

## 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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## Biocon arm, Canara Bank tie up for e-health-care in Odisha

THE FINANCIAL EXPRESS  
7 March 2014

Bangalore, March 6: Biocon Foundation on Thursday said that it has partnered with Canara Bank and the Odisha government for an e-healthcare programme. The initiative aims to set up diagnostic facilities at primary health centres across state while also creating local entrepreneurs to run them. The public-private programme, supported by

the Orissa Trust of Technical Education (OTTET), expects to provide 51,000 villages with access to better healthcare facilities.

As part of the programme, Biocon Foundation, the social activities arm of the Bangalore-based biotechnology company, and OTTET will set up an electronic diagnostic facility and e-health centre at all the primary health centers of the government. These will be managed by local young

entrepreneurs who will be provided loans by Canara Bank and will also receive training to support the medical officers for various healthcare and diagnostic services, said a release from the foundation.

“We aim to strengthen the present public healthcare delivery system in Odisha, by providing solutions around primary and secondary healthcare with effective use of technology. This model will result in the creation of real jobs and development of semi-skilled talent in the rural areas,” said Kiran Mazumdar-Shaw, CMD, Biocon.

“The project aims to provide rapid diagnosis, reduce expenses and cut down hospitalisation while ensuring transparency and accountability for every single patient,” said OTTET’s managing trustee KN Bhagat. ■

## KVK, Dibrugarh to manufacture biofertilizers, biopesticides

THE ASSAM TRIBUNE  
3 March 2014

Dibrugarh, March 3-In a major development, the Krishi Vigyan Kendra (KVK), upper Assam’s only farm science centre located at Romai Kordoibam village, some 14 km here, on Monday instituted a biotechnology department with a laboratory to locally support the farming community of the region with biofertilizers and biopesticides.

Farmers from the region can procure fertilizers, pesticides and other high yielding seeds from the farm science centre. Agricultural scientists through the biotechnology department will produce biofertilizers like Azotobacter, Phosphate Solubilizing Bacteria (PSB), azos-pirillum,

rizobium, enriched compost and “Azolla (nitrogen). The biopesticides, which will be produced at the centre, include Bioveer, Biometta, Biozium, Biosona, Biolium and Biotime.

The hiotechnology department was simultaneously inaugurated on Monday after the formal inauguration of the new farm science centre complex by Revenue Minister Prithibi Majhi. Earlier, the KVK was run from a rented house. It was established in April 2007 under the Directorate of Extension Education, Assam Agricultural University, Jorhat vide the sanction of the Indian Council of Agricultural Research (ICAR).

The inauguration of the new complex and the department of biotechnology (DBT) was attended

among others by Dr. KM Bujarbarua, Vice Chancellor of Assam Agricultural University (AAU), Dr Bidyut Kumar Sharma, Director of DBT-AAU Centre, Dr. Rajumoni Bordoloi, Principal Secretary, ICAR-NEH region, Barapani, Dr. Ajaoy Kumar Gogoi, Zonal Project Director, Zone III, ICAR, Meghalaya, Dr. Ranjit Kumar Saud, Associate Director of Extension of Education, Publication and Information, AAU, Dr HC Bhattacharya, Director of Extension Education, AAU and Dr. HK Bhattacharya, Programme Coordinator, KVK, Dibrugarh.

The minister while addressing the gathering said that green revolution should be brought by extensive farming in the fields and not by movements on streets. In obvious reference to peasant leader Akhil Gogoi, Majhi said that a section of farmers was violating laws and staging unlawful demonstrations in the garb of democratic movements. “Agricultural movements must be about demanding better ways of farming, seeking agricultural tools like agri machines and irrigational projects,” he said. ■

# Sugar to power smart phones for 10 days!

FREE PRESS JOURNAL  
3 March 2014

Heard of a battery that consumes sugar and can run your smart phone for 10 days? This bio-battery may soon become a reality.

Researchers at Virginia Polytechnic Institute and State University, popularly known as Virginia Tech, have designed a new bio-battery with a greater output

per weight than the typical lithium-ion batteries used in most electronics.

A bio-battery converts sugar into energy much like our metabolism - decomposing sugar into carbon dioxide and water while releasing electrons. "By using the lithium-ion battery for example, your phone can only last for one day in the future, it would use sugar as the fuel. Then the phone could last 10 days," explained Zhiguang Zhu, a researcher at

Virginia Tech.

The new bio-battery fully converts sugar into energy which means more power output than previous bio-batteries and a greater battery charge than common lithium-ion batteries. The new bio-battery gets its efficiency by using a novel system of enzymes which are proteins that help the reaction to take place.

The system uses two active enzymes that liberate two pairs of electrons from the sugar while 10 other enzymes help to reset the reaction inside the bio-battery. Once the reaction is reset, the active enzymes release another quartet of electrons. ■

# Regulator starts examining the safety of combination drugs

ASKS MANUFACTURERS TO SUBMIT DATA TO CENTRAL REGULATOR, NOT STATE-LEVEL ENTITIES

BUSINESS LINE  
12 April 2014

The drug regulator's fight to weed out potentially unsafe combination drugs is picking up pace. The Central Drugs Standards and Control Organisation which is headed by the DCGI, has started examining the safety of fixed-dose combination drugs, which are formulations used for a variety of medicines ranging from antibiotics to painkillers.

The CDSCO, which intends to regularise this segment, wanted both small and large manufacturers to get its approval. But, despite the directive, many continued to get it done at the local level. Some of the known FDC manufacturers include smaller entities such as Restech

Pharma, Naxpar Pharma, Unix Biotech, as well as big names like Cipla.

The Drug Controller General of India has once again asked Drug Controllers at the State and Union Territory level to inform all manufacturers of fixed-dose combination drugs that they need to make presentations regarding the safety and efficacy of their drugs before the Central regulator, DCGI GN Singh told Business Line.

All such manufacturers, whose drugs had not received approval from the DCGI earlier, are required to submit relevant data and applications before the CDSCO before end of August, Singh said.

## EXPERT PANELS

According to a circular sent to the State and Union Territory Drug

Controllers, the manufacturers are expected to submit published data regarding safety and efficacy of the drugs, original data generated by the manufacturers, and the regulatory status of the drugs in other countries, along with original pack and package inserts.

The DCGI office has also constituted 10 expert committees to examine the applications being received.

FDC drugs, which are considered new drugs, were brought under the ambit of the DCGI in May 2002. The DCGI was given the authority to grant permissions/licences for these new drugs under Rule 122 of the Drugs Act.

In this regard, the DCGI had first sent notices to FDC manufacturers in January last year, asking for safety and efficacy data to be examined by experts.

However, many manufacturers had challenged this order legally, calling it arbitrary.

In December 2013, the Punjab and Haryana High Court stayed an order by the DCGI, while in October the Himachal Pradesh High Court had also put a stay on this order.

However, Singh said that there was "no stay on examining the safety issues." The Ministry of Health and Family Welfare has not been able to get the court stay vacated as yet. ■

## StemCyte to open more cord blood collection centres in India

TO BUILD OVER 5,000 PUBLIC INVENTORIES OF SUCH UNITS IN TWO TO THREE YEARS

BUSINESS LINE  
29 March 2014

StemCyte India Therapeutics, a unit of StemCyte Inc, will open more centres across India to collect umbilical cord blood units and go for public banking of stem cells in a big way to treat diseases such as thalassemia and other disorders.

StemCyte, which offers public and private banking, therapeutics and stem cell transplants with the UCB stem cells, will build over 5,000 public

inventories of UCB units with a focus on more transplants in the next 2-3 years, Kenneth J Giacin, Chairman and Director, StemCyte Inc, said here on Thursday.

The global market for cord blood therapeutics was estimated at \$6.5 billion in 2012 and is expected to show 33.4 per cent Compound Annual Growth Rate in the 2013-20 period. In India, its market is at a nascent stage.

### PUBLIC BANKS

The Indian company, which signed a

MoU during the Vibrant Gujarat Summit 2007, is a joint venture between StemCyte Inc, Apollo Hospitals Enterprises Ltd and Cadila Pharmaceuticals Ltd.

It invested Rs. 50 crore in setting up the centre at Ahmedabad, the country's only UCB storage centre that became operational in 2010, said Deepak Chhabra, COO, StemCyte India. He appealed to gynaecologists, hospitals and parents to store umbilical cord in a big way for use in future. In other countries, governments support public banking of UCBs but India is yet to catch up. So far, the centre has been able to store only about 1,000 public umbilical cord blood units and performed 30 umbilical transplants although 10,000 patients with thalassemia are born annually.

Units from collection centres housed in special kits are flown in to Ahmedabad within 24 hours of childbirth for storage in liquid nitrogen at minus 197 degrees Celsius for 21 years. As in blood banks, the client can retrieve stem cells when necessary, he said. ■

## Oxford varsity wants India to part fund biomedical research, training

BUSINESS LINE  
12 March 2014

The University of Oxford has approached the Indian Government seeking collaborations in medical technology research and training. J. Alison Noble, Director, Institute of Biomedical Engineering, Oxford, told Business Line that to address "an acute shortage" of biomedical engineers in the UK and evolve cost-effective models of healthcare delivery — such as an easily operable ultrasound machine — Oxford

wants India to part-fund some projects, She was at a workshop on Indo-UK collaboration opportunities in medical technology here on Tuesday.

Small companies in the UK make a substantial portion of the \$15-billion medical technology industry in which 3,100 companies work on novel technologies to assist hospitals cut costs and improve treatment. "Small firms help the big ones test out new methods till the point of commercialisation," she added.

She said Indian expertise in developing low-cost machines and operating high-

tech medical equipment will help the industry back home.

In this regard, the university has also begun talks with the Indian Institute of Science in Bangalore.

"We are planning to make it a student exchange programme. We are particularly interested in imaging technology that can predict premature births."

### SUCCESSFUL SPIN-OFFS

She added that university spin-offs — research ventures that branch off from colleges as companies — is common in her country, and the Indian Government should fund researches by hospitals and universities to bring new technologies in healthcare. The Institute of Biomedical Engineering has 10 spin-off firms so far. Mohanasankar Sivaprakasam, head of healthcare innovation centre at IIT-Madras, explained that for any concept to work in India, it should be cost-effective.

Technology with a "wow factor" and improved outcomes but priced beyond affordability will not sell, he added. ■

# Regulating stem cell therapy

THE HINDU  
12 March 2014

Revised set of guidelines on stem cell research was recently released by the Indian Council of Medical Research and the Department of Biotechnology, seven years after an earlier one was issued. Despite claiming that the revision was necessitated by a need to “reflect new scientific and clinical findings” that have changed the landscape of stem cell research being undertaken in the country and its possible translation, there is a glaring omission that reflects a lack of application of the mind. The guidelines make it abundantly clear that any use of stem cells in patients except to treat various haematological, immunological and metabolic disorders using haematopoietic stem cells should, by default, be considered as clinical trials.

The exemption is on the grounds that the use of haematopoietic stem cells to treat the said disorders has been “established as a standard of medical care.” Of course, the use of bone marrow (containing haematopoietic stem cells) to treat diseases like leukaemia has been in vogue in India since the 1960s. But what has been overlooked in the new guidelines is that treating damaged corneas by limbal transplantation for limbal stem cell deficiency should also be considered as an established method of care; limbal stem cells are transplanted from the healthy eye to the damaged eye of the same patient to treat an affected cornea. No other alternative method is currently available to treat such cases. For the last few years, a handful of tertiary eye hospitals in India have been treating such cases using limbus stem cells; since 2001, one institute alone has treated nearly 1,000 patients. Though the

use of limbus stem cells is not as old as haematopoietic stem cells, about 1,500 patients with corneal damage have been treated so far; there is also sufficient evidence to prove its safety. Hence, there is a compelling reason for the ICMR and the DBT to apply the same yardstick and correct the anomaly.

Though belated, the decision to call all the untested “therapies” offered to gullible people as clinical trials is indeed commendable. This would end the rampant exploitation of patients by some doctors. Many untested and unproven stem cell treatments are being offered as a magic bullet for many types of diseases and conditions. Similarly, several untested techniques to separate, grow and expand specific stem cells are available in the country. Besides failing to produce the promised benefits, there is a real possibility of causing greater harm to patients when stem cells are manipulated in the laboratory. But with many clinics and hospitals already offering stem cell therapy for a wide variety of conditions, it remains to be seen how swiftly they can be regulated under the new guidelines. ■

# Compulsory licence for another cancer drug?

DIPP WANTS TO KNOW WHY GENERIC VERSION OF BRISTOL-MYERS SQUIBB'S DRUG IS NEEDED

BUSINESS LINE  
3 April 2014

After allowing an Indian firm to sell the generic, or copied, version of Bayer's anti-cancer drug Nexaver, the Centre is now considering doing the same for Dasatinib, made by US drug major Bristol-Myers Squibb (BMS) and sold under the brand name Sprycel.

Only, the Department of Industrial Policy and Promotion (DIPP) wants the

Health Ministry to clarify the reason under which it wants approval.

If the Health Ministry can prove that denial of generic manufacture of this drug could lead to a national emergency or a situation of extreme urgency, the DIPP can allow its manufacture via a notification.

But if the Health Ministry wants the compulsory licence on the grounds that the patented version of the leukaemia drug is not affordable by the masses,

then the approval of the Indian Patent Office is required. A month's dosage of BMS's patented medicine costs around ₹ 60,000.

## ONLY ONE LICENCE SO FAR

India has granted only one compulsory licence — a permit to produce versions of patented medicines without the consent of the patent holder — so far. It has allowed Hyderabad-based Natcotosell a generic version of Bayer's anti-cancer drug, Nexaver.

The Nexaver licence was, however, granted by the Indian Patent Office, not the DIPP, as it was sought on the grounds of non-availability and high price of the patented drug.

Approaching the Indian Patent Office for a compulsory licence under the Patents Act (Section 84) is more



complicated than getting it under the provision (Section 92 of the Act) where the Centre issues a notification. Generic manufacturers have to go to the Patent Office individually to seek a licence. In October 2013, the Patent Office had rejected the application of Mumbai-based BDR Pharmaceuticals to make a generic version of Dasatinib.

Following this, the Health Ministry approached the DIPP, asking it to grant a licence by issuing a notification. "We pointed out to the Health Ministry that as per the law, we can do so only when it can conclusively prove that denying it could lead to a public health crisis, or if it gives an undertaking that it wants it for public non-commercial use, where the medicines will be purchased by

## HEALTH ISSUES

- ❖ Approval can be given if Health Ministry can prove that denial of drug can lead to a national emergency
- ❖ Bristol-Myers Squibb's patented drug costs around ₹60,000 for a month's treatment
- ❖ Only Natco has been given a compulsory licence so far, to make Bayer's Nexaver

the Government," a DIPP official told Business Line.

The Health Ministry has to collate data on the number of patients suffering due to unavailability of the patented medicine to convince the Government that there are grounds to grant the compulsory

licence to address a situation of public urgency or national emergency.

In case the Health Ministry wants the licence to be issued in order to bring down the price of the medicine and expand its reach, it has to be granted by the Controller of Patents, he added. ■

## Strand Lifesciences' virtual liver gets US patent

BUSINESS LINE  
13 March 2014

Strand Lifesciences has received a US patent for virtual liver, which would aid the pharmaceutical industry in understanding liver-related issues better.

According to a company statement, a virtual liver would help in predicting and assessing hepatotoxicity of novel drug compounds in pre-clinical studies and would also help the pharmaceutical

industry.

Hepatotoxicity is a liver disease caused due to chemical reaction in the liver — both from allopathic or herbal medicines.

The company started work on this in 2007 and is based on a rat's liver, it said. Further, Strand's virtual liver is based on a model of normal liver physiology, which provides insights into how a drug compound or chemical impacts the liver, something which would help a pharmaceutical company to include the

right amount of chemicals in their drugs, according to industry watchers.

Kalyanasundaram Subramanian, Chief Scientific Officer, Strand Lifesciences, said an estimated 50 per cent of drug failures in the clinical trial stage are attributed to toxicity, out of which 60 per cent are attributed to liver injury.

## GROWING CONCERN

Hepatotoxicity has been a big concern in the developed markets, with commonly prescribed drugs such as paracetamol causing liver damage due to excessive use.

Further, common drugs such as Isoniazid, used to treat tuberculosis have also been known to cause liver damage.

As a result, several drugs such as Bromfenac, Troglitazone, trovafloxacin have been withdrawn from the market. ■

# Aurobindo Pharma acquires Actavis operations in 7 European countries

BUSINESS LINE  
2 April 2014

Aurobindo Pharma Ltd has completed the acquisition of certain commercial operations in Western Europe from Actavis Plc. In January this year, the



Hyderabad-based Aurobindo Pharma had signed an agreement with Actavis to acquire its personnel, commercial infrastructure, products, marketing authorisations and dossier licence rights in seven European countries for €30 million.

Both companies had also inked a long-term commercial and supply arrangement.

“The acquisition will make Aurobindo one of the leading Indian pharmaceutical companies in Europe with a top 10 position in several key markets,” Muralidharan, Senior Vice-President of European operations for

Aurobindo, said here on Tuesday.?

## SMOOTH TRANSITION

Aurobindo would work to combine the strength of both enterprises in these markets and to identify and maximise all opportunities.

“We will continue to collaborate with Actavis to ensure business continuity and a smooth transition. In parallel, we will work closely with the acquired management teams to achieve a rapid and successful integration,” he added. Aurobindo’s scrip gained 4.67 per cent on BSE on Tuesday to end at Rs 534.70. ■

# Astra Zeneca sells UK R&D site

BUSINESS LINE  
13 March 2014

AstraZeneca has agreed to sell its Alderley Park research site in northern England to a public-private partnership group as it moves drug discovery to a new global centre in Cambridge. The decision to close Alderley Park was a major blow for the northwest of the country, but the new owner Manchester Science Parks plans to keep the 400-acre site as a biotechnology campus. The sale follows a decision last March by AstraZeneca Chief Executive Pascal

Soriot to move drug research to a new site in university city Cambridge in eastern England - a world-class centre for life sciences. The financial terms of the sale were not disclosed. REUTERS based drug maker had bought Japanese specialty injectables company Irom Pharmaceutical — a transaction more focused on making inroads into the Japanese market. The company did not disclose the size of either of the transactions.

The global leader in injectables and infusion medicines, US-based Hospira, bought Chennai-based Orchid Chemicals and Pharmaceuticals’ injectable

manufacturing facilities for \$200 million in August 2012.

Dr Reddy’s Laboratories marked its entry into the sector with its R193-crore purchase of Netherlands-based specialty injectables company OctoPlus in October 2012.

Mylan kicked off 2013 with a \$1.75-billion buyout of Bangalore-based Agila Specialties, an injectables company and a subsidiary of Strides Arcolab. Private equity firm KKR announced its maiden investment in the pharmaceutical sector — a 35% stake in Hyderabad-based Gland Pharma, an injectables manufacturing company, for \$200 million.

Injectables is already showing its importance, with Dr Reddy’s US revenue in three quarters of 2014 fiscal seeing a strong growth, helped by niche injectable launches. JPMorgan analysts estimate its

complex injectables portfolio, market share benefits and launch of smaller products should support growth over the next two years.

In August 2013, Hyderabad-based Aurobindo Pharma spun off its injectables business into a fully-owned subsidiary named Curepro Parenterals “to strengthen and provide focused growth to the injectable business and to leverage strategic opportunities,” according to a

statement issued at the time.

HSBC analysts estimate that about 50% of known para-IV generic drug approval applications are in specialty therapies – a terminology used to denote complex injectable medicines. A para-IV submission allows a generic firm to challenge a patent and launch a generic version of the drug at the risk of being sued by the innovator or sell a drug that has just gone off-patent with the patent

holder being the only competition.

“There is an emphasis on biologics, vaccines and other such complex therapeutic products,” PwC executive director (pharma life sciences) Sujay Shetty said. He said margins on injectable products range from 10% to 80%. “Vaccines have low margins and command between 10% and 15% while oncology products are high-margin drugs and has margins as high as 75-80. ■

## Glenmark receives \$4 million from Forest Lab as research fee

THE POLITICAL AND BUSINESS DAILY  
26 March 2014

Glenmark Pharmaceuticals has received \$4 million as research fee from Forest Laboratories Inc for drug development, taking the total amount received from the US-based firm to \$15 million so far, the company said today.

The company through its Swiss unit has received \$4 million as research fee payment from Forest Laboratories Inc

for the development of novel mPGES-1 inhibitors to treat chronic inflammatory conditions, including pain, it said.

This collaborative agreement between the two companies was inked in 2012.

Under the terms of the agreement signed in FY 2012-13, Forest made \$6 million upfront payment and also provided an additional \$3 million to support the next phase of work, Glenmark Pharmaceuticals said

in a statement.

In September 2013, Glenmark received an additional amount of \$2 million as research fee payment from Forest Laboratories Inc.

“Hence, the total amount received by Glenmark from Forest Laboratories Inc towards its novel mPEGES-1 inhibitors programme is \$15 million,” the company said.

Glenmark shares were trading at Rs 582.25 apiece on the BSE in afternoon trade, up 0.15 per cent from its previous close. ■



## US FDA nod for Montreal plant, claims Jubilant Life

THE FINANCIAL EXPRESS  
1 March 2014

Jubilant Life Sciences on Friday announced that the US Food and Drugs Administration (FDA) has “approved” its plant in Montreal, Canada. The plant had received a warning letter in February 2013 for violation of good manufacturing

practices.

“The development follows completion of FDA’s review of the company’s responses post the February letter and the subsequent re-inspection conducted at Jubilant’s Montreal facility in September 2013. This development successfully resolves the FDA issues at our Montreal facility,” the drug manufacturer said in a statement.

Stocks of Jubilant Life closed at Rs 124.55, up 6.86% on BSE.

Jubilant Life Sciences is engaged in manufacture and supply of active pharmaceutical ingredients (APIs), generics, specialty pharmaceuticals and life science ingredients. It also provides services in contract manufacturing and drug discovery and development. The company has 10 manufacturing facilities in India, US and Canada and a team of over 6,300 people across the globe.

Currently, Jubilant’s manufacturing plant at Spokane, Washington is also USFDA watch. According to the company’s website, the Spokane plant contract manufactures sterile injectables and allergenic extracts. ■



# Sun takes a shine to Ranbaxy

BUYING A TROUBLED RIVAL WILL MAKE SUN PHARMA A GLOBAL CONTENDER

THE FINANCIAL EXPRESS  
12 April 2014

RANBAXY has brought Daiichi Sankyo nothing but trouble. The Japanese drugmaker paid \$4.6 billion for Ranbaxy in 2008. Dai-ichi Sankyo wanted to expand into the burgeoning market of generic medicines; the Indian company was supposed to be expert at producing such copycat drugs. Instead, it produced scandals, and not the fun sort. American regulators have banned imports from four of its factories. Last year America's Justice Department fined Ranbaxy \$500m for among other things, inventing safety data for some of its medicines.

Though Ranbaxy has been a curse for Daiichi Sankyo, Sun Pharma views it as a shining opportunity. On April 7th Sun, another Indian generic-drug maker, said it would buy Ranbaxy in a deal valuing it at \$3.2 billion. 2.2 times its annual sales. The deal, said Sun's founder and boss, Dilip Shanghvi, is a "landmark" in his company's history. Although Sun will remain the world's fifth-largest generic-drug maker, it will no longer trail far behind the bigger four, and thus will become a strong competitor to them.

Sun is an experienced shopper—it has snapped up 16 companies over the past 20 years—and has improved the performance of a recent target, Taro. But integrating those firms was simple compared with the task ahead. Much depends on whether Sun can yank Ranbaxy out of its regulatory mire. The Food and Drug Administration (FDA), which regulates medicines in America, is scrutinising Indian manufacturers evermore closely. Margaret Hamburg, its commissioner, visited India in February to drive home the point. Even Sun has

run into trouble of late. In March the FDA banned imports from one of its Indian plants. Nevertheless, Mr Shanghvi reckons that Ranbaxy will be a boon Sun is as well-respected a firm as Ranbaxy is toxic. With margins greater than 40%, it is popular among investors. Sun's expertise in formulating copycat drugs helped it ink a deal with Merck, a much bigger American pharmaceutical firm, to develop and sell generic medicines to emerging markets. With Ranbaxy, Sun contends that it can do much more.

The combined company will still be half the size of the world's largest generics maker by sales, Teva of Israel. But Sun's sales will nearly double, to \$4.3 billion, with more revenue coming from more corners of the world. The generics market will swell in both rich and emerging markets, as governments and patients demand more medicines at

lower prices. Generics made up about one-quarter of all drug sales in 2012; by 2017 they will account for more than one-third, thinks IMS Health, a data firm.

Sun will now be better able to profit from this growth. Before the Ranbaxy deal, Sun earned only 17 % of its revenue in markets beyond India and America. Now it will have broader reach, with that share rising to 31%.

Most important, says Sujay Shetty of PwC, a consulting firm, Sun will have new dominance in its two main markets. The deal makes Sun the biggest Indian drugmaker in America, with sales of more than \$2 billion. Crucially, Sun will acquire Ranbaxy's impressive list of "patent challenges": in America, the first firm to challenge successfully a branded drug's patent is rewarded by having all other competitors kept out of the market for six months, enough time to make lots of money.

The merger also makes Sun the biggest drugmaker in India, where demand continues to grow quickly. The combined company will have a 9.2 % market share, nearly 50 % larger than that of its closest competitor, Abbott. "To get all of that for this price, I think it's a very good deal," says Mr Shetty. ■



Much depends on whether Sun can yank Ranbaxy out of its regulatory mire.

## HLL Biotech, tn ink MoU for Rs 594-cr vaccine project

THE FINANCIAL EXPRESS  
4 March 2014

HLL Biotech, a wholly owned subsidiary of HLL Lifecare (HLL), has been selected

as one of the 16 companies for new industrial projects in Tamil Nadu. A memorandum of understanding (MoU), inked in the presence of Tamil Nadu CM Jayalithaa this week, envisages Tamil Nadu

government's backing for HBL's R594-crore project in Chengalpettu. HBL is implementing the Integrated Vaccine Complex (IVC) on a 100-acre land patch in Chengalpettu of Kanchipuram district ■

## Roche to work with oryzon on cancer genes

FINANCIAL CHRONICLE  
8 April 2014

Roche agreed to buy the rights from Spain's Oryzon Genomics to

an experimental drug that's meant to switch on genes that block the growth of cancer, a new area in the crowded field of potential oncology therapies.

Roche will pay Barcelona-based Oryzon \$21 million up front and for meeting near-term targets, plus payments that may exceed \$500 million if the drug meets other goals, Basel, Switzerland-based Roche will also pay royalties if the compound makes it to the market. Oryzon will consider opportunities in coming months for an initial public offering, including in the U.S., Chief Executive Officer Carlos Buesa said in a phone interview.

The purchase gives Roche its first drug in human testing. ■

## US FDA nod for Montreal plant, claims Jubilant Life

THE FINANCIAL EXPRESS  
1 March 2014

Jubilant Life Sciences on Friday announced that the US Food and Drugs Administration (FDA) has "approved" its plant in Montreal, Canada. The plant had received a warning letter in February 2013 for violation of good

manufacturing practices.

"The development follows completion of FDA's review of the company's responses post the February letter and the subsequent re-inspection conducted at Jubilant's Montreal facility in September 2013. This development successfully resolves the FDA issues at our Montreal facility," the drug manufacturer said in a statement.

Stocks of Jubilant Life closed at Rs 124.55, up 6.86% on BSE.

Jubilant Life Sciences is engaged in manufacture and supply of active pharmaceutical ingredients (APIs), generics, specialty pharmaceuticals and life science ingredients. It also provides services in contract manufacturing and drug discovery and development. The company has 10 manufacturing facilities in India, US and Canada and a team of over 6,300 people across the globe.

Currently, Jubilant's manufacturing plant at Spokane, Washington is also USFDA watch. According to the company's website, the Spokane plant contract manufactures sterile injectables and allergenic extracts ■

## Stem cell therapy for degenerative disc disease

DECCAN HERALD  
11 March 2014

Researchers have said that recent development in stem cell research could help treat degenerative disc disease.

Senior author, Wenchun Qu, MD, PhD, of the Mayo Clinic in Rochester, Minnesota, said that this landmark study draws the conclusion in pre-clinical animal studies that stem cell therapy for disc degenerative disease might be a potentially effective treatment for the very common condition that affects



people's quality of life and productivity. Dr Qu said not only did disc height increase, but stem cell transplant also increased disc water content and improved appropriate gene expression.

He said these developments place us in a position to prepare for translation of stem cell therapy for degenerative disc disease into clinical trials.

The increase in disc height was due to restoration in the transplant group of the nucleus pulposus structure, which refers to the jelly-like substance in the disc, and an increased amount of water content,

which is critical for the appropriate function of the disc as a cushion for the spinal column.

The researchers performed a literature search of MEDLINE, EMBASE and PsycINFO databases and also manually searched reference lists for original, randomised, controlled trials on animals that examined the association between IVD stem cell transplant and the change of disc height. Six studies met inclusion criteria. Differences between the studies necessitated the use of random-effects models to pool estimates of effect. ■

## New drug target for controlling high blood sugar discovered

DECCAN HERALD  
21 March 2014

Researchers have identified a new potential therapeutic target for controlling high blood sugar.

Researchers showed that lipid molecules called phosphatidic acids enhance glucose production in the liver. These findings suggest that inhibiting or reducing production of phosphatidic acids may do the opposite.

Senior author Dr. Anil Agarwal,

Professor of Internal Medicine, said that their study establishes a role for phosphatidic acids in enhancing glucose production by the liver and identifies enzymes involved in the synthesis of phosphatidic acids as potential drug targets.

These observations were made while studying a mouse model of lipodystrophy, a rare metabolic disease in which the body is devoid of fat. Lipodystrophy patients often develop diabetes and accumulate fat in the liver because of an imbalance in the body's ability to properly

regulate lipids and glucose.

The causal gene, AGPAT2, which is involved in the synthesis of phosphatidic acid and triglycerides, was removed in the mice, resulting in rodents with generalized lipodystrophy. The research team then examined what impact this genetic manipulation had on phosphatidic acids and glucose production.

The buildup of these lipid molecules was due to an increase in the levels of two enzymes in the liver, diacylglycerol kinase and phospholipase D. Researchers also discovered a marked increase in glucose production in the livers of the lipodystrophic mice.

The lack of normal insulin signaling in these lipodystrophic mice led to unrestricted production of phosphatidic acid, Dr. Agarwal explained, contributing to development of hyperglycemia, or high blood sugar. ■

## India creates own drug to treat gangrene, to be available in a yr

DNA  
30 March 2014

Six years of path-breaking medical research has borne fruit. India will soon have its own drug to treat bacterial infection or gangrene in deeper wounds. So far, the drugs had to be imported from overseas at exorbitant prices.

The state-run Haffkine Bio-Pharmaceutical Corporation Limited has developed a 'mixed anti-gas gangrene' drug which will be used to treat patients susceptible to gangrene. After six years of research, a team of scientists from Haffkine submitted its research report to the department of biotechnology in 2012. After analysing the research and pumping in Rs1.4 crore for a

more detailed study, they created the product to prevent and treat gangrene. The product has got all the necessary permissions, including those from the Food and Drug Administration, to be launched in the market. It is likely to be available within a year.

"This product will be useful in treating all kinds of bacterial infection which are responsible for gangrene. It will be a lot cheaper than the drugs we use at present to treat the disease," said Sambhaji Zhende, managing director, Haffkine Bio-Pharmaceutical Corporation Limited. "It is great news that now an Indian company has its own product to treat gangrene," said Dr Ajay Bhandarwar, senior surgeon and professor, general surgery department, at JJ Hospital.

The patient needs to be injected with the "gas gangrene antitoxin" drug to stop the spread of infection. People who suffer from diabetes, blood vessel disease, colon cancer, frostbite or open fractures can develop gangrene, which is essentially the death of body tissue.

Gas gangrene, also known as clostridial myonecrosis, is a fast-spreading and potentially life-threatening form of gangrene caused by bacterial infection. The infection causes toxins to release gas, which leads to the death of tissues.

"A patient with symptoms of gas gangrene must seek emergency medical attention immediately. Delaying treatment can lead to shock, kidney failure and coma. Also, in some cases, it can result in the amputation of the infected body part," said Dr Bhandarwar.

Gas gangrene can develop anywhere in the body, but it is mostly common in arms and legs. Its symptoms include swelling, blisters that contain gas bubbles near the area of infections, increased heart rate and high fever. Skin in the affected area often turns from pale to brownish-red. Treatment may include antibiotics and surgery to remove the dead tissue. ■

## Bone marrow stem cells may help treat stroke

STEM CELLS CULLED FROM BONE MARROW MAY PROVE BENEFICIAL IN STROKE RECOVERY, SCIENTISTS SAY

DECCAN HERALD  
11 April 2014

Scientists at University of California—Irvine's Sue & Bill Gross Stem Cell Research Center identified 46 studies that examined the use of mesenchymal stromal cells — a type of multipotent adult stem cells mostly processed from bone marrow—in animal models of stroke.

They found MSCs to be significantly better than control therapy in 44 of the studies.

The effects of these cells on functional recovery were robust regardless of the dosage, the time the MSCs were administered relative to stroke onset or the method of administration.

The cells helped even if given a month after the event and whether introduced directly into the brain or injected via a

blood vessel.

"Stroke remains a major cause of disability, and we are encouraged that the preclinical evidence shows [MSCs'] efficacy with ischemic stroke," said neurologist Dr Steven Cramer, clinical director of the Sue & Bill Gross Stem Cell Research Center.

"MSCs are of particular interest because they come from bone marrow,





which is readily available, and are relatively easy to culture. In addition, they already have demonstrated value when used to treat other human diseases.” Cramer said.

He noted that MSCs do not differentiate into neural cells. Normally, they transform into a variety of cell types, such as bone, cartilage and fat cells.

“But they do their magic as an inducible pharmacy on wheels and as good immune system modulators, not as cells that directly replace lost brain parts,” he said.

In an earlier report focused on MSC mechanisms of action. Cramer and colleagues reviewed the means by which MSCs promote brain repair after stroke.

The cells are attracted to injury sites and, in response to signals released by these damaged areas, begin releasing a wide range of molecules.

In this way, MSCs orchestrate numerous activities: blood vessel creation to enhance circulation, protection of cells starting to die, growth of brain cells, etc.

At the same time, when MSCs are able

to reach the bloodstream, they settle in parts of the body that control the immune system and foster an environment more conducive to brain repair.

“We conclude that MSCs have consistently improved multiple outcome measures, with very large effect sizes, in a high number of animal studies and, therefore, that these findings should be the foundation of further studies on the use of MSCs in the treatment of ischemic stroke in humans,” said Cramer.

The research appears in the journal *Neurology*. ■

## Stem cells may help cure bladder problems

FREE PRESS JOURNAL  
24 March 2014

Scientists have now managed to produce tissue from human stem cells that could be transplanted into patients with defective or diseased bladder, says a study, reports IANS. For the first time, scientists have succeeded in coaxing laboratory cultures of human stem cells to develop into the specialized,

unique cells needed to repair a patient’s defective or diseased bladder. The breakthrough was developed at the University of California’s (UC) Davis Institute for Regenerative Cures and published in the scientific journal *Stem Cells Translational Medicine*.

It is significant because it provides a pathway to regenerate replacement bladder tissue for patients whose bladders are too small or do not

function properly, such as children with spina bifida and adults with spinal cord injuries or bladder cancer, reported *Science Daily*.

“Our goal is to use human stem cells to regenerate tissue in the lab that can be transplanted into patients to augment or replace their malfunctioning bladders,” said Eric Kurzrock, professor and head of the division of paediatric urologic surgery at UC Davis Children’s Hospital and lead scientist of the study.

Another benefit of the UC Davis study is the insight it may provide about the pathways of bladder cancer, which is diagnosed in more than 70,000 Americans each year, according to the National Cancer Institute. ■

## Docs to grow ear, nose from body fat

NEW TECH HELPS REBUILD PEOPLE’S FACES WITH CARTILAGE DERIVED FROM STEM CELLS

THE TIMES OF INDIA  
5 March 2014

British doctors will undertake a path-breaking procedure to reconstruct people’s faces with stem cells taken from their fat. The team has successfully grown cartilage in the laboratory and believe it could be used to rebuild ears

and noses.

Great Ormond Street Hospital (GOSH) and the UCL Institute of Child Health (ICH) say the effectiveness of human stem cell therapies for facial reconstruction has been effectively investigated and shows how stem cells could pose a viable alternative to current approaches to facial cartilage

reconstruction such as ear and nose reconstruction. GOSH is world renowned for successfully treating patients born with a malformed or missing ear, a condition known as microtia.

The two-stage ear reconstruction takes cartilage from the patient’s ribs and a new scaffold is moulded and placed beneath the skin from it. Both the clinical and cosmetic results of this procedure have been very good.

However, as Patrizia Ferretti, head of developmental biology unit at the ICH and her co-authors demonstrate in their study, the potential application of human stem cells and tissue engineering could further improve results and would obviate the need for this invasive part of

the procedure, which leaves a permanent defect in the donor site. What the team envisages is taking a tiny sample of fat from the child and stem cells would be extracted and grown from it.

An ear-shaped scaffold would be placed in the stem cell broth so the cells would take on the desired shape and structure. Chemicals would then be used to persuade the stem cells to transform

into cartilage cells.

This could then be implanted beneath the skin to give the child an ear shape.

Dr Ferretti said "We used stem cells harvested from the abdominal tissue of young patients affected by craniofacial conditions to explore, in our laboratories, how these might be used in future surgery.

The use of stem cells from the paediatric

patients themselves circumvents the issue of rejection and would overcome the need for immunosuppressive therapies".

The study suggests that combining stem cells with scaffolds can be of great value for several applications.

In addition to ear and nose cartilage reconstruction, they could be used, for example, to improve the quality of tracheal transplants. ■

## Cataloguing to cure cancer

BIO-WATCH IS A CATALOGUE OF CANCER GENES THAT LIES FINISHED JUST A START OR IS THERE MORE TO THIS MUTATION SCARE ASKS CARL ZIMMER

DECCAN HERALD  
NEW DELHI, 9 MARCH 2014

Cancer is a disease of genes gone wrong. When certain genes mutate, they make cells behave in odd ways. The cells divide swiftly, they hide from the immune system that could kill them and they gain the nourishment they need to develop into tumors.

Scientists started identifying these cancer genes in the 1970s, and their list slowly grew over the years. By studying them, scientists came to understand how different types of cancer develop, and in some cases they were even able to develop gene-targeting drugs. Last May, for example, the Food and Drug Administration approved a drug known as Tarceva to treat lung cancer in which a gene called EGFR has mutated.

### THE ATLAS

The National Institutes of Health, hoping to speed up the identification of cancer genes, started an ambitious project in 2005 called the Cancer Genome Atlas. They analysed 500 samples from each of more than 20 types of cancer and found a wealth of new genes. The data have helped scientists discover more of the

tricks, cancer cells use to thrive at our expense.

"The Cancer Genome Atlas has been a spectacular success, there's no doubt about that," said Bruce Stillman, the president of Cold Spring Harbor Laboratory.

But now, as the Atlas project is coming to an end, researchers at the Broad Institute of MIT and Harvard have published a study in the journal *Nature* that has scientists debating where cancer research should go next. They estimated that scientists would need to examine about 1,00,000 genes - 10 times as many as the \$375 million Cancer Genome Atlas has gathered - to find most of the genes involved in 50 cancer types.

"We now know what it would take to get a complete catalogue," said Eric S. Lander, the founding director of the Broad Institute and a co-author of the new study. "And we now know we're not close to done. We have a lot left to learn."

Traditionally, scientists have identified cancer genes by comparing healthy cells with cancerous ones. If they find a statistically unusually high number of cells with mutations in a particular gene, they

can then examine it to see if it really does help drive cancer - or if it is just carrying a harmless mutation.

Lander and his colleagues suspected this method could miss some genes. While some cancer genes affect most cells of a given type of cancer, other genes are only involved in a fraction of them. (EGFR, the gene treated with Tarceva, is mutated in only about 10 percent of cases of non-small cell lung cancer.) Small samples of cancer cells might not contain the less common mutations.

The Broad Researchers suspected that they could catch some of these missing genes by looking at several cancer types at once, because some genes are not limited to a single type of cancer. For their new study, the scientists examined cancer samples from the Cancer Genome Atlas, as well as cancer samples from the Broad's own collection. All told, they analysed 4,742 samples from 21 types of cancer.

The new study detected many of the genes that other scientists have previously linked to those 21 types of cancer. But they also found new genes that had been overlooked before. All told, they identified 33 genes that they consider strong candidates for playing a role in cancer - a potential increase of the catalogue of cancer genes of 25 percent.

"This was eye-opening to me," said Lander.

### QUESTIONS IN MIND

Lander and his colleagues began to wonder how many genes could be found if scientists looked at more cancer

samples. Was the cancer catalogue almost finished, or only just begun?

“We were able to ask for the first time, Are we there yet?” said Lander.

They extrapolated from their own results to gauge how many more samples scientists would need to look at to find most cancer genes involved in at least 2 percent of cancers of a given type.

To find most cancer genes involved in the 50 most common types of cancer, the researchers estimated that they would have to analyse 1,00,000 samples. In other words, the atlas has gotten us a

tenth of the way to the finish line.

Dr. Harold Varmus, the director of the National Cancer Institute, said the study has raised valuable questions.

“The paper provides some models about what we might think about doing next,” he said. He said the agency is now considering testing Lander’s hypothesis on a few types of cancer by gathering more samples.

Lander and his colleagues argue for finishing off the cancer gene catalogue. “Completing the genomic analysis of this disease should be a biomedical imperative,” they wrote in their new

paper.

In an interview, Lander said knowing most genes involved in cancer would be a powerful weapon against the disease. “How could we think of beating cancer in the long term without having the whole catalogue?” he said. “It would be crazy not to have the information.”

But Stillman of Cold Spring Harbor Laboratory said completing the atlas has to be weighed against other needs. “Whether we need to know every cancer gene, I’d like to see an argument for how that’s going to help the advancement of new therapy,” he said. ■

## HIV vaccine trials pave way for new treatment

DECCAN HERALD  
21 March 2014

A multi-national research team led by Duke Medicine scientists has identified a subclass of antibodies associated with an effective immune response to an HIV vaccine.

Earlier analyses of the results of that trial, known as RV144, suggested that antibodies to sites within a part of the HIV envelope called V1V2 correlated with reduced risk of HIV infection. These antibodies belong to a class called

immunoglobulin G, or IgG.

The new studies by two independent laboratories both found that only one subclass of V1V2-directed IgG antibodies—the IgG3 subclass—is associated with antiviral responses linked to the reduced risk of HIV infection seen in RV144. The experiments were led by Georgia D. Tomaras, PhD, of the Duke Human Vaccine Institute, and Galit Alter, PhD, of the Ragon Institute, with funding in part from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National

Institutes of Health.

In the study led by Tomaras, scientists found that V1V2-specific IgG3 antibodies correlated with a decreased risk of infection in RV144 vaccinees and were linked to HIV-eliminating activity. The researchers also discovered that the level of V1V2-specific IgG3 antibodies in vaccinees’ blood waned rapidly, as did the efficacy of the investigational vaccines tested in the RV144 trial (from 60% efficacy at 12 months post-vaccination to 31.2% efficacy at 42 months).

The study led by Dr. Alter demonstrated that RV144 vaccination induced antibodies able to direct multiple, coordinated HIV-eliminating activities, and that these activities were conducted primarily by V1V2-specific IgG3 antibodies. ■

## Stem cell therapy hope for Parkinson’s

**NINE TRIALS UNDERWAY ACROSS THE WORLD MAY HOLD PROMISE OF POSSIBLE CURE AFTER FIVE TO SEVEN YEARS**

DNA  
11 April 2014

Stem cells and gene hold promising treatment options for Parkinson’s

Disease, say doctors across the globe, including those in Mumbai.

Eleven trials to test stem cell and gene therapies for treating the disease are currently underway. In Mumbai, however,

only two out of these 11 trials were being done — resource constraints led to one being canned and regulatory hurdles have put the other one on hold.

Currently, neuro-augmentative therapies, such as usage of drugs or deep brain stimulation (DBS), are being used to treat Parkinson’s Disease. “The future holds hope for neuro-restorative therapies like that of stem cells or gene infusion. Stem cells are the very primary kind of cells which can take on the function of any body part’s cells after their infusion with that body part. It (the treatment) involves

restoration of brain function to normal. In the next five to seven years, this may pave the way for the future,” said Dr Paresh Doshi, neurologist at Jaslok Hospital on Peddar Road.

Doshi said trial of Duodopa therapy, which involves infusion of an active ingredient gel called Levodopa in the intestines, has been kept on hold. Jaslok Hospital was the only centre in the whole of Southeast Asia that was running the trial.

“Levodopa gets converted into dopamine in the body. Normal levels of dopamine control Parkinson’s Disease,” said Doshi.

A trial to infuse stem cells from the patient’s body into the patient himself/herself had been underway in a small

group of patients in India, but it had to be stopped due to the inability to recruit more patients. Doshi said, “We could only recruit four patients for two years. However, a similar trial is underway in China and another trial, which explores adipose tissue stem cells, is underway in South Africa.”

In January, medical journal The Lancet reported that after 16 years of trials, gene therapy is showing promising results in humans. “Three genes that promote the formation of dopamine-generating cells in the brain were injected in the brain, bound with a viral vector, in 15 patients. ...dopamine... becomes deficient in patients with Parkinson’s,” The Lancet report stated.

Three patients from the UK and

12 from France in advanced stages of Parkinson’s Disease underwent an operation, wherein the virus with the three genes was injected in their brains. The patients, who had become stiff due to the disease, showed a 30% improvement in their movement after the surgery. After four years of follow-ups, they continued to improve and dopamine kept on being produced in their brain, in parts where it was not being produced before.

“Presently, there is no established stem cell/gene therapy for Parkinson’s Disease or any other neurological disorder. However, I am quite sure that in five to seven years, we will have neuro-restorative therapies available for many such diseases,” said Dr Alok Sharma, head, neurology at Sion hospital. ■

## GEAC Clears Way for Wider GM Crop Trials

10 PROPOSALS REVALIDATED ALLOWING PHASE II TESTING OF GM WHEAT, RICE, COTTON

THE ECONOMIC TIMES  
22 March 2014

After a gap of one year, the statutory body for approving genetically modified crops, the Genetic Engineering Advisory Committee (GEAC), met on Friday. No new proposals for genetically modified crops were taken up, instead the committee re-validated 10 proposals for wider field trials for genetically modified maize, wheat, rice and cotton in upcoming rabi season.



These proposals had been cleared for limited field trials in 2011-12, but clearance for larger trials were pending as the committee had not met. The decision will allow Mayhco, BASF India and Monsanto India to go ahead with wider or phase II field trials for these genetically modified crops. Phase II trials will mean that the crops can be grown in larger areas.

Sources said that the committee is likely to take up new cases when it meets next on April 25. At that time it is expected to take up as many as 70 proposals, which expected to include a wider variety of food crops.

The floodgates for trials for genetically modified food crops were opened in late

February, when environment minister Veerappa Moily cleared field trials for genetically modified rice, wheat, maize and castor. These proposals had been recommended for clearance by the GEAC in March 2013. These recommendations had been put on hold by the then environment minister Jayanthi Natarajan on the grounds that the Supreme Court was hearing a public interest litigation opposing field trials for GM crops in the absence of an effective and independent regulator. Moily had made it clear that there was no reason why the GEAC could not consider and allow field trials for GM food crops as the Supreme Court had at no point asked the government to hold back on



taking decisions. The Technical Expert Committee appointed by the court had recommended a moratorium on all field trials till an effective and independent

regulator is put in place. The Supreme Court is expected to continue hearings on the public interest litigation later this month. This committee, sources

indicated, has chosen to wait for the court's order before it takes up fresh proposals for GM food crops, so as to avoid further controversy. ■

## Clue to viability of rice

DECCAN HERALD  
12 March 2014

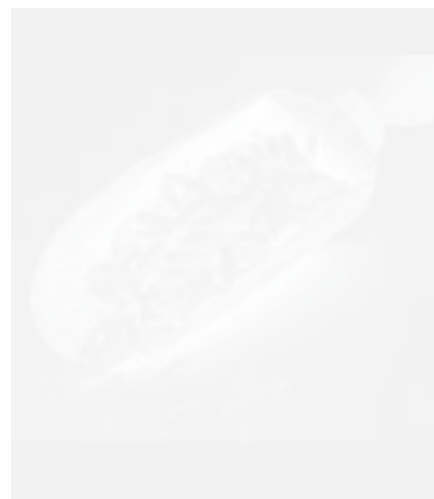
Scientists from India and Australia have found that a native Australian grass growing in Queensland state could hold the key to ensuring the long-term viability of rice, a crop critical to global food security, PTI reports from Melbourne. Deputy Director of Queensland University of Technology's (QUT) Centre for Tropical Crops and Bio-commodities, Sagadevan Mundree, said rice is one of the most important staple foods throughout the world

but salinity and drought stresses were putting the crop's long-term future under enormous pressure.

Mundree heads a team of scientists working in partnership with scientists in India to determine whether strategies adopted by the Australian native resurrection grass could be used to genetically improve abiotic stress tolerance in rice.

"QUT has developed a strategic partnership with the International Centre for Genetic Engineering and Biotechnology in New Delhi and the Tamil Nadu Agriculture University

in Coimbatore in southern India," Mundree said. ■



## Gene find could be key to 'super rice' route

THE FINANCIAL EXPRESS  
3 April 2014

Scientists, including an Indian-origin researcher, have identified a set of genes that could be key to the development of the next generation of tough and disease-resistant 'super rice'.

"As the Earth's human population marches towards 9 billion, the need for hardy new varieties of grain crops has never been greater," researchers said.

It won't be enough to yield record harvests under perfect conditions. In an era of climate change, pollution and the global spread of pathogens, these new grains must also be able to handle stress, they said.

Researchers at the Michigan Techno-

logical University identified a set of genes that could be key to the development of the next generation of super rice.

Analysis by biologist Ramakrishna Wusirika and PhD student Rafi Shaik uncovered more than 1,000 genes in rice that appear to play key roles in managing its response to two different kinds of stress: biotic, caused by infectious organisms like bacteria and abiotic, caused by environmental agents, like nutrient deficiency, flood and salinity.

Traditionally, scientists have believed that different sets of genes regulated plants' responses to biotic and abiotic stress.

However, Wusirika and Shaik discovered that 1,377 of the approximately

3,800 genes involved in rice's stress response played a role in both types stress.

"These are the genes we think are involved in the cross talk between biotic and abiotic stresses," said Wusirika. About 70% of those "master" genes are co-expressive - they turn on under both kinds of stress.

Typically, the others turn on for biotic stress and turn off for abiotic stress. Scientists looked at the genes' response to five abiotic stresses — drought, heavy metal contamination, salt, cold and nutrient deprivation — and five biotic stresses - bacteria, fungus, insect predation, weed competition and nematodes.

A total of 196 genes showed a wide range of expressions to these stresses. "The top genes are likely candidates for developing a rice variety with broad stress-range tolerance," Wusirika said.

The study was published in the journal *Plant Physiology*. ■

## GEAC Clears Way for Wider GM Crop Trials

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## New bio-engineered trees make it easier to produce pulp

The Financial Express  
3 April 2014

Gene find could be key to 'super rice' route

Washington, April 2: Scientists, including an Indian-origin researcher, have identified a set of genes that could be key to the development of the next generation of tough and disease-resistant 'super rice'.

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stress-range tolerance,” Wusirika said.

The study was published in the journal *Plant Physiology*. ■

## Moiily permits field trial of GM crops

New Delhi, DHNS: A change at the helm of the Ministry of Environment and Forests (MoEF), combined with factors such as the upcoming Parliamentary election has ushered in a drastic change in the government’s policies, one of them being its stand on GM crops.

After having taken over as Environment minister in December, Veerappa Moily on Thursday allowed field trials for several genetically modified crops being

developed by private agriculture and biotechnology companies.

The government’s move comes after keeping GM crop trials on hold for almost a year. The decision to withhold field trials was taken by the Genetic Engineering Appraisal Committee (GEAC) in March 2013. Former environment minister, Jayanthi Natarajan kept these decisions in abeyance, citing a public interest

litigation against GM crops that was being heard in the Supreme Court.

However, Moily took a different stand, arguing that the court had not placed curbs on field trials. “There was a misunderstanding. The Supreme Court did not ban field trials. We are approving the GEAC decisions subject to certain conditions and no objections from the state government,” he said on Thursday.

GM crops to be tested in field conditions include several varieties of cotton, rice, maize and castor. While some of them will undergo field trials, the GEAC has approved pollen flow and other on-site studies for many varieties. It also increased trial locations in various climatic zones. ■

## New bio-engineered trees make it easier to produce pulp

THE ASIAN AGE  
5 April 2014

Researchers have genetically engineered trees that will be easier to break down to produce paper and biofuel. a breakthrough that will mean using fewer chemicals, less energy and creating fewer environmental pollutants. “One of the largest impediments for the pulp and paper industry as well as the emerging

biofuel industry is a polymer found in wood known as lignin,” said Shawn Mansfield, a professor of Wood Science at the University of British Columbia, Canada. Lignin makes up a substantial portion of the cell wall of most plants and is a processing impediment for pulp, paper and biofuel. Currently the lignin must be removed, a process that requires significant chemicals and energy and causes undesirable waste.

Researchers have now used genetic engineering to modify the lignin to make it easier to break down without adversely affecting the tree’s strength. “We’re designing trees to be processed with less energy and fewer chemicals, and ultimately recovering more wood carbohydrate than is currently possible.” said Mansfield. Researchers had previously tried to tackle this problem by reducing the quantity of lignin in trees by suppressing genes, which often resulted in trees that are stunted in growth or were susceptible to wind, snow, pests and pathogens. The structure of lignin naturally contains ether bonds that are difficult to degrade. Researchers used genetic engineering to introduce ester bonds into the lignin backbone that are easier to break down chemically. ■

## New biofuel to power future missiles, rockets

THE TIMES OF INDIA  
28 March 2014

The next generation of super powerful fuel may come from an engineered bacterium. Researchers at the Georgia Institute of Technology have engineered a bacterium to synthesize pinene — a hydrocarbon produced by trees that could potentially replace high-energy fuels such as JP-10 in missiles and other aerospace applications.

By inserting enzymes from trees into



the bacterium, Georgia Tech scientist Stephen Sarria boosted pinene production six-fold over earlier bioengineering efforts.

To be competitive, the researchers will have to boost their production of pinene 26-fold. Though a more dramatic improvement will be needed before pinene can compete with petroleum-based JP-10, the scientists believe they have identified the major obstacles that must be overcome to reach that goal.

They say it may be possible to

produce pinene at a cost lower than that of petroleum-based sources. If that can be done —and if the resulting biofuel operates well in these applications — that could open the door for lighter and more powerful engines fueled by increased supplies of high-energy fuels.

Pinene dimers which are formed from the dimerization of pinene have already been shown to have an energy density similar to that of JP-10.

For the full report, log on to [www.timesofindia.com](http://www.timesofindia.com). ■

## Unravelling a genetic puzzle

IF CHROMOSOMES ARE NOT SET IN A PRE-DETERMINED PATTERN IN THE NUCLEUS OF A CELL, IT CAN LEAD TO SOME CANCERS AS WELL AS THAT RARE DISEASE PROGERIA, ON WHICH THE FILM PAA WAS BASED. T.V. JAYAN SPOKE TO SCIENTISTS WHO MAY HAVE CRACKED THE PLACEMENT PUZZLE

THE TELEGRAPH  
10 March 2014

An Indian research team that includes a research student who hails from a remote village in West Bengal may have resolved a problem that puzzled cell biologists for over a century.

The genetic material of any living organism is arranged in different

chromosomes found inside the nucleus of a cell. Scientists have known for a while that gene-rich chromosomes are found closer to the centre of the nucleus while gene-poor chromosomes are more often found on the fringes, anchored to the nuclear envelope.

But the mechanisms behind such an organisation — largely followed in each healthy living cell — have remained an

enigma. Now a team of researchers led by Gautam Menon, a biophysicist at the Institute of Mathematical Sciences in Chennai, seems to have theoretically solved the problem. The findings appeared in the top-rated *Nucleic Acids Research* recently. Interestingly, most of the number-crunching was done by Nirmalendu Ganai, a young researcher from a village called Chak in Murshidabad district. Ganai is a doctoral student with Surajit Sengupta, a computational physicist with the Tata Institute of Fundamental Research (TIFR), Hyderabad campus.

Understanding how chromosomes are packed inside the nucleus has many clinical implications. The incorrect placement of chromosomes is seen in many cancers. Similarly, when chromosomes are incorrectly tethered, it leads to a rare genetic disorder called progeria, which causes accelerated biological ageing and is familiar to Indians because Amitabh



Bachchan played a victim of this disease in the 2009 movie Paa .

A clue to how chromosome organisation works can be of tremendous help in disease biology. “In many cancers, particularly epithelial cancers, the number of chromosomes in a cell will go up abnormally. For instance, cells affected by a certain type of pancreatic cancer would have 80 or more pairs of chromosomes, instead of the 23 pairs in a normal cell. Similarly, in some colorectal cancer cells, there will be an extra copy of chromosome 7,” says Kundan Sengupta, an assistant professor at the Indian Institute of Science Education and Research (IISER), Pune. The IISER scientist plans to collaborate with the team to test its findings in lab experiments.

“In cancer cells, there would be many chromosomes competing for position and disrupting their normal arrangement, quite like too many rich people vying for the same prime property in the heart of a metropolis,” Sengupta says.

Almost all cells in the human body have 23 pairs of chromosomes. The number of chromosomes can vary from organism to organism. For instance, the fern Adders-tongue is known to have the highest number of chromosome pairs — 1260, while jumper ants — native to Australia — have just two pairs of chromosomes.

During cell division (the process of yielding two daughter cells which

happens all the time in a cell), DNA — a molecule that can be as long as two metres — housed in each chromosome is duplicated and tightly packed again without any overlapping in daughter cells. In the progeny cells too, the chromosomes continue to occupy the same approximate location as in the mother cell.

“Scientists knew for a while that the way individual chromosomes positioned was not completely random. They follow something called gene-density-based segregation in cell nuclei,” says Menon.

Menon and his colleagues have been able to mathematically resolve this old and classic problem in the biology of cell nucleus: why chromosomes segregate by gene density and why they form “territories” in the nucleus.

“What we hypothesise is that chromosomes that are most shaken around by proteins that consume energy and move on them would occupy more central positions while others move to the fringes,” TIFR’s Sengupta told KnowHow.

“Using a polymer model for different chromosomes in the nucleus, thinking of them as monomers linked together, we have been able to illustrate this principle,” he says.

### **NIRMALENDU GANAI**

According to Menon, this problem has been on his mind for a while. “Sengupta

and I have been collaborating for some time. When Nirmalendu, after a master’s in physics from Presidency College enrolled for a PhD under Sengupta, he needed a problem to work on. At that point in time Sengupta was working at the Indian Association for Cultivation of Science in Calcutta. I suggested this,” Menon says.

“I was quite impressed by Nirmalendu. I have had many students, including some from top-notch educational institutions. But I have rarely seen the kind of independence and thoughtfulness shown by Nirmalendu,” says Menon.

“Shortly after he enrolled for the research, he got a job as a lecturer in a government-aided college in Nadia. He continued the research, often travelling to Calcutta after his college hours. The association continued even after Surajit moved to the TIFR Centre for Interdisciplinary Sciences in Hyderabad. He would travel to Hyderabad on holidays, including Puja holidays, and keep constantly in touch with both of us through emails and over the phone,” Menon says.

“I really enjoyed working on this interesting problem, which required a high degree of number-crunching,” says Ganai.

“There is a lot of promise in this work. Very few works from India have used interdisciplinary models like these to unravel a difficult problem like this,” says IISER’s Kundan Sengupta. ■

## ‘Stem cells to be used in facial reconstruction’

THE ASIAN AGE  
16 March 2014

Human stem cells could be a viable alternative to current approaches to facial cartilage reconstruction such as for ear and nose, said a new study

The effectiveness of human stem cell therapies for facial reconstruction

has been investigated by Great Ormond Street Hospital (COSH) and the UCL Institute of Child Health (ICH).

For patients born with a malformed or missing ear, a condition known as microtia the two-stage ear reconstruction involves taking cartilage from the patient’s ribs and from this, a new scaffold is moulded and placed beneath the skin Both the clinical

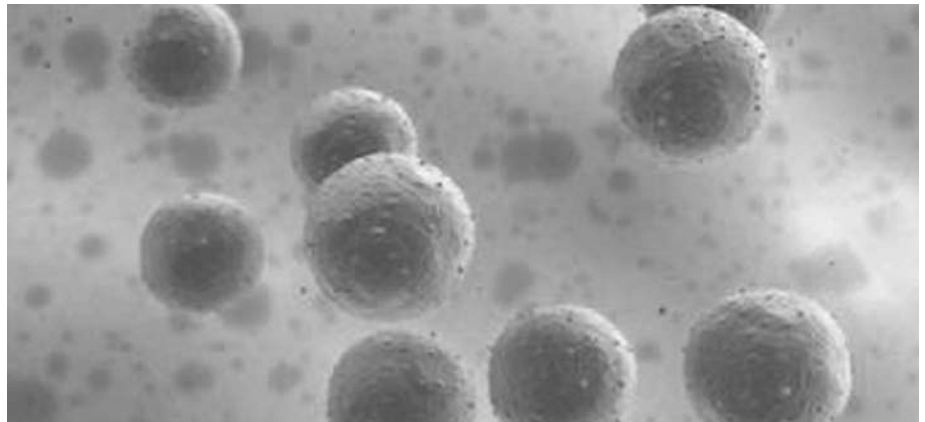
and cosmetic results of this procedure have been very good

However as Patrizia Ferretti, Head of Developmental Biology Unit at the ICH and her coauthors demonstrate In their study, the potential application of human stem cells and tissue engineering could further improve result and would obviate the need for this invasive part of the procedure, which leaves a permanent defect in the donor site a statement released here said.

“We used stem cells (hADSCs) harvested from the abdominal tissue of young patients affected by craniofacial

conditions to explore, in our laboratories, how these might be used in future surgery. The use of stem cells from the paediatric patients themselves circumvents the issue of ("ejection and would overcome the need for immunosuppressive therapies," Frerretti said. In addition to ear and nose cartilage reconstruction, they could be used, for example, to improve the quality of tracheal transplants. Scaffold cellularisation in vivo (within the body) is a lengthy and uneven process. "Currently I take the rib cartilage from the chest to make an ear but if we could produce a block of cartilage using stem cells and tissue engineering, this would be the Holy Grail for our field." Neil Bulstrode, Consultant Plastic Surgeon at GOSH, said. The paper has been published in the journal *Nanomedicine*. ■

- ❖ In addition to ear and nose cartilage reconstruction, the stem cells could be used, for example, to improve the quality of tracheal transplants. Scaffold cellularisation in vivo (within the body) is a lengthy and uneven process.



## IIT scientists developing stem cells for heart

HINDUSTAN TIMES  
3 March 2014

A team of scientists at IIT Madras are developing stem cells to grow into cardiac cells, which can eventually lead to treatment of severe heart problems.

The cells will now be surgically administered into specifically created rat models at the Central Drug Research Laboratory in Lucknow. The project

is being funded by the department of Biotechnology.

"We have developed cardiac patches isolated from biological material and proved the functionality of the cells. These patches when put into the ischemic heart can help reverse the dying cells," says Rama S Verma, professor, department of biotechnology, IIT-M.

Stem cell therapy holds a lot of promise in the field of medical science,

he said adding: "Besides opening new avenues this may also help in preventing an organ transplant."

After the patches are surgically administered in the rats, he said: "We will check for all the physiological parameters like heart rate and blood flow. This will then help us in analysing the survival rate."

Besides heart, IIT-M scientists are also experimenting with stem cells for treating liver diseases. They have programmed stem cells derived from cord blood and bone marrow to grow into liver cells. The cells were grown in a special polymer gel.

"If the trials on animals prove to be successful, we will move on to experimenting on humans," he added. ■

## Slamming Brakes on Stem Cell 'Breakthrough'

THE NEW INDIAN EXPRESS  
15 March 2014

A Japanese research institute said on

Friday that a study which promised a revolutionary way to create stem cells should be quashed after claims its data was faulty, dealing a huge blow to

what was touted as a game-changing discovery.

Riken institute head, Ryoji Noyori, who jointly won the Nobel Prize for chemistry in 2001, also heaped criticism on lead researcher Haruko Obokata for her "sloppiness" and warned the controversy could shake the public's faith in research.

The findings, published by 30-year-old Obokata along with other Japanese

researchers and a US-based scientist in the January edition of journal *Nature*, outlined a relatively simple way to grow transplant tissue in the lab.

Among key concerns was that researchers used erroneous images, crucial to supporting the study, which resembled those used in Obokata's doctoral dissertation in 2011.

The findings said that white blood cells in newborn mice were returned to a versatile state through a simple process that involved incubating diem in a weak acidic solution followed by a spin in a centrifuge and immersion in a growth culture. ■



## Chromosomal Crux

THE FIRST SYNTHETIC EUKARYOTIC CHROMOSOME IS HERE—AND IT BRINGS WITH IT MANY POSSIBILITIES

THE FINANCIAL EXPRESS  
3 April 2014

Scientists in the US have created the first synthetic chromosome for baker's yeast, the BBC has reported. While synthetic chromosomes have been created before, this is the first success with an eukaryote (an organism whose cells have nuclei housing its chromosomes). A team of researchers, led by Dr Jef Boeke of Langone Medical Centre at New York University, replaced the genes in the original chromosome with

synthetic ones before inserting the chromosome—named Syn III—into the yeast nucleus. The new cell underwent division, thus passing a crucial viability test.

Such synthetic biology assumes significance for two reasons. One, it can be used in industrial production of certain chemicals—Mosquito One, a drug developer, successfully demonstrated production and extraction of artemisinin, a key component in anti-malarial drugs, using a synthetic gene in yeast. There is research under way to

harvest key human hormones using non-human cells and synthetic genes. So, if a chromosome laden with genes coding for many proteins can be synthesised, a single cell can be used to produce many biochemical products. More impressively, the research team junked some of the base pairs in the original gene—Syn III has 2,73,871 base pairs while the original had 3,16,667 pairs. So, not only is it possible to produce many bio-chemicals simultaneously, but also to choose each specific one. The larger ramification, however, is for genetic research itself. Being an eukaryote, yeast is related to all plants and animals—humans share as many as 2,000 genes with it. So, the successful synthesis of a yeast chromosome opens up doors for synthesising, some day, a human chromosome ■

## Origins of bad fat traced back to embryo

DECCAN HERALD  
11 March 2014

Fat that gets deposited around vital organs in the body can be traced back to a single cell in a developing embryo, British scientists have claimed.

Using laboratory mice, researchers have now shown that up to 50 per cent of visceral fat in the body can be traced back to a cell in a developing embryo. Visceral fat is the fat that forms around the heart, intestines and other vital organs and is different

from subcutaneous fat that sits under the skin and is a much bigger threat to health.

The findings will help to increase our understanding of obesity and its health consequences and could lead to new opportunities for prevention or treatment, the University of Glasgow said in a release today. These early fat cells express a gene called *Wt1* but subcutaneous fat cells do not, suggesting that the two types of fat come from different sources.

The team also found cells expressing Wtl in the visceral fat of adult mice.

These cells continued to make more fat cells throughout the life of the animal, in a similar way to stem cells.

Understanding how to regulate these cells could lead to interventions that help stop the body from laying down any more bad fat around the

organs, the scientists suggest.

Visceral fat is particularly dangerous because it is not visible from the outside and people with a lot of it can still appear slim.

Having a lot of visceral fat increases the risk of cancer, type 2 diabetes, heart disease and Alzheimers disease.

Although all fat carries health risks,

subcutaneous fat can be beneficial because it provides us with energy, cushioning and insulation.

“Determining the origins of good and bad fat has been one of the big unanswered questions in obesity research”, said Dr. You-Ying Chau from the MRC Human Genetics Unit and the study’s lead author. ■

