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Intas ready for its first biotech product launch

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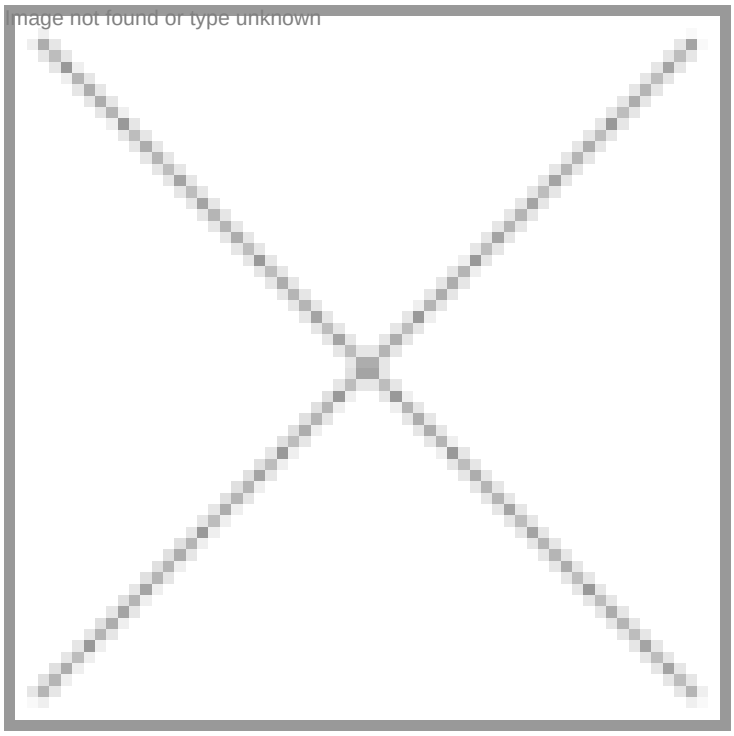

Intas Biotechnology, a division of Ahmedabad based Intas Pharmaceuticals, will launch its first biotech product, Neukine, a granulocyte colony-stimulating factor (G-CSF) in June. Further, within a span of 12 months, it expects to release two more biotech productsâ€"erythropoietin, used for cancer and kidney disorders, and interferon, used for therapeutic applications in cancer and infectious diseases.

R Chandrasekaran, vice president, marketing, biotech and oncology, observed, "Intas would enter the less regulated international market in a span of 3-9 months after releasing the products in India. The present market potential for these biotech products is approximately $97 million. And Intas is looking at 20 percent of the market share in the first year of its product launch. In India, while the market potential for G-CSF is Rs 20 crore that of erythropoietin and interferon is over Rs 50 crore and Rs 35 crore, respectively." Intas has identified the market for its biotech products and looks to introduce them in the Latin American and Asia Pacific countries. It believes in taking the small-volume high-value business route.

Intas Pharmaceuticals has so far invested close to Rs 40 crore in Indus Biotherapeutics Ltd, a wholly owned subsidiary of Intas Pharmaceuticals. It has already begun exporting proteins to other countries.

Chandrasekaran informed, "Indus Biotherapeutics started as R&D center in 2000. It has a team of 25 scientists including seven PhDs and is working on recombinant products such as interleukins, growth factors and hormones. The multi-product bulk manufacturing facility is fully operational and the facility is being used for production, fermentation, cell culture and downstream processing of recombinant DNA products. The manufacturing facilities are approved by TGA â€“Australia, MCC-South Africa and MCA-UK."

â€¦ launches Arsenox

Intas has announced another developmentâ€”an affordable treatment for relapsed Acute Promyelocytic Leukemia (APML), a cancer of white blood cells that can affect patients at any time in their lives. Announcing this R Chandrasekaran said, "Arsenox is a significant advance in the treatment of patients with APML. These patients would already have tried the standard treatment available. Another positive aspect of Arsenox is its cost. At present the treatment for APML is out of reach for many people due to its high costs. Arsenox is now accessible and very affordable as compared to the regular treatment available. In fact, it will be one-tenth of the standard treatment's cost." Standard treatment available is with ATRA and anthracyclines. The cost of treatment using ATRA and anthracyclines ranges between Rs 6 lakh and Rs 8 lakh.

NPIL looking at collaborations

Nicholas Piramal India Ltd (NPIL), which has embarked on a focused R&D program in the areas of new chemical entity (NCE), new drug discovery system (NDDS), and process development, is looking at collaborations with the innovators instead of going for generics according to Ajay Piramal, chairman, NPIL. The NPIL chairman said that the company's track record and credibility in respecting IPR is extremely good and is respected globally.

It is setting up a R&D facility in Goregaon, Mumbai spread over an area of 200,000 sq. ft. The new facility will focus on rheumatology and cancer research, apart from NCEs and NDDS. It is investing close to Rs 75 crore in this project, which will provide space for 400 scientists. One-third of the work has been completed. Besides, it has a small R&D center in Chennai and is planning to set up one more in Bangalore.

NPIL is making forays into biotechnology in key therapeutic areas for which it has formed global alliances. Recently, it signed an MoU with Biogen Inc. to market Avenox in India. The product, which was launched in January 2004, has fetched it Rs 5 crore in sales and NPIL is very bullish on this product. Vijay Shah, chief operating officer, informed, "We are looking at launching other therapeutic products in India and are discussing with global players in this regard. NPIL is poised to take advantage of the opportunities that will emerge in the bulk activates and intermediates market for contract manufacturing at attractive price points, for both on-patent and of-patent drugs." NPIL has also filed its first patent for its own NCE, an anticancer molecule NP102 in India and the US.

â€¦ to set up research station in Rajasthan

NPIL is setting up a small research station in Rajasthan to study the opportunities in plant biotechnology in the Thar desert. Dr Swati Piramal, director, strategic planning and communications, NPIL informed, "We are investing Rs 5-10 crore on this project.

Dr Saran Narang, one of the world's most renowned molecular biologists, who is also on our Scientific Advisory Board, will head this project. Dr Narang will develop the research station and will bring his team to study the opportunities in plant biotechnology in Rajasthan. The whole project will commence by end of this year. It is expected to take two-three years to complete."

Wockhardt sets up subsidiary in the US

Wockhardt Ltd, having three biotech products in its basket, has unveiled plans to establish its own sales and marketing organization in the US to drive its business in the world's largest pharmaceutical market. "We are seeking an exponential growth in our US business over the next few years. Towards this end, we are beefing up the research and development, manufacturing, regulatory and legal infrastructure in India and establishing a sales and marketing organization in the US, " informed Habil Khorakiwala, chairman, Wockhardt Ltd.

More than 150 professionals at various levels at Wockhardt in India are supporting the company's US generics' business by working on non-infringing technologies, filing Abbreviated New Drug Applications (ANDAs) and liaising with the US regulatory

bodies. Arthur Maher, a marketing professional with over 20 years of experience in the generic pharmaceutical industry, has been appointed as president of Wockhardt USA Inc. to provide a new thrust to the company's US business. Wockhardt has also relocated Dr Sanjay Patel, president, corporate scientific affairs, from India to the US. He will guide Wockhardt's scientific and technical affairs in India, Europe and the US. Ramesh Sesha, senior vice president, intellectual property, has also been relocated to the US office.

"With the growing consolidation in the US generics business, buyers now have fewer companies to deal with. The market is looking for new players with good credentials. Indian companies are now as much known for their quality as for their cost-effective prices. The timing is just right for Wockhardt for a push into the US, " said Maher.

Rasi to launch Bt-cotton

Salem-based Rasi Seeds (P) Ltd has became the first South Indian company and second company nationally to receive approval from Genetic Engineering Approval Committee (GEAC) for commercial cultivation of RCH2 Bt (bacillus thuringiensis) variety of cotton seeds developed by Rasi. This approval extends for commercial cultivation in the central and southern parts of the country. It is launching Bt-cotton seeds from this kharif season.

Jaikumar, vice president, marketing, Rasi Seeds informed, "Rasi Seeds will release approximately 3 lakh packets of Bt-cotton in six statesâ€" Andhra Pradesh, Gujarat, Karnataka, Maharashtra, Madhya Pradesh, and Tamil Nadu at the prevailing market price, i.e., Rs 1,600 per packet.

Rasi Seeds has taken four years to launch Bt-cotton seeds in India. Jaikumar is optimistic about the growth of the Bt-cotton market in India. He said, "The market is very positive, as this will benefit the farmer by reducing the cost of insecticides, reduce pollutions due to use of insecticides and also increase the yield of cotton."

It may be noted that last year the GEAC deferred a decision on the application of Rasi Seeds, a sub-licensee of the Bt cotton technology which was acquired by Mahyco from Monsanto, USA, for seed production of transgenic cotton hybrids, namely, RCH-134 and RCH-138 in an area of 200 hectares for Kharif 2003 Northern RCH- region because of non-availability of basic data.

India has $2 billion R&D opportunity to tap: Jasti

With global pharmaceutical leaders looking at outsourcing their research activities to India, the opportunity in R&D sector is worth $2 billion. "But there is hardly any major coordinated activity on this front," said Venkat Jasti, managing director, Suven Life Sciences. As a small step in that direction, Suven and two other organizationsâ€"Chennai-based Shasun Chemicals and Drugs Ltd and Mumbai-based Innovasynth Technologiesâ€"have formed an alliance called Life Sciences Alliance in March last year with Austin Chemicals, USA, to win contracts for R&D activities. "The aim of the alliance is to provide a platform for both Indian and international pharma majors to discuss issues, which are coming in the way of getting the orders. The alliance is an effort in integrating capabilities and synergies of pharmaceutical companies from the US and India to help globalize pharmaceutical drug development process," said Jasti.

Dr B Sahu, president and CEO, Innovasynth Technologies noted that India could become the best choice for drug discovery companies based out of the US and Europe. These companies are eager to leverage on Indian talent to reduce the time and cost involved in the drug discovery process through collaborative efforts with the Indian companies. However, ethical, environment, and IPR issues are coming in the way. "But as India is a signatory of the WTO agreement and has to implement the patent rules with effect from January 2005, the government would act upon it. This would support the companies in getting the orders in discovery development and process," Sahu added.

Taiyo to invest Rs 40 crore

Taiyo Lucid Pvt Ltd, a joint venture between Mumbai-based Lucid Colloids Ltd and Japanese Taiyo Kagaku Co Ltd is building a state of art manufacturing plant at Aurangabad in Maharashtra. The new plant will manufacture water-soluble dietary fibre and other nutritional products and ingredients.

Taiyo Lucid is investing about Rs 40 crore in the first phase of the project. The Japanese company is providing the proprietary technology. The plant will go into commercial production in June this year. This new venture will come out with value added products, as Lucid was earlier only exporting the raw materials.

Taiyo Kagaku will globally market the products under its brand name of Sunfiber through Novartis Nutrition and Novartis Consumer Health (licensees of Taiyo) in the US under its brand name Benefiber. Both these are natural products, manufactured from agro raw materials, which grow mainly in India and are widely consumed as a vegetable throughout the country.

Suven's revenues up by 27.76%

Suven Life Sciences' total income for the 12 months ending 31 March 04 stood at Rs 51.71 crore as compared to Rs 46.99 crore for the corresponding period of previous year. Export revenue in the current year registered 13 percent growth and increased from Rs 31.03 crore to Rs 35.13 crore.

Praj Industries' net up by 245%

Praj Industries Ltd has recorded an increase of 244.63 percent in its net profit for the year ended 31 March 2004 to Rs 8.34 crore as against Rs 2.42 crore in the previous year. The income from operations of the biotechnology solutions grew by 24.21 percent to Rs 109.49 crore in 2003-04 as compared to Rs 88.15 crore in the last fiscal year.

Alfa's net up by 56%

Alfa Laval has recorded a 56 percent growth in its net profit for the quarter ended 31 March 2004. Its profits stood at Rs 23.47 crore as against Rs 15.09 crore. The company also recorded an increase of 29.54 percent in its income from operations to Rs 115.89 crore in the period compared to Rs 89.46 crore the same quarter the previous year.

Lupin to commence Phase-I trial for psoriasis oral treatment

The Mumbai based Lupin Ltd has got the approval for the commencement of Phase-I clinical trial of its investigational new drug candidate LLL-3348 (Desoris) from the Drug Controller General of India (DCGI). Desoris is orally bioavailable and proposed for the treatment of chronic stable plaque type psoriasis, the global market for which is estimated to be over $3 billion.

"Lupin is one of the few companies to get an Investigational New Drug Application (INDA) approval for New Chemical Entities (NCE). The approval is a testimony to Lupin's world-class R&D. It marks a significant step in Lupin's long-term strategy towards becoming an innovation-led transnational pharmaceuticals company," Lupin chairman Dr Desh Bandhu Gupta said.

"There is an imperative need for effective and safe drugs to be made available in global pharmaceutical market for this chronic inflammatory skin disorder. In addition, the side effect profile of existing drugs leads to marked reduction in patient's compliance, " said Dr Sudershan Arora, president-NCE, Lupin Ltd.

Desoris is an herbal aqueous extract that acts through a novel mechanism of action that effectively modulates the cellular function leading to a marked psoriatic lesion improvement without any toxic effect. Lupin has developed this product in the form of capsules. Lupin has already accomplished the therapeutic evaluation and safety profiling of the herbal extract and will start the Phase-I clinical trials shortly. Based on animal data, Desoris has been found to be efficacious and safe. Animal pharmacokinetic data suggests that the botanical Desoris could be used once a day. This is Lupin's second INDA based on herbal R&D, which has been approved. Prior to this, Lupin's INDA for the prophylactic treatment of migraine was approved by the DCGI in December 2003.

Glenmark's GRC-3886 to enter Phase-I clinical trials

A team of scientists at the New Drug Discovery Centre of Glenmark Pharmaceuticals Ltd, a $100 million Indian market leader in therapeutic segments like dermatology and respiratory, has discovered a novel, potent and highly selective drug candidate for Chronic Obstructive Pulmonary Disorder (COPD) and asthma.

Glenmark Pharmaceuticals is currently completing its pre-clinical studies for the compound, GRC-3886. The compound having demonstrated high efficacy and safety in pre-clinical studies is expected to enter Phase-I clinical trials in the UK in July 2004. The Phase-I clinical studies will be conducted by Quintiles, a leading global Contract Research Organization. With this, Glenmark has also decided to move GRC-3886 ahead of its previous PDE4 inhibitor GRC-3015.

Glenn Saldanha, MD and CEO of Glenmark Pharmaceuticals, said, "Comparative pre-clinical animal studies indicated that GRC-3886 has a better efficacy and side effect profile than Roflumilast, Cilomilast and Rolipram". GRC 3886 is claimed to be a highly selective inhibitor of the human PDE4 enzyme that is associated with the COPD and asthma disease conditions. GRC 3886 has shown very promising results in the preclinical studies that spanned two broad phasesâ€"in-vitro studies and in-vivo studies (conducted on animal models).

Akorn, Strides sign MoU

Akorn Inc. and Strides Arcolab Ltd signed an MoU to market products for the US hospital market. This will be accomplished through a 50:50 joint venture company (JVC) between Akorn and Strides. The JVC will outsource from Strides an exclusive product pipeline of grand fathered and ANDA products in finished dosage forms including liquid injectable, lyophilized, powder fill parenterals and soft gel capsules and tablets. And from Akorn sales, the JVC will outsource marketing and distribution capabilities for the US hospital and US retail markets. The ANDAs developed for the JVC by Strides will be owned exclusively by the JVC.

Currently, Strides has a total of 12 manufacturing plants worldwide. It is expected that four plants in India, including a new facility for Cephalosporins that is expected to be commercialized by the fourth quarter of 2004 will address the JVC's manufacturing needs to ensure cost-effective manufacturing. The JVC is targeting launches of grandfathered products in the US by the first quarter of 2005 and plans to begin ANDA filings by the end of 2004.

Arun Kumar, managing director and group CEO, Strides said, "The Akorn and Strides JVC is a true reflection of the Strides partnership philosophy. Using our niche manufacturing and product development skill sets, Strides will ramp up its ANDA strategy for the US hospital market with the resources provided by Akorn to reduce the time-to-market."

Taiwan keen on BT in India

Taiwan with $206 billion forex reserve is seriously looking to invest in India and increase the two-way trade from the present $1.39 billion in 2003, said Huey-Ching Yeh, secretary general, Ministry of Economic Affairs (MOEA), Taiwan. Yeh, who is leading a nine-member business delegation to India, said that Taiwan's forex, which is the second largest in the world, was keen to enhance mutual benefits through building official channel for economic consultation with India.

Addressing an industry gathering, organized by the Confederation of Indian Industry (CII) he said that the outlook of India-Taiwan economic relations should be to build comprehensive economic relations and create a win-win situation between India and Taiwan.

R Vishwanathan, joint secretary (Investment & Trade Promotion), Maharashtra, said that there has been a paradigm shift in the minds of Indian people. They are more confident and are willing to go global. VK Mathur, chairman and managing director, Inapex Ltd, said, "India offers opportunities to re-locate in a competitive setting and simultaneously, India can be Taiwan's natural partner in knowledge-based industries and develop synergies in hi-tech areas."

DaimlerChrysler interested in Biodiesel

Its not only the Indian organizations like railways and HPCL, even the world's oldest automaker DaimlerChrysler has embarked on a project to prepare biodiesel from the extracts of "jatropha plants" as a viable alternative to the conventional energy. It has been working on the project in association with the Hohenheim University, Germany, and the Council for Scientific and Industrial Research of India. It had established two small plantations on eroded land in two climatic regionsâ€"sub-humid (Orissa) and semi-arid (Gujarat). These Jatropha curcas oil seed tree plantations were expected to recover eroded soils and render them usable for agricultural purpose again as well as to produce bio-oil that could be used for biodiesel production.

The five-year project was launched in 2003 and had been broadly divided into three phases. In the first phase a test drive of a

Mercedes-Benz C-class car was on the biodiesel for over 5,000 km and at the end of the drive conclusive facts would be drawn about actual reduction in pollution and the fuel's adaptability to different climatic conditions.

GeneTech diversifies

Hyderabad-based GeneTech is in an expansion mode. The five-year-old diagnostics company after making a name of itself in cytogenetics, molecular genetics and biochemical genetics is expanding its area of activity to include pharmacology related contract research and is in negotiations with some biotech companies for the same.

Looking at the wide opportunity in the gene expression area, GeneTech founding director Dr Anuradha Udumudi said, "The company is looking beyond medical genetics to pharma genetics. We have been focused on diagnostics so far but now we are reorganizing resources to include contract research and training."

Ocimum unveils iRNAwiz

Ocimum Biosolutions announced the launch of its niche product "iRNAwiz", a comprehensive and intuitive tool for the design of siRNA on its third birthday. The tool provides the user with flexibility to define his own search templates, set regions of interest based of wide variety of criterion like ORFs, UTR regions, introns and exons, secondary structures, motifs and domains, and post design analysis of successful siRNA.

Anuradha Acharya, CEO, Ocimum Biosolutions said, "We are very excited. We provide scientists with the essential tools and analytics necessary to speed up and manage their research efficiently. We believe that scientists will be able to significantly speed up their research in the field of siRNA design."

Bhat Bio-Tech ISO certified

Bhat Bio-Tech India (P) Ltd has received the ISO 13485 : 1996 Certificate from UL India Private Ltd. With this, Bhat Bio-Tech is believed to be the first diagnostic and biotech company in India to receive this certification. ISO 13485 is the certificate for medical devices, which is the prerequisite for getting CE marking and US FDA approvals. Dr Shama Bhat, CMD, Bhat Bio-Tech, described the growth of BBI, from one product in 1996 to more than 60 products in 2004 as a significant achievement. The company plans to get into biopharmaceutical products too.