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YES Bank to assist Maharashtra biotech project

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YES Bank, the new-age private sector bank, has been appointed as advisor to the Government of Maharashtra for its proposed life sciences and biotechnology project in Mumbai. The project has been undertaken as a part of Mumbai's future development plan. Under this project, YES Bank will focus on developing a comprehensive business and financial strategy to leverage Mumbai's inherent strengths and future growth plans to realize the life sciences and biotechnology industry potential in the city.

Speaking on the occasion, Sanjay Ubale, secretary, Special Projects, Government of Maharashtra said, "The Government of Maharashtra has assigned this project to YES Bank based on its in-depth knowledge and expertise in the life sciences and biotechnology sector."

Describing this as a significant milestone, Rana Kapoor, MD and CEO, YES Bank said, "We consider this project an outstanding opportunity to contribute towards further developing the life sciences and biotechnology sector, where India and Mumbai city in particular, have a crucial role to play."

YES Bank has identified life sciences and biotechnology as a focus area . It has institutionalized a team of professionals with relevant industry and commercial expertise to service client needs in targeted segments, which include pharmaceuticals, healthcare, biotechnology (including agri-biotech), medical equipment and devices, specialty chemicals, contract research and manufacturing services, nutrition and natural products.

GEAC approves trials for Bt cotton hybrids

The Genetic Engineering Approval Committee (GEAC), of ministry of Environment and Forests, Government of India, has approved large-scale trials and seed production of several hybrids of Bt cotton developed by Jalna-based Maharashtra Hybrid Seeds Company (Mahyco) and Secundrabad-based Nuziveedu Seeds.

The Bt cotton hybrids, which were approved, include: MRC 6304 Bt for Central Zone and MRC 6918 Bt and MRC 6928 Bt for South Zone containing Cry 1Ac gene (MON 531), MRC 7326 BG-II, MRC 7301 BG-II, MRC 7160 BG-II and MRC 7201 BG-II for Central and South Zone containing stacked genes Cry 1Ac gene and Cry 2Ab gene. (Bollgard II) has been developed by Mahyco, while NCS 145 Bt (Bunny) and NCS 207 Bt (Mallika) for Central and South Zone containing Cry 1Ac gene (MON 531) has been developed by Nuziveedu Seeds.

Shantha's new vaccine manufacturing complex inaugurated

In a strategic move to further strengthen its position as the largest supplier of the Hepatitis B vaccine to the UN Agencies globally, Shantha Biotechnics announced the inauguration of its new GMP compliant vaccine manufacturing facility. Dr YS Rajasekhara Reddy, chief minister of Andhra Pradesh, inaugurated the plant.

"The 80,000-sq.ft facility has been designed by expert consultants from Germany and is equipped with the best plant and machinery available for the purpose of manufacturing vaccines," informed Varaprasad Reddy, managing director, Shantha Biotechnics. It will produce the DTP (Diphtheria, Pertussis and Tetanus) vaccine initially. These antigens will be conjugated with the Hepatitis B vaccine to make a combo DTP-Hepatitis B vaccine. Shantha Biotechnics' R&D team has successfully completed the formulation of the combo vaccine and would be soon rolled out from this facility.

In addition to this, Shantha Biotechnics plans to have a comprehensive vaccines portfolio to service markets in developing countries. Built at a cost of Rs 40 crore, the facility has three production suites that will enable Shantha Biotechnics to produce several types of vaccines. The facility has an installed capacity of 300 million doses.

Reddy stressed, "Since the beginning, Shantha has been consistent in meeting its core objective of researching and developing affordable healthcare products for the world. The introduction of the first indigenously produced combo DTP-Hep B vaccine from this newly built state-of-art facility by Shantha will further our efforts in this direction and play a key role in meeting the growing demand for world class therapies that are competitively priced and easily affordable to people across the social order." To commemorate the occasion, Shantha also donated one lakh doses of Hepatitis-B vaccine to the state government.

Geo Chem to set up a CRO in Mumbai

Geo Chem Laboratories is setting up a Clinical Research Organization (CRO) of international standards in Mumbai by the name Ace Bio-Med Pvt Ltd. The CRO will commence its operations by end of November. Ace Bio-Med is expected to provide clinical research services for bio availability/bio equivalence projects in compliance with the GCP and GLP guidelines.

Dr Mary Francis, CEO, Ace Bio-Med, said, "The company will provide contract research services for the pharmaceutical industry, conduct trial on human volunteers and analyze the results. It is supported by a qualified team of professionals."

Dr Francis further said, "The clinical operations would be performed at our facility that accommodates up to 52 volunteers. The bio analytical laboratory will be equipped with automated LC-MS-MS and HPLC systems. With the latest HPLC and LC-MS-MS and with full implementation of quality control and quality assurance procedures, to produce quality data acceptable with no compromise."

Ace Bio-Med aims to become a center of excellence in CRO sector and is eager to expand its operations across India by undertaking clinical trials for various disease state and molecular screening of various drug entities.

Geo Chem Laboratories is mainly involved in inspection, monitoring of trade and shipments and testing and certification of raw materials, agricultural products, processed foods and beverages etc. It has 22 branches across India with staff strength of over 1100.

Organica Biotech increases its revenue to Rs 1.4 crore

Organica Biotech, a company dedicated to the development and marketing of environmental friendly products that offer effective natural solutions for everyday problems has increased its sales revenue to Rs 1.4 crore against last year's sales of Rs 60 lakh. In 2001-02, its sales were stood at Rs 16 lakh.

Dr Ganesh Kamath, director, Organica Biotech said, "We are expecting positive growth and looking at a growth rate of over 100 percent in the current year."

Promoted by technocrats, it has developed bioproducts in the environmental, agriculture, aquaculture and industrial spheres such as Bioclean STP, Bioclean Aqua, Magic gro super Bioclean compost, Bioclean pond clarifier. It is planning to introduce magic gro series in agricultural segment during the year. These products match the international standards and are covered by the US patents. Its products utilize specific functions of microbes to bring about desired biochemical changes.

Organic Biotech started its commercial production in 2001 and has invested about Rs 10 lakh in R&D activities during 2003-04. It is planning to increase its R&D budget to Rs 50 lakh (Rs 20 lakh for R&D and Rs 30 lakh for infrastructure development for the current year). The company is expected to invest Rs 100 lakh on infrastructure development in 2005-06. It has filed

four international patents, of which three have received the grants. It has entered into a marketing alliance with Green Solutions and Green Earth Agro to market its products.

President Dr Kalam inaugurates Wockhardt biotech park

The President of India Dr APJ Abdul Kalam inaugurated the Wockhardt Biotech Park that has six dedicated manufacturing plants at Aurangabad. This Rs 200-crore biopharmaceutical complex is spread over 3 lakh square feet and has capacities to cater to 10-15 percent of the global demand for major biopharmaceuticals.

...develops Glargine

A team of scientists at Wockhardt has claimed to have made a technology breakthrough by developing and mastering the technology to make glargine, a new generation advance on insulin. "We will initiate Phase III clinical trials with Glargine and we expect to introduce it in India in next 18 months," said Habil Khorakiwala, chairman, Wockhardt Ltd.

With the introduction of glargine and convenient delivery devices like pens, Wockhardt will have a comprehensive range of products for the management of diabetes. Further Khorakiwala announced, "In the case of diseases like cancer, the body's immune system finds it extremely difficult to handle the cancer cells. Biotechnology products like interferon, which we expect to launch next year, help improve the immune defence system."

MediBic Alliance invests in Strand Genomics

Strand Genomics, a Bangalore-based global life sciences informatics company announced that MediBic Alliance, the investment arm of MediBic Japan, has taken a minority equity stake in Strand. MediBic is a Japanese pharmacogenomics and pharmaceutical consulting firm. MediBic and Strand will jointly develop products and technologies for their drug discovery and development customers. They will offer products along with customization services and provide consulting in the areas of genomics, proteomics, clinical studies, predictive ADME/toxicology and other pharmaceutical R&D areas. "Strand will partner with MediBic towards forming a comprehensive virtual discovery pipeline," said Vijay Chandru, CEO, Strand Genomics.

"This partnership provides us with the platform to offer an integrated discovery and development system. Strand has a strong core capability in applying advanced mathematical solutions to solving life science data analysis problems and is recognized as a leader in developing in-silico tools. The combined effort of both the companies can position us to offer a truly in-silico platform for the entire drug development pipeline," said Dr Yasuhiro Hashimoto, president and CEO, MediBic.

... gets \$1 million grant

Further, Strand Genomics announced that it has received a grant of about \$1 million for developing in silico hepato-toxicity predictive models. The grant is from the Technology Group at ICICI and the Sponsored Research and Development Program (SPREAD) fund of the World Bank in India. Strand will collaborate with Central Drug Research Institute (CDRI) to develop a modeling approach, primarily employing systems biology techniques to capture pathway dynamics in liver toxicity studied via mathematical representations and analysis of computationally intensive simulations. Scientists at CDRI would design and run assays to support the modeling effort at Strand.

... co-marketing agreement with CombiMatrix

Strand Genomics has entered into a co-marketing agreement with CombiMatrix. Under this arrangement, CombiMatrix will market Avadis, Strand's flagship software for microarray data analysis as a preferred solution for the CombiMatrix system. "Strand and CombiMatrix will develop an interface to facilitate ordering of CombiMatrix's CustomArray products through Avadis," stated Dr Amit Kumar, president and CEO, CombiMatrix.

Nicholas signs in-licensing agreement with Genzyme

Nicholas Piramal India (NPIL) has signed an in-licensing agreement with Genzyme Corporation, USA for synvisc viscose supplementation for the Indian market. The agreement is poised to augment NPIL's presence in the field of Orthopedics.

NPIL's in-licensing deal is a five-year exclusive strategic alliance. According to the official press release, "Synvisc has global sales of \$250 million. The Indian market size for this drug is estimated at Rs 20 crore. NPIL will market and distribute the product in India on exclusive basis".

Currently NPIL's Ortho-therapy area includes two divisions—MS and Speciality. NPIL is the third largest player in the 'pain' market, with a 5.5 percent share of the therapy.

France keen on India partnerships

France is looking at partnering with Indian companies to take advantage of the biotech boom. Dominique Girard, ambassador of France to India, said, "Biotechnology is a promising and potential industry for us. It is an upcoming and growing industry. We are looking at partnership with Indian companies in biotechnology/life sciences space besides other industries".

Speaking to BioSpectrum Girard, who was in Mumbai said, "We are (India and France) in good relations. We want to develop our economy along with the economic growth of India. Things in India have changed in the last few years. We want to continue to develop strong relations with India."

Commenting on the biotechnology regulatory issues in France, he said, "Our government is very proactive. But the farmers are still under the cloud of bad experience they faced few years ago. We are making efforts to bring in awareness about the advantages of biotechnology. To promote biotechnology/nanobiotechnology/ life sciences we have conducted an international bio nanotechnology conference recently."

France is the second country after China in the world to attract significant Foreign Direct Investment (FDI). He also pointed out that the FDI stocks in France have been on positive trend over the years from Euro 100 billion in 1993 to over Euro 300 in 2001. This is mainly due to many advantages such as location, economic power, high quality labor force, skilled workforce in science and technology, high level of education and low labor costs and R&D spending in innovations.

As a first effort to attract the attention of the Indian companies to make investment in France a team lead by Clara Gaymard, ambassador at Large, special representative of France for International Investment and president, Invest in France has visited New Delhi and Mumbai and met the industry people including a few from pharmaceutical companies.

Vascular completes clinical trials in Europe

The Bangalore-based Vascular Concepts announced satisfactory progress on its various clinical trials in Europe. These trials, covering three products, will enable the company to establish its presence in Europe.

Vascular Concepts had commenced a 60 patient trial on its platinum coated stent, "Propass" last year. According to Dr Thomas Ischinger, principal investigator and professor of Cardiology, at Klinikum Bogenhausen in Munich, "The results are comparable, if not superior, to any other non-drug eluting stent or passive coated stent."

Vascular Concepts also recently completed a clinical study on "Prograft", a covered stent graft, at Kardiologische Centrum in Frankfurt, Germany and Klinikum Bogenhausen in Munich, Germany. This trial focused on patients who have had blockages after coronary artery bypass surgery, medically termed as saphenous vein graft lesions. 39 patients implanted with this stent showed a TLR of 17 percent after one-year follow-up. Also the European clinical trials on "Pronova" (Euronova), the company's Sirolimus coated drug-eluting stent, commenced in March 2004. According to the report made available by the hospital, the acute results with the Pronova stent have been most satisfactory.

Swaminathan Jayaraman, managing director, Vascular Concepts said, "We are pleased with these findings as this proves, yet again, the versatility, reliability and the world class quality of our products. These findings, and further tests that are in progress, will ensure that we obtain the CE Mark approvals for marketing these products in Europe".

The Vascular Concepts is engaged in the design, development and manufacture of endovascular medical devices that address the treatment of arterial diseases.

Biocon's cancer drug enters phase II trials

Biocon Biopharmaceuticals, Biocon's JV with the Cuban Institute CIMAB, has commenced phase II clinical trials of its drug TheraCIM (h-R3), a humanized monoclonal antibody, for the treatment of head and neck cancers.

"The company's achievement marks a substantial advancement in Biocon's recombinant bio-therapeutic portfolio and brings us closer to commercializing the first such proprietary product," informed Kiran Mazumdar-Shaw, CMD, Biocon.

The company commenced its trials after obtaining all the necessary approvals. This drug has received a fast track approval from the National Regulatory Authority of Cuba and "Orphan Drug" status from the European Agency for the Evaluation of Medicinal Products (EMA) to treat cancer patients. The company also announced that all clinical trial data pertaining to this drug is posted on the company web site. "The data posted online is testimony to the safety and effectiveness of TheraCIM (h-R3) monoclonal antibodies to treat head and neck cancers and a reiteration of our core policy of transparency," said Shaw.