

## News Snippets

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### **Ranbaxy's Goa plant gets MHRA approval**

The dosage forms manufacturing facility of Ranbaxy Laboratories Ltd in Goa has received approval from Medicines and Healthcare products Regulatory Agency (MHRA), UK, for its tablets manufacturing unit.

### **Ranbaxy gets USFDA nod for anti retroviral drug**

Ranbaxy Laboratories has received a tentative approval from the US Food and Drug Administration (USFDA) to manufacture and market Lamivudine tablets, 150 mg. This is Ranbaxy's and India's first tentative approval from the USFDA under its expedited review process to support the PEPFAR (President's emergency plan for AIDS relief initiative). In combination with other anti retroviral agents (ARVs), Lamivudine tablets are indicated for the treatment of HIV infection.

Commenting on this development, Dr Brian W Tempest, CEO and managing director, RLL, said, "We are pleased with the tentative approval for Lamivudine granted by the USFDA. This is a major step in making our life saving ARV medicines available to more and more HIV/AIDS patients in the developing world. We will continue with our efforts to obtain speedy approval for all our ARVs with the USFDA in support of PEPFAR. In tandem we are also pursuing WHO prequalification for the same products."

### **Ranbaxy acquires Efarme's generic product portfolio**

Ranbaxy Laboratories has acquired a generic product portfolio accounting for 18 products belonging to the Spanish pharmaceutical company EFARMES, SA Unipersonal for sale in the Spanish market. The products belong to the Cardio Vascular System (CVS), Central Nervous System (CNS) and Pain Management segments. The agreement has been entered between Barcelona-based Laboratorios Ranbaxy SL, the wholly owned subsidiary of Ranbaxy and EFARMES of Spain.

EFARMES is a leading company in the development of pharmaceutical products. Products are developed by EFARMES following its own understanding of market opportunities as well as on an exclusive, customized contract basis.

Commenting on the development, Peter Burema, regional director Europe, CIS & Africa, Ranbaxy said, "We are happy to join hands with EFARMES. The acquisition fortifies our presence in Spain while augmenting our existing product portfolio."

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### **Transasia Bio-Medicals wins 'Most Promising SME' award**

Transasia Bio-Medicals Ltd has won two coveted awards in recognition of being India's Most Promising SME of the Year-2005. This award is an initiative to recognize the contribution of Small and Medium Enterprises (SMEs) towards the growth of the Indian economy. The CRISIL, who did the scrutiny of the businesses, received an overwhelming response from over 5000 SMEs from all parts of the country. The SME segment contributes 60 percent to India's GDP. Transasia's founder chairman and managing Director, Suresh Vazirani, received the award from KV Kamath, chairman, ICICI at a function in Mumbai recently.

Distinguishing Transasia from the other 5000 aspirants, are its outstanding achievements. It is not only the leading diagnostic company in India, it has also made inroads into global markets with high technology diagnostic life saving products fully designed and manufactured in India, installed in more than 50 countries. Transasia's alliance with Japan's No.1 company Sysmex for global marketing of model 'CHEMIX-800, with the dual Transasia Sysmex logo, is a milestone for Indian technology manufacturers.

The success has been built on the 25 year old strong foundation of investment in the best technology, research and development, commitment to quality and customer service.

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### **Zydus Cadila commences Phase I clinical trials on ZYH1**

Zydus Cadila has received permission from the Drug Controller General of India (DCGI) to conduct Phase I clinical trials on its new molecular entity "ZYH1. It may be recalled that Zydus Cadila had filed its first IND (Investigational New Drug) application for ZYH1 with the DCGI in January 2005. This novel agent for treatment of metabolic disorders has been designed and developed by Zydus Research Centre, the research wing of Zydus Cadila.

The Phase I studies will focus on evaluating the safety profile of ZYH1. The clinical trials will be conducted at Zydus Research Centre that has capabilities to conduct Phase I clinical trials. "ZYH1 is expected to address the issue related to patients suffering from dyslipidemia in both diabetic and non-diabetic condition," said Dr BB Lohray, president, Zydus Research Centre.

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### **GE Healthcare, MediCity ink MoU for diagnostic and R&D facility**

The president and CEO of GE India, Scott R Bayman signed a Memorandum of Understanding (MoU) with Dr Naresh Trehan, chairman, MediCity in New Delhi to develop a diagnostic and R&D facility. The MoU between GE and Dr Trehan's MediCity, a \$250 million world-class Integrated Healthcare Facility, was announced in the presence of Jeffrey R Immelt, chairman and CEO, GE and Kapil Sibal, minister of science and technology, Government of India.

Under the MoU, GE India and MediCity will collaborate in a number of initiatives to create a medical institute of world standards specifically in the areas of high-end medical diagnostics, clinical research and development, utility services like power generation and distribution, lighting, water treatment and other environmentally friendly solutions. This is GE's first such collaborative venture worldwide and is also the first instance in Asia, where a leading technology provider has entered into a partnership with a center of excellence in healthcare services and research. MediCity, which has been envisioned as a multi-disciplinary high-tech medical institute spread over 43 acres in Gurgaon, and clinically modeled after global centers of excellence such as Johns Hopkins and Mayo Clinic in the US, is expected to be operational by 2007.

Speaking on the occasion, Jeffrey Immelt said, "Our vision at GE Healthcare is to bring the latest healthcare technologies to India. Today, we've taken a giant leap in that direction by partnering with Dr Naresh Trehan and MediCity. At GE, we are increasing our focus on India. As India grows and flourishes on the world stage, I am enthused about India's growth potential

and the exciting opportunities ahead for us. GE's commitment to India is unwavering, and we are here for the long-term." Dr Naresh Trehan, said, "The vision for MediCity is of a campus that is the epicenter for cutting edge medical research and innovation in Asia. MediCity will also be a strong demonstration of India's tremendous strengths in medical sciences to a global audience."

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#### **Workshop on clinical research and CDM in July**

The fourth international workshop on Clinical Research and Clinical Data Management for Global Submission will be held on July 30-31 at Hotel LeMeridien, Pune. The workshop is being organized by Bioinformatics Center, University of Pune.

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#### **German Remedies launches Betaferon for multiple sclerosis**

German Remedies, a part of the Zydus Group, has launched Interferon beta-1b under the brand name "Betaferon" for the first time in India for the treatment of multiple sclerosis. Betaferon is a subcutaneous injection and is the only Interferon efficacious even in the secondary progressive stages of multiple sclerosis. The product is being marketed in collaboration with Schering AG, Germany.

Betaferon was launched in the US in 1993. This drug was a breakthrough effort in the treatment of multiple sclerosis. It is estimated that 1.5 million people suffer from multiple sclerosis worldwide. Betaferon is the top global product of Schering AG with over 2,00,000 patients on this treatment worldwide, registering sales of 780 million Euros in the year 2004.

"The launch of Betaferon is yet another step towards a strong collaborative enterprise between Zydus and Schering AG in offering innovative healthcare therapies in the fields of female healthcare, cancer therapy and radiology," said J C Jani, executive director of Zydus Cadila and head of German Remedies.

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#### **CCMB scientists create thermostable variant of lipase**

Scientists at the Centre for Cellular and Molecular Biology (CCMB) have reported an advance that has the potential to end the effective monopoly in the field of thermostable enzymes used by the Indian detergent industry. The work of the researchers focused on improving the stability of a lipase or a fat splitting enzyme even when exposed to high temperatures. The approach they followed was primarily based on deliberately generating large variations in gene sequences and picking up the desired variants by screening. This approach is called as "directed evolution". Unlike natural evolution that operates on the organism, this approach targets the protein itself. Their study, which has been published in the Journal of Molecular Biology, demonstrated that the approach of incorporating structural information during screening offers an sufficient and minimalist solution for the enhancement of a desired property of a protein and in addition suggests strategies for enhancing thermostability.

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#### **ITRC signs MoU with Amity**

The Indian toxicology Research Centre (ITRC), Lucknow has entered an MoU with Amity for sharing and pooling of resources towards research and training, industrial development and for societal projects. The collaboration shall focus particularly in the areas of environmental management, standardization and quality control, commercialization of technology and for better conservation of natural resource in the country. The agreement was signed through the Amity School of Natural Resources and sustainable development, which already has a successful MoU with the National Botanical Research Institute (NBRI), Lucknow as well as several other leading government institutions.

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#### **G BioSciences launches hands-on-training program in India**

G Biosciences, a US-based company involved in the development and manufacturing of proteomics products, has launched BioScience Excellence, a hands-on biotechnology training program for Indian students. The training for its first set of 20 students started at its facility in NOIDA. According to Dr Alam, CEO, G BioSciences, "Our educational kits supplement the education through hands on experience. It took us about two years to design the curriculum with inputs from teachers across the globe. We also plan to launch some interdisciplinary courses like regulatory compliance and IPR."

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### **India all set to become the new KPO hub: CII**

India is all set to move from being the most preferred business process outsourcing (BPO) destination to a knowledge process outsourcing (KPO) destination. A paper prepared by the Confederation of Indian Industry (CII) has revealed that KPO would grow at 46 percent to reach a staggering \$17 billion by 2010. Besides, the study points that the growth of services sector would be more than 8 percent and its contribution to India's GDP would be more than 51 percent, affirming that India's transition from being a BPO destination to a KPO destination is imminent.

According to the CII paper "India In The New Knowledge Economy", areas with significant potential for KPO include pharmaceuticals, biotechnology, and ICT, besides legal support, intellectual property research and design and development for automotive and aerospace industries. India stands to gain from its inherent strengths in the healthcare sector, pharmaceutical and biotech sector and ICT sector, it adds.

According to the paper, India could emerge as a global KPO hub as the business requires specialized knowledge in respective verticals and the country's large number of engineering and technical institutes are geared to address the manpower demand.

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### **Indian pharma industry to grow from \$6 b to \$48 b by 2010**

During the second meeting of the CII National Committee on Drugs and Pharmaceuticals 2004-05, an interactive session with Dr Montek Singh Ahluwalia, deputy chairman, Planning Commission, was organized. A presentation on global India Pharma Inc was made to Dr Ahluwalia focusing on the potential of the Indian pharmaceutical industry which was poised for growth from \$6 billion to \$48 billion by 2010. There was also a detailed discussion on the issues that the pharma industry is currently grappling with. The committee, led by Ajay Piramal, chairman, Nicholas Piramal India Limited urged for an increased spend on healthcare, liberalization of price control, Schedule M compliance for minimum manufacturing standards, OTC policy and implementation of recommendations of the Mashelkar Committee. The need for data protection, scaling up average expenditure on R&D, fostering public-private partnerships, increasing the capacity and capability in contract manufacturing and clinical trials was also reiterated.

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### **Orchid receives GLP certification**

Orchid Chemicals & Pharmaceuticals Ltd (Orchid) has received the Good Laboratory Practices (GLP) certification for its state-of-the-art R&D centre located in Chennai. This certification covers areas like physical-chemical testing, safety pharmacology and pharmacokinetic studies, toxicity studies, mutagenicity studies and analytical and clinical chemistry testing. Issued by the National GLP Monitoring Authority, this certification will provide a strong thrust to Orchid's ongoing new drug discovery (NDD) research programs.

Orchid is driving growth through a twin strategy of catering to the expanding global generics market and fulfilling the need for enhanced new drug pipeline. As part of this strategy, apart from USFDA compliant generics formulation facilities, Orchid has established a new world-class drug discovery and development infrastructure. Orchid has end-to-end capabilities to develop and screen New Chemical Entities (NCEs) from the basic in-silico drug design to validation of compounds in various pre-clinical models.

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### **Prof. P Balaram is IISc director**

Prof. P Balaram, chairman, Division of Biological Sciences, Molecular Biophysics unit, Indian Institute of Science (IISc), has been appointed as director of IISc. Prof. Balaram, who started his career at the IISc as a lecturer in 1973, has held several positions in the Institute and has been honored with many awards and fellowships including the Padma Shri in 2002, the HK Firodia Award in 2003, the GD Birla Award for Scientific Research, the Jawaharlal Nehru Birth Centenary Visiting Fellowship (Indian National Science Academy) in 1996, the Mahendralal Sircar Prize (IACS, Calcutta) and the Goyal Prize in the Life Sciences category. He is also the Editor of Current Science and has been on the editorial board of science publications such as Journal of Peptide Research, International Journal of Peptide and Protein Research, Indian Journal of Biochemistry and Biophysics etc. Prof. Balaram has to his credit 364 research publications and one edited book. He has also been also associated with several government bodies and committees including the Basic Biology Task Force of the Department of Biotechnology (DBT), the Department of Science & Technology, the CSIR and the Science Advisory Committee to the Union Cabinet.

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### **Advanced Biochemicals to double its R&D expenditure**

Advanced Biochemicals Ltd, a leading industrial biotechnology company in India, has announced that it is increasing its total

R&D expenditure in 2005-06 to 8.64 percent of its turnover as against 4.36 percent during the pervious year. The company has achieved some breakthrough in prevention therapy in its course of nutraceuticals research. Its nutraceutical research is targeted at tuberculosis, leprosy, obesity, cancer and cardiovascular diseases. It has set up an R&D lab in the pharma sector.

It continues to focus on developing new enzymes-based customized products for food industry without any side effects. The products of Advanced Biochemicals have been analyzed and screened by competent regulatory organizations and have answered required qualitative tests. Advanced Biochemicals has come up with a product in its leather segment that helps in reducing the pollution as it reduces the usage of lime, sulphide and solvent. A product for sewage treatment has also been successfully developed and commercialized through Delhi Jal Board.

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