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Glenmark Pharmaceuticals SA (Switzerland), a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd (Glenmark), has filed for Phase I clinical trials for GRC 8200, its leading DPP-IV inhibitor compound, with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. The Phase I study will be conducted by Parexel a UK-based CRO. And it would be completed in February 2006.

Glenn Saldanha, managing director and CEO of Glenmark, said, "We have a very aggressive timeline and hope to be the fourth to market with GRC 8200 in the DPP-IV class. We expect GRC 8200 to be launched on the US market in 2010."

Glenmark has an aggressive clinical development plan for GRC 8200 that will help reduce the gap with some of these competing molecules in early clinical trials. Along with Phase I trials, Glenmark plans to initiate a Proof Of Concept (Phase IIA) study in South Africa in January 2006 on diabetic patients. Further, it has already commenced various other non-clinical studies and expects to file an IND with the US FDA between April-June 2006 in order to commence Phase II.

Glenmark has commenced early discussions with potential partners in the regulated markets to collaborate on the clinical development, filing and marketing of this product. This is in line with its policy of partnering its NCEs with strong development and marketing partners for North America, Europe and Japan.

Zydus Cadila receives tentative US FDA approval

Zydus Cadila has received tentative approval from the US FDA for its Abbreviated New Drug Application (ANDA) for Divalproex Sodium DR Tablets. The product, an anti-convulsant that falls in the CNS segment, will go off patent in January 2008. The annual sales of Divalproex Sodium DR Tablets as per IMS in 2004 in the US market were estimated at \$680 million.

The tentative approval for Divalproex Sodium DR Tablets is the latest in a series of developments that mark Zydus Cadila's foray in the US generic markets. So far the group has received 6 ANDA approvals. The group recently launched Atenolol in the US market through its US subsidiary Zydus Pharmaceuticals USA. The process of filing ANDAs began in 2003-04 with the group filing 12 ANDAs. Till date, the group has filed 27 ANDAs and 32 DMFs.

CIMAP signs MoU with SRI on collaborative research

The Central Institute of Medicinal and Aromatic Plants (CIMAP), Lucknow and Shriram Institute of Industrial research (SRI), Delhi have agreed to collaborate for joint projects in the area of product development based on medicinal and aromatic plants, towards developing international standards for herbals and R&D for plant molecular biology and biotechnology.

A MoU was recently signed in this regard at CIMAP in Lucknow by Dr SPS Khanuja, director, CIMAP, Lucknow and Dr RK Khandal, director, Shriram Institute for Industrial Research (SRI), New Delhi.

Under the agreement CIMAP shall extend need based technical guidance to SRI in a project mode in the area of medicinal and aromatic plants and their products and actively collaborate with SRI in the areas of mutual interest complementing the existing capabilities.

BPO service for pharma and biotech industry

Take Solutions, a technology enabled business solutions company, is all set to launch a new BPO for the pharmaceutical and biotech industry, by the end of December 2005, in Chennai. Take Solutions CEO, Ram Yeleswarapu said, "Pharmaceutical companies, from June 2005 are required to provide the United States' Food and Drug Administration (FDA) all products information in XML format in compliance with the structured product labeling (SPL) standard. This BPO division would help both pharma and biotech manufacturers satisfy the FDA norms. Besides, it will also benefit the Indian pharma and biotech exporters, to meet the FDA norms."

Americos introduces trifunctional dyes

Americos, an Ahmedabad-based firm mainly into production and marketing of enzymes, garment wash and textile specialty chemicals, auxiliaries, smart colorants, and dyestuffs has introduced trifunctional dyes, which are especially synthesized to produce cost effective cloudy effect on cotton garments.

Speaking to BioSpectrum, Gaurav Khanna, director of sales, Americas Industries, said, "We have set up a state-of-the-art R&D center to remain abreast with the latest knowledge frontier and our focus has always been on producing Concept Driven Chemicals. The objective of this center is to achieve new developments in the garment and finishing industries."

SPC Biotech to manufacture green plastic

SPC Biotech, a Hyderabad-based company is working on to manufacture biodegradable plastics (green plastic) from agricultural feedstock like cornstarch using its own technology.

SPC Biotech in association with Biopolymer Research Laboratory, Cuttack has done considerable research and developed the technology and will be commercializing an eco-friendly product.

Speaking to BioSpectrum, MS Shankara Prasad, managing director, SPC Biotech said, "We have made an investment of about Rs 4 crore in the pilot project with an installed capacity of 300 Mt. The actual project will have an installed capacity of 10000 Mt with a project cost Rs 30 crore. And commercial production will start from August 2006."

Sanofi Pasteur introduces Vaxigrip

Sanofi Pasteur, a global vaccines player recently introduced Vaxigrip, its global preventive vaccine against influenza for the

season 2005-2006 in India. Vaxigrip is a suspension for injection in prefilled syringe of 0.5ml in a box of 1 or 20 or in an ampoule of 0.5ml. Vaxigrip is produced by Sanofi Pasteur in Lyon, France and is marketed in India by Sanofi Pasteur and Ranbaxy.

In a press release, a Sanofi Pasteur spokesperson said, "Influenza is a more serious condition than a cold and can be life threatening for some people showing a high risk of associated complications. Vaxigrip can be administered to young children, working adults, pilgrims, elderly and patients suffering from diabetes, asthma, cardiac and pulmonary disorders."

Strand's avadis achieves GeneChip-compatible status

Strand Life Sciences announced that its avadis software application has achieved GeneChip-compatible status with the Affymetrix Inc. GeneChip microarray platform and that it has joined the Affymetrix GeneChip-compatible Applications Program, which provides customers with a broad spectrum of software solutions for biomedical research and development.

As a GeneChip-compatible software provider, Strand Life Sciences is committed to seamlessly integrating its tool avadis with the Affymetrix GeneChip platform.

avadis is Strand's flagship product and is a comprehensive tool for microarray data analysis. avadis brings in data mining techniques and software engineering to microarray gene expression data analysis.