cardiomyocytes - heart muscle cells. The cardiomyocytes were then loaded into the chip, an enclosure made of synthetic rubber-like material called silicone. The scientists have described their work in the journal *Scientific Reports*.

The silicone housing is connected to a network of channels filled with nutrients that nourish the cells just as oxygenated blood feeds the heart muscles. About 24 hours after the cells are loaded onto the chip, the tissue begins to beat. "This is elegant research that merges engineering and medicine," said Shiladitya Sengupta, an assistant professor of medicine and health sciences technology at the Massachusetts Institute of Technology, who was not associated with the work. "This is an indication of where technologies are headed - we will increasingly see such three-dimensional organoid systems that better mimic human physiology to study the effects of medicines before they reach humans," Sengupta told this newspaper.

The UCB team has already tested the device by examining how the heart-on-a-chip responds to four common drugs used to treat cardiovascular conditions. In one set of tests, they observed that after half an hour of exposure to a drug called isoproterenol, a drug used to treat slow heart rate, the beat rate of the heart tissue increased from 55 beats per minute to 124 beats per minute. "It takes on an average \$5 billion to develop a drug with research and development making up 60 per cent of costs," Healy said in a media release from the UCB. "A well-designed model of a human



organ could cut costs and time to bring a new drug into the market."The scientists say the device could also help in studying the mechanisms of certain

cardiovascular diseases. In the long-term, the researchers hope the device could also be used for personalised medicine. "It may help doctors evaluate which

medicine is most suitable for a specific patient," Mathur said. "This technology could some day be used to create hearts-on-chips for individual patients." ■

New device separates cancer cells from blood

APRIL 7, 2015
The Economic Times

Scientists, including one of Indian-origin, have developed a low-cost device that uses sound to separate circulating cancer cells from blood samples for diagnostic, prognostic and treatment purposes. "Typically, the circulating tumour cells (CTCs) are about one in every one billion blood cells in the sample," said Tony Jun Huang, professor of engineering science and mechanics at Penn State University.

Unlike conventional separation methods that centrifuge for 10 minutes at 3000 revolutions per minute, surface acoustic waves can separate cells in a much gentler way with a simple, low-cost device. Acoustic-based separations are potentially important because they are non-invasive and do not alter or damage cells. However, in order to be effective for clinical use, they also

need to be rapidly and easily applicable.

"With an integrated experimental/modelling approach, the new generation of the device has improved cell sorting throughput more than 20 times higher than previously achieved and made it possible for us to work with patient samples," said Ming Dao, from Massachusetts Institute of Technology. Researchers, including Subra Suresh, president, Carnegie Mellon University, worked both experimentally and with models to optimise the separation of CTCs from blood.

They used an acoustic-based microfluidic device so that the stream of blood could continuously pass through the device for separation. Using the differential size and weight of the different cells they chose appropriate acoustic pressures that would push the CTCs out of the fluid stream and into a separate channel for collection. Tilted-angle standing surface acoustic waves can separate cells using very small amounts of energy.

All these features make the acoustic separation method, termed acoustic tweezers, extremely biocompatible and maximise the potential of CTCs to maintain their functions and native states. If two sound sources are placed opposite each other and each emits the same wavelength of sound, there will be a location where the opposing sounds cancel each other.

Because sound waves have pressure, they can push very small objects, so a cell or nanoparticle will move with the sound wave until it reaches the location where there is no longer lateral movement, in this case, into the fluid stream that moves the separated cells along. The researchers used two types of human cancer cells to optimise the acoustic separation - HELA cells and MCF7 cells. These cells are similar in size.

They then ran an experiment separating these cells and had a separation rate of more than 83 per cent. They then did the separation on other cancer cells, ones for which the device had not been optimised, and again had a separation rate of more than 83 per cent. The research was published in the journal PNAS. ■

IITM completes cancer drug trials

MYDIGITALFC.COM
March 11, 2015

IIT Madras has completed pre-clinical trials of humanised immunotoxin that can replace the chemotherapy drugs

used for the treatment of leukemia or blood cancer. Post clinical trials, the molecules, which are low on side effects, have a potential to even garner a market of over \$100 billion. Several major global research firms are

currently in the process of developing humanised immunotoxins. The biotechnology department of IIT Madras has been working, for the past 10 years, on humanised immunotoxins and has developed eight molecules. The chemotherapy drugs used at present kill the normal cells along with the diseased ones and trigger side effects including decrease in immunity, anemia, hair loss, nausea, and inflammation of the digestive tract.

“The immunotoxins developed by us have proved to be more effective in targeted therapy and thus minimal side effects. In several cases, the patients undergoing chemotherapy die due to infections caused by low level of immunity. These molecules have proved their efficacy for most of the blood cancers, including acute myeloid leukemia, chronic myelogenous leukemia and cutaneous t-cell lymphoma,” said Rama S Verma, who heads the research team in IIT Madras.

According to him, some of the global research institutions like National Institute of Health in the

US are in the pursuit of developing humanised immunotoxins. At present, immunotoxins are generally developed from plants or animals. The human body usually recognises these molecules as foreign bodies. In case of humanised immunotoxins, the body responds better and they “minimally touch and affect normal cells”, he added.

IIT Madras is starting its clinical studies on the molecules — producing the immunotoxins in large quantity and testing it on animals in order to determine the maximum dosage of each immunotoxin that can be administered without causing harm. “We look at the

absorption, distribution, metabolism, and excretion of the drug in the animal, and then extrapolate the amount required for a human,” Verma further explained. The research is being funded by department of bio-technology, government of India. The institute plans to either tie-up with pharma companies or find private investors to fund clinical trials post animal studies. If all goes well, it hopes that the molecules can be commercially produced in five years. “Considering the incidence of leukemia, the market for the molecules is huge and valued more than \$100 billion,” he further added ■

Blood test can predict whether young kids will be future diabetics

BUSINESS STANDARD
February 27, 2015

A new study has found that by measuring the presence of autoantibodies in the blood of young children could detect the development of type I diabetes.

The Environmental Determinants of Diabetes in the Young (TEDDY) study conducted by Lund University explained

that with the early detection it would be possible to predict whether the immune system in children has begun to break down the body’s own insulin cells or not.

The team of researchers mentioned that if the autoantibody that was discovered first attacks the insulin (IAA) than it could be taken as a indication of development of type I diabetes, or if the first autoantibody targets GAD65

(GADA), a protein inside the insulin-producing cells or if both autoantibodies are found together initially.

Ake Lernmark, lead researcher said that they have realized that autoantibodies often appear during the first few years of life and the presence of antibodies in the blood was a sign that the immune system has reacted to an intruder such as a virus or a bacteria.

The research showed that 6.5 percent of children had their first autoantibody before the age of 6, as 44 percent of young kids had an autoantibody against insulin (IAA) by the age of 1-2, 38 percent of kids were detected with GAD65 autoantibodies until the age of two and then remained constant, and almost 14 percent of little kids had both autoantibodies at the age of 2-3. ■

Antibiotic use in livestock sector set to rise

THE HINDU
March 26, 2015

With rising incomes fuelling more demand for meat, India needs to worry

about antibiotic usage in growing animals for food, especially poultry, according to a recent study. Such antibiotic use could contribute to the spread of drug-resistant microbes, which are already

a major public health problem. The issue of antibiotic consumption by the livestock sector is a global one, but particularly so for emerging economies, according to a paper published online earlier this month by the Proceedings of the National Academy of Sciences (PNAS).

Greater affluence in low- and middle-income countries was driving “an unprecedented growth in demand for animal protein,” noted a team of researchers in the paper. More intensive livestock production systems brought



MEDICAL BIOTECH

with it greater use of antibiotics, which are administered not just to treat sick animals but also at sub-therapeutic doses as growth promoters and to keep animals from catching disease. The researchers used statistical models that combined antimicrobial use in a number of high-income countries with data about livestock densities to map global antimicrobial utilisation in 2010. They then projected the antimicrobial use to 2030.

They found that the global consumption of antibiotics for production of animals would rise by 67 per cent over those 20 years. In the 'BRICS' – Brazil, Russia, India, China and South Africa – antimicrobial consumption would go up 99 per cent, up to seven times the projected population growth in those countries. In India, antimicrobial consumption for meat production could more than double by 2030, according to Thomas P. Van Boeckel, a postdoctoral

researcher at Princeton University and first author of the paper.

At least 23 per cent of this increase is attributable to more intensive production systems and the rest to more animals being grown, he said in an email. Moreover, such antimicrobial consumption in India would be growing at a little over four per cent a year while its human population grew at only around one per cent annually. There could be a rise of 477 per cent in antimicrobial use by the poultry sector between 2010 and 2030, while it would be 164 per cent for pig farming. "Thus it is really in the poultry sector that things should be kept under close scrutiny and where the efforts to limit consumption should be targeted," remarked Dr. Van Boeckel.

"Given the significant increases we have seen in infections that are not treatable using common antibiotics, we should take the issue of unnecessary antibiotic consumption very seriously,

whether in humans or in animals," said Ramanan Laxminarayan, a senior author of the paper and director of the Center for Disease Dynamics, Economics & Policy at Washington, D.C. in the U.S. in an email. He is also Vice President, Research and Policy, at the Public Health Foundation of India in Gurgaon.

"Most people are probably not aware that the meat they consume comes from animals that are fed a steady low dose of antibiotics to increase their weight gain and compensate for poor hygiene on farms," he added. "Globally, intensive livestock farming has increased food production at a low cost per unit produced, but perhaps at an unrecognised price paid in increased antimicrobial resistance," the researchers observed in the PNAS paper. They called for "urgent and concerted action in all countries" to limit the overuse and abuse of antimicrobials in food animal production. ■

Ready-to-use flu vaccine in sight

THE TIMES OF INDIA
March 18, 2015

Serum Institute of India (SII) has developed a ready-to-use influenza vaccine that promises to offer protection against three influenza viruses, including swine flu. The ready-to-use liquid vaccine will be easier to administer than the present reconstituent vaccine, Nasovac-S, which requires one to mix the vaccine powder with a diluent before vaccination.

SII will apply to the Drug Controller General of India (DCGI) shortly to introduce the new intra-nasal vaccine in the market. "We will apply to the DCGI in the coming days for authorisation for this product. If all goes as planned, the liquid trivalent seasonal influenza vaccine

should be available any time this year," Adar Poonawalla, executive director and SII chief executive officer, told TOI.

Poonawalla said the internationally available vaccine in the US was also in the liquid form. "Our ready-to-use influenza vaccine also falls in the same category. This will offer the vaccine more acceptability among the medical fraternity," he said. SII executive director Rajeev Dhere said that since the new liquid vaccine would be easier to administer, it would simplify mass immunization. "The vaccine has been found to be as stable, safe and effective as the current vaccine," he said. The influenza virus is transmitted primarily by droplets or respiratory secretions of infected persons. Influenza occurs all

over the world, with an annual global attack rate estimated at 5-10% in adults and 20-30% in children.

Influenza is associated with considerable economic burden arising from healthcare costs, lost days of work or education, and general social disruption across all age groups. Secondary bacterial pneumonia is a frequent complication of influenza infection, particularly among the elderly and individuals with certain chronic diseases, resulting in a significant level of morbidity and mortality.

Next-gen quadrivalent influenza vaccine may be out next year: Serum Institute of India has also developed a next-generation quadrivalent seasonal influenza vaccine which will offer protection against four strains of influenza viruses, including swine flu. "The development part of this vaccine has nearly been completed. If all goes well, it will be available next year. The vaccine will be the first of its kind developed in Asia," said Adar Poonawalla said. ■

New strategy in identifying SNP in cotton genome

ISAAA
April 8, 2015

The use of single nucleotide polymorphism (SNP) as a marker is very useful in studying genetic variations in plants and other studies. However,



difficulty in identifying and observing SNP was observed when studying plant with complex genome such as cotton. In a study conducted by researchers from Texas A&M University and USDA-Agricultural Research Service a new strategy was developed to ease the identification of SNP in *Gossypium* spp. (cotton) Malvaceae genome.

By employing the Illumina next-generation sequencing platform,

a total of 54 million reads were collected from restriction-enzyme-digested DNA from the four cotton species. These were then filtered by a bioinformatic software, Stack, producing over 20,000 new cotton SNP combinations. This strategy will be helpful in plant genetic mapping, linkage and genetic diversity studies and can also be applied to other plant species having complex genomes. ■

Can organic and GM crops co-exist?

BUSINESS LINE
April 3, 2015

Can organically cultivated crops and genetically modified crops co-exist especially, in adjoining fields? This has been an issue of debate for some years now. The issue at hand is the potential of contamination of organic crop through pollen drift from non-organic or GM crop cultivated in proximity.

While companies selling genetically modified seeds claim that the technology is not in conflict with organic cultivation as the former helps reduce use of pesticides, those engaged in organic cultivation perceive GM technology as not purely organic. GM crops still need integrated pest management and

integrated nutrient management. There are issues with organic certification too.

The matter has come to a head in a court in Western Australia where owners of two neighbouring fields — one cultivating organic oats and the other GM canola — are fighting over cultivation rights and duty of care. The organic farmer has lost his certification because his neighbour planted modified canola. Commercial cultivation of GM canola was permitted by the Australian government sometime in 2009-2010.

The outcome of the legal dispute is keenly awaited. The court is likely to rule on the relative rights and obligations of neighbouring farms. The outcome may also potentially force amendments to the organic certification process.

Clearly, the issue is not about desirability or otherwise of GM crops and their contribution to the market; but whether organic and non-organic cultivation can harmoniously co-exist.

It may be a coincidence that the legal dispute in faraway Australia has come up at a time when the Indian Government has permitted field trials of GM crops, subject to State government's approval. Maharashtra, for instance, has decided to allow firms to undertake field trials of select crops.

Given that landholdings in India are rather small — over 80 per cent of farmers own less than two acres — the issue of co-existence of GM and non-GM crops assumes greater importance. Currently, Bt Cotton is the only GM crop commercialised. Over the last several years, area under modified cotton cultivation has expanded and currently stands at nearly 90 per cent of the total area under cotton (11-12 million hectares). ■

Seed firms begin field trials of GM crops in Maharashtra

BUSINESS LINE
March 31, 2015

At least five large seed companies, including Monsanto, Mahyco and BASF, have started field trials of genetically-modified (GM) crops in Maharashtra, which granted permission earlier this year. The companies are focussing on crops such as rice, corn, chickpea and cotton.

Mahyco, for instance, has started carrying out trials for GM rice in the Konkan region of coastal Maharashtra. The company eventually wants to develop a rice variety which will be tolerant to

salinity in the environment. Others such as Monsanto, BASF, Sungro Seeds and a large seed company based out of Andhra Pradesh have either started conducting field trials or are in the process of carrying out the same.

PUBLIC-PRIVATE PARTNERSHIP

Mahyco, through its group company Sungro, is actively working on developing a GM chickpea (chana). Sungro is developing the seeds through a public-private partnership with Assam Agricultural University, which could increase farm production by 20-25 per cent.

Since the permission was granted in January, the company is waiting for the right weather to carry out the trials, according to an industry source.

German chemical company BASF, which also has a plant sciences division, is in the process of carrying out field trials for rice. The company, in a statement to Business Line, said "field trials are part of a global research project that aims to significantly increase rice yields.

Through these trials in India, BASF will select the genetically enhanced rice lines which will be best adapted to Indian growing conditions and therefore most suitable for Indian rice farmers." Monsanto is also carrying out trials for cotton and corn in Maharashtra, as a part of trials nationwide.

The company, in an email statement, said: "We understand that the Genetic Engineering Approval Committee has approved field trials requests of various organisations, including that of Monsanto. State no-objection certificates have also been secured." ■

Gene may help reduce GM contamination

THE TIMES OF INDIA
February 21, 2015

Researchers, including those of Indian-origin, have identified a gene that may help reduce contamination of conventional crops by genetically modified (GM) crops.

The plant gene discovered by University of Guelph scientists might help farmers reduce the risk of GM contamination and quell arguments against the use of transgenic food crops, said Sherif Sherif, lead author of a new research paper describing the findings.

This is believed to be the first-ever study to identify a gene involved in altering fruit trees that normally

cross-pollinate - needing one plant to fertilise another — into self-pollinators, said Sherif.

Sherif said researchers might one day insert this gene into GM crops to prevent their pollen from reaching other plants. "There are a lot of transgenic crops worldwide," said plant agriculture professor Jay Subramanian, Sherif's PhD supervisor and a co-author on the paper.

"There is concern about pollen from them being able to fertilise something in the wild population, thus creating 'super weeds'," Subramanian said. The researchers found a gene making a protein that naturally allows a small handful of plants to self-pollinate and make fruit before the flower opens. Peaches, for example, have closed flowers, unlike their

showy-flowered plum and cherry cousins that need pollen from another tree to fertilise and set fruit.

Other co-authors on the paper are Guelph professors Jaideep Mathur, Department of Molecular and Cellular Biology and GopiPaliyath, from Department of Plant Agriculture, along with Islam El-Sharkawy, a former research associate with Subramanian; and colleagues at the National University of Singapore.

Besides aiding crop farmers and food producers, their discovery might be a boon to perfume-makers, said Subramanian. Used in fragrant perennials such as jasmine, the gene might keep flowers closed and allow growers to collect more of the aromatic compounds prized by perfume-makers. "That's when volatile compounds are peaking. When the flower opens, you lose almost 80 per cent of those volatiles," said Subramanian. ■

‘Darbha’ grass, a natural preservative

THE HINDU
March 16, 2015

Traditional tropical grass, Darbha, has been identified as an eco-friendly food preservative.

This finding was evolved in a research study undertaken jointly by the Centre for Nanotechnology and Advanced Biomaterials (CeNTAB) and the Centre for Advanced Research in Indian System of Medicine (CARISM) of the SASTRA University, Thanjavur, under the supervision of Dr. P. Meera and Dr. P. Brindha respectively.

Darbha (*Desmotachyabipinnata*) is a tropical grass considered a sacred material in Vedic scriptures and is said to purify the offerings during such rituals. At the time of eclipse, people place that grass in food

items that could ferment and once the eclipse ends the grass is removed.

A systematic research was conducted by the SASTRA University researchers, in which cow's curd was chosen as a food item that could ferment easily.

Five other tropical grass species, including lemon grass, Bermuda grass, and bamboo were chosen for comparison based on different levels of antibiotic properties and hydro phobicity.

Electron microscopy of different grasses revealed stunning nano-patterns and hierarchical nano or micro structures in darbha grass while they were absent in other grasses.

On studying the effect of various grasses on the microbial community of the curd, darbha grass alone was found to attract enormous number of bacteria

into the hierarchical surface features.

These are the bacteria responsible for fermentation of cow's curd.

During eclipse, the wavelength and intensity of light radiations available on the earth's surface is altered. Especially, the blue and ultraviolet radiations, which are known for their natural disinfecting property, are not available in sufficient quantities during eclipse.

This leads to uncontrolled growth of micro-organisms in food products during eclipse and the food products are not suitable for consumption. Darbha was thus used as a natural disinfectant on specific occasions, say researchers at SASTRA University.

Further, the scientists say that darbha could be used as a natural food preservative in place of harmful chemical preservatives and the artificial surfaces mimicking the hierarchical nano patterns on the surface of darbha grass could find applications in health care where sterile conditions were required.

This entire research was funded by the SASTRA University's Research Fund. ■

Golden rice provides Vitamin A, says activist

AFTERNOON
March 20, 2015

Dr. Patrick Moore, co-founder of Greenpeace and currently a leading activist in the Golden Rice Campaign, a genetically modified (GM) crop variant for rice, organised a press meet to explain about how two million children die every year due to Vitamin A deficiency and how this can be avoided. The meet began with an address by Dr. C.D. Mayee, President of Indian Society for Cotton Improvement who explained about the status of GM crops in India. After that, Dr. Moore took the stage to give a short brief about his history and why he left Greenpeace. He then explained about 'Golden Rice'.

"Golden Rice is a genetically modified crop in which three beta-carotene biosynthesis genes are added to the rice seed so that it can provide Vitamin A when it is consumed," said Dr. Moore. He then explained about which countries face the most deaths for Vitamin A deficiency. "India along with many other African countries face this situation. Since most of the poor families can't afford vegetables, they buy a cup of rice to suffice their hunger. But this leads to Vitamin A deficiency which the rice doesn't cover. Around the world, at least two million children die every year from diseases related to Vitamin A deficiency. Between 250,000 and 500,000 go blind because of the same," said Dr. Moore. He then listed which institutes had

researched and found no side effects from consumption of the rice.

He also explained how many countries have had trials for the same crop and how propaganda is being used to prevent its cultivation while farmers who actually cultivated it were happy with the produce.

When asked about whether it will have any effect on the fertility of the soil on which it will be produced, Dr. Moore said, "Golden Rice will be like any other conventional rice and can come in varieties. Right now it isn't drought, salt or flood tolerant but research is being done towards the same. So it won't affect fertility of the land and we are starting with covering the Vitamin A deficiency." Asked how much the farmers would have to pay for the seeds, Dr. Moore explained, "Farmers who earn less than \$10,000 in a year will be given seeds free of cost." He then ended his presentation with a round of applause from guests present. ■

Hope of vaccine for heart disease

THE TELEGRAPH
April 2, 2015

A molecule crafted out of human, snake and bacterial proteins to control the human immune system may serve as a vaccine against coronary heart disease, studies by scientists in India, Hungary and Britain have suggested. Scientists at the Thrombosis Research Institutes (TRI) in London and Bangalore and at the University of Szeged, Hungary, have shown that the protein molecule can reduce the risk of atherosclerosis, the build-up of fatty deposits in arteries that can clog these vessels and trigger heart attacks.

While other research groups in Europe and America have experimented with the idea of tweaking the immune system to reduce heart disease risk over the past decade, the TRI researchers say their molecule is expected to be more efficient in preventing atherosclerosis than earlier vaccine candidates.

The strategy of using vaccines to prevent heart disease seeks to control inflammation, a key process that contributes to atherosclerosis.



Most candidate vaccines have been aimed at regulating some element of the inflammatory process that leads to the accumulation of fatty deposits along the walls of arteries.

“But atherosclerosis is a multi-factorial chronic condition with several factors involved in the process,” said Xinjie Lu, a senior scientist at TRI, London. Proteins aimed at a single element of this inflammatory process are likely to reduce about 20 per cent of the atherosclerotic lesion. Lu and his colleagues have designed what they call a multi-epitope, or chimeric, molecule from several components of human, bacterial and snake proteins to target several inflammatory pathways.

“The snake protein by itself is only a backbone - it has no role in regulating the immune system,” said Lakshmi Mundkur, head of molecular immunology at the TRI, Bangalore, who had earlier collaborated on the research project but was not directly associated with the latest studies. In new research reported today in the journal PLOS One, the scientists have shown that the chimeric molecule can

significantly prevent the build-up of fatty deposits in laboratory mice.

The average size of the atherosclerotic lesions was much smaller in the mice that received the candidate vaccine than in mice that did not. “We believe such multi-epitope molecules are excellent candidates for developing a vaccine against atherosclerosis,” Lu said. Scientists say the multi-epitope vaccine may be visualised as a string with multiple beads on them, the snake protein functioning as the string and the human and bacterial proteins as the beads. This molecule has been shown to work on several arms of the human immune system.

Other candidate vaccines against atherosclerosis, developed by independent groups in Europe and the US, too have had human clinical trials. A phase I study on 80 human volunteers had found a candidate vaccine safe and well tolerated in tests, a European Society of Cardiology session was told three years ago. ■

Plant extract fights brain tumour

THE INDIAN EXPRESS
February 12, 2015

Scientists have discovered in cell cultures,

animal models and human tumour tissue that a harmless plant extract can be applied to treat Cushing Disease caused by a tumour.

“Silibinin is the major active constituent of milk thistle seeds. It has an outstanding safety profile in humans and is already used for the treatment of liver disease and poisoning,” informed lead researcher Marcelo Paez-Pereda from the Max Planck Institute of Psychiatry in Munich. Cushing Disease is caused by a tumour in the pituitary gland in the brain.

The tumour secretes increased

amounts of the stress hormone adrenocorticotropin (ACTH) followed by cortisol release from the adrenal glands leading to rapid weight gain, elevated blood pressure and muscular weakness.

Patients are prone to osteoporosis, infections and may show cognitive dysfunction or even depression. After silibinin treatment, tumour cells resumed normal ACTH production, tumour growth slowed down and symptoms of

Cushing Disease disappeared in mice.

“We knew that Cushing Disease is caused by the release of too much ACTH. So we asked ourselves what causes this over production and how to stop it,” Paez-Pereda said. In their first experiments the researchers found tremendously high amounts of the heat shock protein 90 (HSP90) in tumour tissue from patients with Cushing Disease. In normal amounts HSP90 helps

to correctly fold another protein, the glucocorticoid receptor which in turn inhibits the production of ACTH.

“With silibinin we might have discovered a non-invasive treatment strategy not only for the rare Cushing Disease but also for other conditions with the involvement of glucocorticoid receptors such as lung tumours, acute lymphoblastic leukaemia or multiple myeloma,” Paez-Pereda concluded. ■

New compound may treat HIV, drug-resistant TB

THE TIMES OF INDIA
February 26, 2015

Researchers, including one of Indian origin, have developed a new molecule that may treat multi-drug resistant tuberculosis and even HIV infection. While standard anti-TB drugs can cure most people of Mycobacterium tuberculosis infection, improper use of antibiotics has led to new strains of the bacterium resistant to the two most

powerful medications, isoniazid and rifampicin.

“Multi-drug resistant TB is spreading rapidly in many parts of the world,” said Vasu Nair, Georgia Research Alliance Eminent Scholar in Drug Discovery in the University of Georgia College of Pharmacy. “There is a tremendous need for new therapies, and we think our laboratory has developed a strong candidate that disrupts fundamental steps in the bacterium’s reproduction

process,” said Nair, lead author of the study in the journal *Bioorganic and Medicinal Chemistry Letters*.

Just like other living organisms, the genetic information contained in M tuberculosis undergoes a complex process known as transcription in which the bacterial enzyme, DNA-dependent RNA polymerase, or RNAP, produces TB RNA. This molecule is involved in processes that produce critical bacterial proteins that the organism needs to survive.

Nair and his colleagues said they were surprised to discover through preliminary experiments that the compound also exhibited strong anti-HIV properties, opening the door for dual therapeutic applications. The risk for developing TB is between 26 and 31 times greater in people living with HIV than those without HIV infection. ■

Hope in cancer drug resistance fight

THE TELEGRAPH,
February 11, 2015

Using a mix of biology and mathematics, Indian, Canadian, and American scientists have discovered how some cancer cells survive the initial onslaughts of anti-cancer drugs and have proposed a new strategy to curb resistance to chemotherapy. The researchers say their

research - based on breast cancer cells growing in laboratory glass vials and mice with breast tumours - is expected to help avert the frustrating emergence of chemotherapy-resistant tumours that do not respond to anti-cancer drugs.

Medical researchers have known for long that cancer cells can become resistant to anti-cancer drugs through genetic mutations, but how some

cancer cells are able to survive the chemotherapy before the emergence of resistance has remained unclear. “It turns out some cancer cells behave chameleon-like to evade chemotherapy,” Shiladitya Sengupta, assistant professor of medicine at the Harvard Medical School, and a team member told *The Telegraph* over the telephone. “The cells literally change their coats - new proteins which emerge on their surfaces change their shapes and protect them from anti-cancer drugs. They just hunker down and eventually spawn the cells resistant to chemotherapy.” The eight-member team in research institutions in Bangalore, Boston, Tucson and Waterloo set out to

unravel the process through which some cancer cells survive initial attacks by a class of anti-cancer drugs called taxanes used to treat breast and ovarian cancers, among other malignancies.

While the initial attacks by taxanes are able to kill the majority of tumour cells, some cancer cells sprout two proteins on their surfaces that allow them to become tolerant to taxanes. These cells serve as the seeds for the tumours that emerge later as cancer cells resistant to the anti-cancer drugs. But the findings, reported today in the journal *Nature Communications*, also point to what the scientists say could be a way to avert resistance. Laboratory studies suggest that the cells in their protected form appear especially susceptible to another cancer drug called dasatinib.

The researchers used mathematical models that factored in the growth rate of these protected cancer cells and calculated the optimum time at which dasatinib should be added to the initial taxane chemotherapy to kill

these cells as well and curb the risk of resistance."If dasatinib can eliminate all of these chameleon-like cells, we may be averting the emergence of resistance," said Sengupta. In laboratory tests and studies on mice, the scientists observed that this strategy of using a pair of drugs with an appropriate gap in time between the two curbed the emergence of resistant tumours."The two drugs work as partners - the first one targets the majority of cancer cells, dasatinib targets what could be the seeds of resistant tumours," Sengupta said. This combination therapy killed the cancer cells in the laboratory and extended the survival period in mice.

"If this is shown to work in humans, we could stretch anti-cancer drugs to work longer for patients," said Venkatraman Radhakrishnan, an oncologist at the Adyar Cancer Centre, Chennai, who was not associated with the research."Under current practice, if patients return with a relapse, we have to use a different set of drugs - not what

we've already used earlier - because of the possibility of resistance. If this two-drug strategy works, we might be able to use a drug that has already worked on a patient once again."

The scientists say the effects observed in the tumour cells and mice will need to be established in human patients through clinical trials. "But since both taxanes and dasatinib are both approved drugs already in the market, we're hoping the trials can be initiated fairly quickly," a team member said. Team members pooled complementary skills in the research: Biswanath Majumder and Pradip Mazumder at the India Innovation Research Centre and Mitra Biotech in Bangalore studied human cancer cells in the laboratory; Aaron Goldman, Sengupta, Sudarshan Ravi conducted animal studies in Boston; Mohammad Kohandel and Andrew Dhawan in Canada worked with the Boston team on mathematical modelling; and David Goldman in Tucson studied the pathology of the cancer cells. ■

Nano-hydrogels find and kill cancer cells

MUMBAI MIRROR
February 10, 2015

Mexican researchers have successfully created bio-compatible nano-sized hydrogel structures that can transport and release drugs at cancer sites without affecting other parts of the body.

Hydrogels are materials that are commonly used in everyday objects such as contact lenses or diapers, in order to control humidity. Chemical engineers at the University of Guadalajara (UdeG), in Mexico have developed a new tech that uses thermosensitive nanoparticles (nano-hydrogels) to control the release of anticancer drugs inside the human body.

The idea is that the drug can be

enclosed within the nano-hydrogels and transported directly to cancer cells where it can be released without damaging other parts of the body. This is possible because hydrogels offer the option of dosing a myriad of active substances on the site desired and can be administered as dry or swollen pills by different routes: oral, nasal, buccal, rectal, transdermal, vaginal and even ocular. The drug release can be triggered by a change in pH levels, or temperature.

The new advancement also lets the researchers add magnetic particles to the hydrogels nanopolymer with the aim of producing a force field to raise the temperature, which is necessary to destroy cancer cells. "We used nano-hydrogels loaded with drugs and

injected them into the patient. With the characteristic that while passing through the bloodstream the drug is not detected nor attacked by the immune system, this due to their physical and chemical properties which make them compatible with the body," said Eduardo Mendizabal Mijares, professor at the Department of Chemistry, at the University of Guadalajara.

The research, focused on developing thermosensitive nano-hydrogels which through a polymerisation technique, mixes substances with different chemical and physical characteristics, achieving a chemical reaction and forming a set of small spheres called polymers. By combining emulsion polymerisation and microemulsion the researchers were able to synthesise structured hydrogels which have better mechanical properties than conventional hydrogels.

These materials are used primarily in the biomedical area as diagnostic tools in membranes, coatings, microcapsules,

implants for applications of short or long-range and systems of controlled drug release. The nano-hydrogels have shown very good characteristics of biocompatibility with the human body,

due to their physical properties, which make them resemble living tissues, especially by its high water content, its elastic consistency, and its low interfacial tension which prevents them from

absorbing proteins from body fluids.

The nano-hydrogels could also be used to regenerate tissue or mend fractures, serving as substrates for cell growth. ■

Gold nanotubes launch a three-pronged attack on cancer cells

UNIVERSITY OF LEEDS
February 13, 2015

Scientists have shown that gold nanotubes have many applications in fighting cancer: internal nanoprobes for high-resolution imaging; drug delivery vehicles; and agents for destroying cancer cells. The study, published today in the journal *Advanced Functional Materials*, details the first successful demonstration of the biomedical use of gold nanotubes in a mouse model of human cancer.

Study lead author Dr Sunjie Ye, who is based in both the School of Physics and Astronomy and the Leeds Institute for Biomedical and Clinical Sciences at the University of Leeds, said: "High recurrence rates of tumours after surgical removal remain a formidable challenge in cancer therapy. Chemo- or radiotherapy is often given following surgery to prevent this, but these treatments cause serious side effects. Gold nanotubes – that is, gold nanoparticles with tubular structures that resemble tiny drinking straws – have the potential to enhance the efficacy of these conventional treatments by integrating diagnosis and therapy in one single system."

The researchers say that a new technique to control the length of nanotubes underpins the research. By controlling the length, the researchers were able to produce gold nanotubes with the right dimensions to absorb a type of light called 'near infrared'. The study's corresponding author Professor Steve Evans, from the School of Physics and Astronomy at the University of Leeds, said: "Human tissue is transparent for certain frequencies of light – in the red/infrared region. This is why parts of your hand appear red when a torch is shone through it.

"When the gold nanotubes travel through the body, if light of the right frequency is shone on them they absorb the light. This light energy is converted to heat, rather like the warmth generated by the Sun on skin. Using a pulsed laser beam, we were able to rapidly raise the temperature in the vicinity of the nanotubes so that it was high enough to destroy cancer cells."

In cell-based studies, by adjusting the brightness of the laser pulse, the researchers say they were able to control whether the gold nanotubes were in cancer-destruction mode, or

ready to image tumours. In order to see the gold nanotubes in the body, the researchers used a new type of imaging technique called 'multispectral optoacoustic tomography' (MSOT) to detect the gold nanotubes in mice, in which gold nanotubes had been injected intravenously. It is the first biomedical application of gold nanotubes within a living organism. It was also shown that gold nanotubes were excreted from the body and therefore are unlikely to cause problems in terms of toxicity, an important consideration when developing nanoparticles for clinical use.

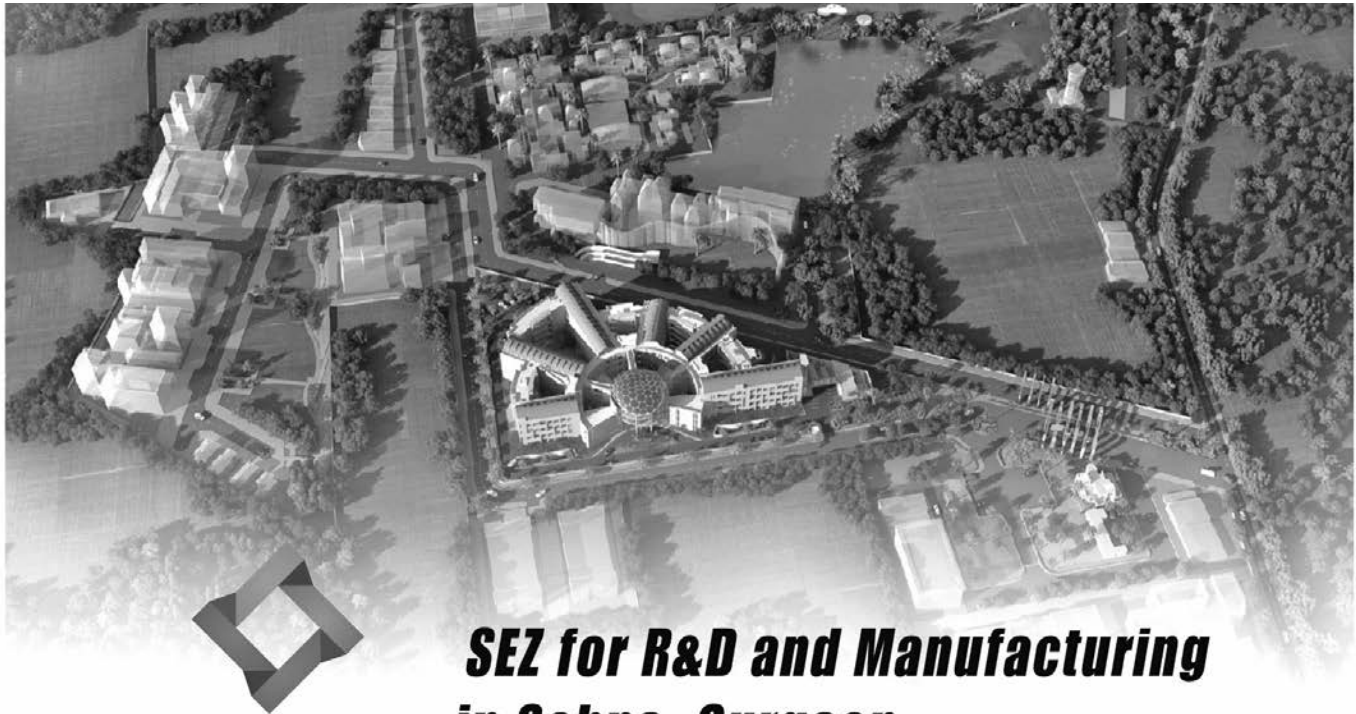
Study co-author Dr James McLaughlan, from the School of Electronic & Electrical Engineering at the University of Leeds, said: "This is the first demonstration of the production, and use for imaging and cancer therapy, of gold nanotubes that strongly absorb light within the 'optical window' of biological tissue. "The nanotubes can be tumour-targeted and have a central 'hollow' core that can be loaded with a therapeutic payload. This combination of targeting and localised release of a therapeutic agent could, in this age of personalised medicine, be used to identify and treat cancer with minimal toxicity to patients."

The use of gold nanotubes in imaging and other biomedical applications is currently progressing through trial stages towards early clinical studies.

Further information

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(Actual Pictures)

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