

## Online forum for clinical research specialists launched

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The Indian Society For Clinical Research (ISCR) has been launched in India. This is the only broad-based association of its kind where clinical research professionals across India can network and contribute to the development of the industry. The ISCR will create a repository of information on clinical research in India that will be available on the Internet. ISCR will also monitor legislative and regulatory developments and make representations to the government and other agencies on behalf of the clinical research community. Through the Society, patients and patient support groups can interact with clinical research experts. In addition, new entrants in the field will now have greater access to expert training.

Dr Shoibal Mukherjee, president, ISCR, said, "The rising trend of clinical research activities in the country will allow patients early access to potentially life-saving therapies. The government is playing its part in moving towards a regulatory atmosphere that is conducive to research of the highest ethical and quality standards. Evolving guidelines and increasing numbers of patients, sponsors, CROs, SMOs and investigator sites participating in clinical development, make it vital for a society such as ISCR to unify efforts and bring all stakeholders together."

### Madras varsity to offer course on Immunotechnology

The University of Madras has signed an MoU with Chennai-based Mediclone Biotech Pvt Ltd, to launch a two-semester PG

Diploma program in immunotechnology. The course would enable post graduate students in life sciences to acquire basic knowledge in immunotechnology.

A Mathiyalagan, managing director, Mediclone Biotech Pvt Ltd, said, "The specialized course on immunotechnology would provide training in theory and practice." The course would focus on the diagnostic and therapeutic tools derived from immunology, namely, monoclonal antibodies and their derivatives, natural and recombinant vaccines, gene and cell therapy. Further, the course provides a broad view of the subject covering recent developments in both basic and applied research in the field of innovative biotechnology. The University of Madras would conduct the course for a batch of 10 and Mediclone Biotech, which would also share their knowledge and experience, would absorb the professionals of the next three batches, over the next three years.

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### **Cadila to invest Rs 40 crore in European biotech company**

Pharma major Cadila Healthcare Ltd has said that it will invest Rs 40 crore to acquire stake in a Europe-based biotech company. The board of directors at a meeting held on Aug 27, 2005 approved in principle an investment in equity of up to Rs 40 crore in a European biotech company. The decision is subject to satisfactory due diligence to be carried out by the company.

### **Polyclone ties up with Australia's Emphron**

Polyclone Bioservices, a Bangalore-based biotech start-up, has tied up with Emphron, an Australian boutique bioservices and microarray consulting major, for joint consulting in data analysis, data mining and experimental design for proteomics and genomics. "Our objective is to cater to high-density array analysis and production of high content low-density arrays, which is further upstream of whole genome analysis," said Naveen Kulkarni, CEO, Polyclone. This tie-up will establish a synergy between Emphron's data analysis capabilities with Polyclone's microarray core facility being set up at the University of Agricultural Sciences in Dharwad. "The focus is on developing novel arrays and also providing all the tools to the researcher to maximize the benefit of our products," he said.

Kulkarni added, "This development ensures we can offer a whole gamut of services to the biotechnology industry, especially in the pursuit of high throughput, parallel experimentation and miniaturization." Emphron was founded by renowned biotech statistician Dr Mervyn Thomas in 2003.

### **Ranbaxy opens new R&D facility**

Ranbaxy Laboratories Ltd (RLL) opened its third state-of-the-art drug discovery research centre, at Gurgaon. The research facility was formally inaugurated by the President Dr APJ Abdul Kalam. Dr Brian Tempest, CEO & Managing Director, RLL, said, "We believe that R&D is one of our key competitive strengths and the addition of this facility further enhances our capabilities in the area of drug discovery and development systems."

The new R&D centre is housed in a brand new building in the same campus as Ranbaxy's earlier research facilities. The new R&D center will focus on new drug discovery and the development functions of medicinal chemistry, analytical development, pharmacology, molecular technologies, infectious diseases, metabolism and pharmacokinetics.

### **Suven Life Sciences embarks upon new DDDSS model**

Suven Life Sciences Limited, a pioneer in CRAMS, in its endeavour to become a collaborative research partner for global life sciences companies has embarked on a new business model DDDSS (Drug Discovery and Development Support Services) in January 2005. Launch of this business model coincided with Intellectual Property regime in India. Within a short span of 8 months, Suven could attract the second business opportunity in drug development segment of DDDSS, a Phase II clinical trial with data submission to US-FDA for an oncology product of a US company. Suven is currently in negotiations with three more US customers for new business opportunities in Phase II & Phase III clinical trials.

### **Glenmark's drug receives US FDA approval for more clinical trials**

Glenmark Pharmaceuticals S.A, a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd, announced that the group's

lead PDE-4 inhibitor GRC 3886 has received US Food and Drug Administration (FDA) approval to proceed further in clinical testing within the United States. The molecule has also been granted its International Non-proprietary Name (INN) "Oglemilast" by a WHO body, based on an expert advisory panel's recommendations.

Oglemilast (GRC 3886), Glenmark's novel, oral, long-acting PDE4 inhibitor being tested for the indications of Asthma and COPD, had successfully completed Phase I single and multiple dosing studies in the UK in March 2005. Forest Laboratories, Glenmark's development and marketing partner for the drug in the territory of North America, had submitted an Investigational New Drug (IND) filing early this year to the FDA.

The filing incorporated both pre clinical data as well as safety data in human volunteers generated during the Phase I trials. The FDA has now approved the IND filing thereby allowing Oglemilast to be evaluated in further clinical trials in human volunteers. As indicated earlier, the drug is on course to enter Phase II clinical trials by early 2006 in the US.

Glenn Saldanha, managing director and CEO, Glenmark Pharmaceuticals said, "The clinical development of GRC 3886 is on schedule, spurred by this recent approval of Forest's IND filing by the US FDA. We are very excited by the performance of this molecule in Phase I trials and the recent IND approval and are working with our collaboration partners on accelerating the development program for the molecule."