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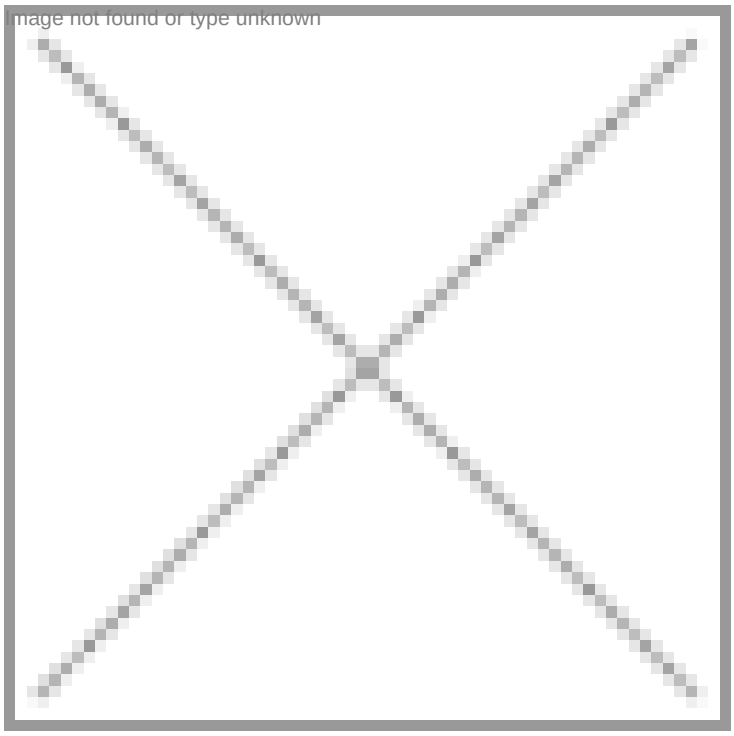

Biocon, Amylin to jointly develop diabetes drug

Indian biotech major, Biocon, and US-based Amylin Pharmaceuticals have entered into an exclusive agreement to jointly develop, commercialize and manufacture a novel peptide therapeutic for the potential treatment of diabetes.

Amylin and Biocon will collaborate to develop the therapeutic potential of the compound and share development costs. The research will center on Amylin's 'phybrid' technology. A phybrid is a peptide hybrid molecule that combines the pharmacological effects of two peptide hormones into a single molecular entity.

Under the terms of the development and commercialization agreement, Amylin will provide expertise in peptide hormone development, particularly in the area of phybrid technology, as well as metabolic disease therapeutics. Biocon will utilize its expertise in recombinant microbial expression to manufacture the compound and also leverage its experience in pre-clinical and clinical development of diabetes products.

"This agreement fully leverages the synergistic capabilities of the two companies. Amylin's knowledge of peptidetherapeutics and their leadership in the diabetes market, paired with Biocon's capabilities in process development, manufacturing and clinical development, provide this global program with the potential to effectively bring a novel therapy to patients living with diabetes," said Dr Kiran Mazumdar-Shaw, chairman and MD, Biocon."

Daniel M Bradbury, president and CEO of Amylin Pharmaceuticals, said, "This program could unleash the potential of cutting-edge peptide science to transform the lives of patients with diabetes."

Redefine the frontiers of healthcare: CII conclave

The two-day brain-storming conclave, Life Science Conclave 2009, organized by the Confederation of Indian Industry (CII) in New Delhi on August 27-28, 2009, featured six sessions and three panel discussions that were addressed by 62 eminent speakers. The issues debated in the conclave provided an opportunity for the Indian pharma and biotech industry to assess their position in becoming a major partner of the progress.

Dinesh Trivedi, minister of state for health and family welfare, Government of India, while speaking at the conclave, stressed

on the need for preventive measures rather than solely focusing on curative measures. Trivedi also stressed the need to strengthen diagnostic centers in the country acknowledging the frugal healthcare spending of the central government in the healthcare segment.

Trivedi emphasized the need for a change in the international and national attitude, and mindset towards Indian healthcareas it continues to have the requisite knowledge and skills as well as the market. He also suggested a novel e-health card system to document the complete medical history of all citizens down to the village level.

Dr VM Katoch, secretary, department of health research and director general, Indian Council of Medial Research, while speaking about India's wealth of knowledge, underlined the need for removing the 'bottlenecks' to convert this knowledge into products with further industry and academic co-operation. He also stressed the need for further inter-ministerial co-operation among the various government departments.

Citing the strategic importance of India in the pharmaceutical sector, Bruce Ross, country director, India, US Food and Drug Administration reiterated the US government's commitment to continue its trusting relationship with regulatory counterparts in other countries, such as India. Ross said that India has the largest number of FDA approved drug manufacturers outside the US with Rs 6,708 crore ($1.38 billion) of exports to the US market in 2007–08 growing at 39 percent.

Avesthagen to raise Rs 700 crore from markets

Bangalore-based life sciences company, Avesthagen has revived plans for an IPO, and will raise about Rs 700 crore fromthe domestic and international markets. The funding will be used to commercialize 40 products, which are in various stages of development to market. Having initially announced the IPO last year, the company had to postpone the plans after markets fell due to global meltdown.

Dr Villoo Morawala Patell, founder and CMD, Avesthagen, said, "The IPO is slated to coincide with the time that our biosimilars are ready to hit the market place. From an investment perspective, I believe mid-2010 will see a global turnaround and a good business environment, such that all our stakeholders will benefit from investing in the company."

Avesthagen, which currently holds 560 patents will be valued based on its patent and product portfolios. Avesthagen, which is expected to touch a turnover of Rs 100 crores this fiscal, is yet to decide on the bankers, and would like to hold on to the promoter stake, which is currently at 32 percent while private equity (PE) players hold up to 28 percent. PE investors include ICICI Ventures, Fidelity and New York Life Investment Management India Fund.

Each of Avesthagen's four strategic business units are expected to run as independent profit centers with dedicated management teams. Avesthagen has many products in the pipeline that need to be monetized and brought to the consumer. Recently, the company cleared one mammalian biosimilar monoclonal antibody product by the regulatory agency in India for clinical trials, and three other biopharma products have entered pre-clinicals.

CHiCTR, CTRI to encourage clinical trials in China, India

Pharma and biotech companies are attempting to combat escalating R&D costs and lengthy clinical trial timelines by improving patient recruitment, and the efficiency of clinical trial analysis/reporting. The biopharmaceutical market has recognized the opportunities and advantages that exist by conducting clinical trials in emerging markets. Although these markets offer a number of significant benefits over traditional clinical trial settings, there remain a variety of challenges and problems associated with conducting trials in emerging regions.

Announcing the release of a report on 'Emerging Clinical Trial Locations: Market Dynamics and the Changing Healthcareand Regulatory Environment' by Business Insights noted that Russia is one of the world leaders in patient enrolment with an average patient recruitment rate in 2006 exceeded 4.7 patients per site per month. For some nosologies, this figure is 10 times higher than in Western Europe and the US.

The Chinese Clinical Trial Register (CHiCTR) and The Clinical Trials Registry in India (CTRI) have helped to encourage all clinical trials in these regions to be registered before the enrolment of the first participant, and to disclose the mandatory 20 items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset.

By the end of May 2009, 895 clinical trials were registered in India, as against 150 clinical trial approvals in the year 2006 by the Drug Controller of India (DCI). India is able to offer significant cost savings compared with clinical trials conducted in western countries. Phase I trials are approximately 50 percent cheaper than western equivalents, while phase II and phase III are 60 percent less expensive.

The Chinese CRO market was valued at Rs 1,209 crore ($250 million) in 2008. The market is expected to grow at a CAGRof 33 percent over the next four years to reach Rs 3,825 crore ($791 million) in 2012. By that time, Chinese CROs will account for an estimated 2.3 percent of the global CRO market.

India to monitor CROs closely

In an effort to give a conducive business environment to CROs in the country the Indian regulatory agency has released draft rules for mandatory registration of all Clinical Research Organizations (CRO) across the country. Approved by the Drug Technical Advisory Board (DTAB), India, the draft guidelines are to standardize practices among such organizations and mandate strict adherence of standard operating procedures.

The guidelines are not standalone and the objective is to improve overall quality of clinical trials by working hand-in-handwith other applicable rules, like Schedule Y, Indian GCP guidelines and Ethical Guidelines for Research on human subjects by

ICMR.
According to the draft made available to the public, the guidelines cover all organizations, individuals, institutions and companies that take the responsibility of initiation, management or coordination of a clinical trial. Thus, the draft rule makes it clear that the CRO can carry out its activities according to the contract with the sponsor, only if it is duly registered under the rules by the licensing authority. Before the organization registers, it needs to declare that the licensing authority has the right to inspect its premises at any given time and examine the process, procedure and documents of any trial taken care by the organization.

ISO certification for Cryo-Save India

Cryo–Save India, a part of Cryo-Save Group, Europe's largest adult stem cell storage bank, achieved a significant milestone with TUV Rheinland, Germany, conferring the India operations an ISO 9001:2008 certification. TUV Rheinland, a leading quality management systems registrar from Germany, certified Cryo-Save India after examining the lab on various parameters.
Cryo-Save India is dedicated to the highest quality standards and is the only company in its category to have received ISO 9001:2008 certification from TUV Rheinland, within such a short duration since commencement of its operations. The certification from TUV Rheinland helps to strengthen the processes and systems employed by Cryo-Save India, which include fully-automated systems that ensure no human intervention in storage and retrieval process along with a unique dual storage process.
As part of the ISO 9001 process, TUV performed on-site assessments, examining the Cryo-Save India documention procedures and audited its overall operations. To determine continued compliance with ISO 9001:2008, TUV would conduct periodically scheduled audits at Cryo–Save India and examine and monitor its business operations. Quality Council of India, the authority in India for ISO-related standards, too can conduct random audits to verify organization's compliance to declared practices.

SIRO Clinpharm expands operations in Europe

SIRO Clinpharm, a global Contract Research Organization (CRO) with its base in India, US, Europe and Israel, has opened its new office in Prague, Czech Republic.
"Czech Republic has an excellent resource base of Good Clinical Practice (GCP) trained, well-qualified clinical research personnel. Our new office in Czech Republic will further strengthen our operational capabilities in Europe," said Scott Spector, president, Strategic Operations, Europe.
Dr Ladislav Pecen will be in charge of operations in Czech Republic for SIRO. To begin with, SIRO will roll out clinical monitoring, biostatistics and statistical programming services from the new office. From its offices in Offenbach, Germany, and Mumbai, SIRO has been offering these and other services like clinical data management, quality assurance, medical writing, medical affairs and pharmacovigilance for more than a decade.
"We established our presence in Europe with the acquisition of Omega Mediation, a Germany-based CRO in April 2008. During the last 18 months, as a part of our global strategy, we have expanded our capabilities by opening offices in north east and south east Europe. We have already started eyeing other countries in Western Europe for further expansion," said Dr Chetan Tamhankar, CEO of SIRO Clinpharm.

MakroCare signs partnership with OmniComm

Indian CRO MakroCare has partnered with OmniComm Systems, one of the fastest growing companies and a leader in integrated electronic data capture (EDC) solutions for clinical trials.
"MakroCare offers a best-of-breed suite of clinical technologies for managing global clinical trials, including customized interactive voice response (IVR) and web applications, comprehensive clinical trial management systems (CTMS) and drug safety and pharmacovigilance systems. The integration of the TrialMaster System into our clinical platform offers our customers an extremely powerful solution," said Dr Rajeev Naithani, director, CDM.
"Partnering with OmniComm allows CROs to offer their customers a first class EDC product and gives them a competitive edge in the bidding process," said Stephen Johnson, COO of OmniComm. "It's a win for everyone involved, the CRO, OmniComm and most importantly the clients that we serve."
With this partnership, MakroCare is entitled to use with the flexible, intuitive and robust EDC solution, TrialMaster. For clinical trials, a dedicated hosted environment and comprehensive training and support for TrialMaster.