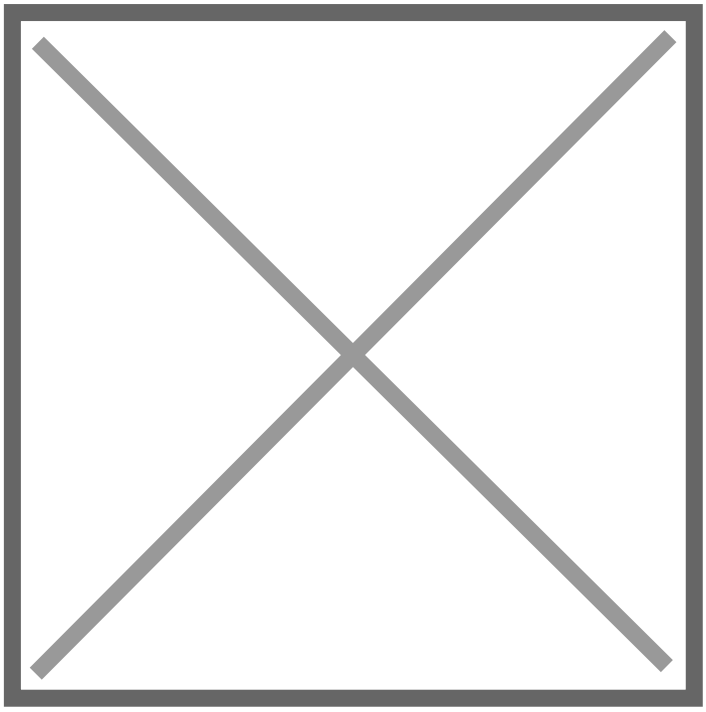
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CEL-SCI to commence phase III trial

09 May 2011 | News



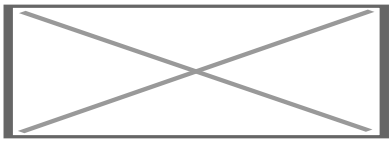
Vienna-based, CEL-SCI Corporation, announced that it received approval to begin enrollment of patients in its phase III clinical trial of multikine in India from the Directorate General of Health Services Office of Drug Controller General (India) Ã¢â?¬â?? the Indian equivalent of the FDA.

India is an important country for this clinical trial, which is being held in nine countries because about 15 of the 48 clinical centers for this global trial will be located in India and also because India has the greatest number of head and neck cancer cases in the world. It is expected that patient enrollment in India will be about four-six times faster than would be possible in US clinical centers. The global phase III trial for multikine was started in the United States in late December 2010. CEL-SCI expects to commence the trial in other countries around the world within the next 30-60 days. Multikine is the company's flagship immunotherapy developed as a first-line standard of care in the treatment of head and neck cancer.

Phase II clinical trials of multikine demonstrated that the product was safe and well-tolerated and eliminated tumors in 12 percent of the subjects withinÂ less than a month into treatment. The multikine treatment regimen was also shown to kill, on average, about half of the cancer cells in the subjects' tumors before the start of standard therapy.

Max Neeman enrols 15,000 for phase IV metabolic disorder trial

India's leading CRO Max Neeman meets enrollment and timeline of 15,000 patients for a large, phase IV metabolic disorder trial across 1,200 sites throughout India. As a leading Indian CRO, the company has completed multiple Phase IV studies for global sponsors with thousands of patients successfully enrolled.Â A 30,000 patient enrollment study across 1,500 sites is currently in-process with four more in the pipeline.



Current ph IV success and activities are due to a specific business model Max Neeman created for such 'Observational studies' based on over 10 years of experience. Segments of the business model include: zonal stratification of >1000 sites and SOPs to improve quality of patient data retrieved in large studies. More than 30 CSRs have been developed to date.

The prevalence of diabetes in India is second only to China with 50.8 million people diagnosed with the disease and expected to rise steeply in the coming years. More large ph IV studies are predicted and Max Neeman is prepared with a ph IV strategy that is a combination of operational excellence (via Six Sigma practices), dedicated and trained project management teams, flexible delivery models, a customized approach and integrated technology. All these combine to deliver positive results on a customer's objective in a swift and cost effective manner.

GVK extends USFDA GOBIOM license

GVK Biosciences extended its Clinical Biomarker Database (GOBIOM) license to the Biomarker Qualification Group of the US Food and Drug Administration (USFDA). The GOBIOM database, which has the latest and updated information on all the biomarkers reported in various clinical and preclinical studies, will be of enormous use to the USFDA in its Biomarker Qualification Process.

The GOBIOM database is a comprehensive collection of all the clinically evaluated, exploratory and preclinical biomarkers that are associated with different therapeutic areas reported in global clinical trials and in clinical and preclinical studies. GOBIOM contains information on 12,000 biomarkers comprising biochemical, genomic, imaging, metabolite, cellular and physiological markers with multiple data points covering experimental, analytical, clinical and statistical data with their qualifications under different medical interventions.

SIRO Clinpharm expands in Asia

SIRO Clinpharm, a leading IndianÂ Contract Research Organization (CRO), announced the launch of its operations in Malaysia.

SIRO had announced in 2010, strategic alliances with CROs in South Korea and Taiwan. Malaysia is a highly developed and fast growing clinical trials destination and this attracted SIRO to expand its reach.

SIRO began its operation in India back in the year 1996 and this has made SIRO one of India's most experienced CROs.

India comes together to improve healthcare

To address the issue of lack of healthcare access in India, a conference 'Healthcare Access Week' (April 4-9, 2011) was organized by India Health Progress in Mumbai. This conference highlighted the various incremental steps taken by healthcare organizations towards better healthcare access for the Indian patients by bringing together all the stakeholders for a unified cause. Representatives from various healthcare organizations, NGOs and pharmaceutical companies shared their contributions towards the improvement of healthcare in India. Although considerable growth trajectories have been marked by the Indian economy, the healthcare system is still ailing and more than 65Â percent of the Indian population does not have access to quality healthcare.

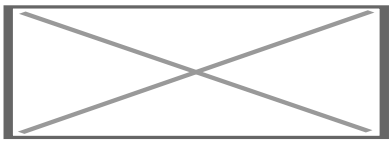
Speaking on the occasion Mr Ranga Iyer, healthcare consultant and former MD, Wyeth, said, Ã¢â?¬Å?We need to join hands and raise our voice towards the Ã¢â?¬Å?lack of access to healthcare in India so that the healthcare condition of our country can be improved. I hope today's initiative will act as a catalyst towards motivating everyone for taking initiatives for better healthcare system in India.Ã¢â?¬?

Given India's enormous economic strides, since the early 1990s, continued healthcare inaccessibility is particularly disappointing. Although around 70 percent of Indians live in rural and semi-urban areas, nearly 80 percent of healthcare facilities and medical personnel are based in cities and other urban centers.

The objective of this conference was to appreciate and showcase the initiatives undertaken to provide healthcare access to all, thus creating an environment for developing improved policy framework for healthcare in India. Furthermore, this initiative would act as a catalyst towards encouraging everyone for taking more initiatives for better healthcare in India.

New stem cell bank at Hyderabad

With stem cells gaining awareness among the public, more and more research organizations are coming forward with new initiatives in this area. Recently, the launch of a new stem cell bank and processing center for therapy at Hyderabad byÂ Tran-Scell Biologics &Â Pacific Hospitals, during the BioAsia 2011 event was one among those.



Incorporated in 2009, Tran-Scell Biologics was founded for cord blood private banking service at Hyderabad, India, at first. It entered this new era of health industry with a bold and unique business model. Tran-Scell proposes to integrate the chain of business vertically, beginning with stem cell preservation, processing, and up to clinical applications by being a third party processed clinical grade stem cell provider. Now in 2011, it has come up with new stem cell bank and processing center atÂ Jubilee Hills, Hyderabad.

The facility currently has cord blood stem cell banking service initiated as well as introduced onto the market.Â Tran-Scell collects processes and stores the new born baby's cord blood stem cells for a specified period, which may later be a potential source material for debilitating disease condition. Cord blood is believed to be a major source of stem cells for transplantation worldwide, which can be used to treat major diseases like cancers and bone marrow failure syndromes, inborn errors of metabolism, blood disorders and immune deficiencies also with a great promise in the treatment of neural injury, diabetes, heart conditions.

With the aim ofÂ adding value to the birth experiences, the company offers second chances to those who may face life threatening diseases in future.

India to start GM rubber trials soonÂ

The Rubber Research Institute of India (RRII) based out of Kottayam will soon commence field trials of genetically modified (GM) rubber in the state of Maharashtra. The field trial has been approved by the Genetic Engineering Approval Committee (GEAC) under the Union Ministry of Forests and Environment (MoFE) during its meeting late last year.

Rubber Board Chairman, Ms Sheela Thomas, said that field trials will be conducted at Chethakkai Thombikandam in Kerala and in Dapchari Thane in Maharashtra, and will last for 14 years. On the other hand, MoFE stressed that the trials would be conducted in closely controlled environment, not in areas where commercial rubber trees are planted.

Agilent launches Headspace Sampler for GC applications

Agilent Technologies, the world's premier measurement company and a technology leader in chemical analysis, life sciences introduced a headspace instrument for gas chromatography (GC) sample analysis, the 7697A Headspace Sampler. Based on Agilent's automatic liquid sampler (ALS) technology, the 7697A Headspace Sampler features superior performance without loss or degradation of volatile components found in the gas portion of partitioned GC samples.

Headspace sampling allows the introduction of volatile compounds, from virtually any matrix, directly into a GC or GC/MS instrument. The technique is relatively simple when compared to other injection techniques, such as purge and trap, and keeps instruments cleaner than the standard liquid injection. The 7697A Headspace Sampler is available as both a high-end sampler with 111-vial capacity or as a mid-range unit with 12-vial capacity.

Cole-Parmer announces partnership with picoSpin

PicoSpin has engaged Cole-Parmer to sell their new breakthrough spectrometry product internationally. The exclusive rights apply to the picoSpin Benchtop NMR Spectrometer, an innovative and disruptive technology that combines low price and a compact footprint, with true spectroscopic capability. With this combination of sought-after features, research labs and educators now have affordable access to a dedicated NMR spectrometer.

Cole-Parmer has been a leading global source of laboratory and industrial fluid handling products, instrumentation, equipment, and supplies since 1955. Ã¢â?¬Å?You can deploy multiple units within a factory to continuously monitor process fluids and control them all from a web browser anywhere in the world. Students can experience NMR hands-on in chemistry lab courses and in their research projects,Ã¢â?¬? says Dr John Price, president and chief scientist of picoSpin, LLC. Ã¢â?¬?

Evolva to buy out R&D partner

Emerging biotech firm, Evolva, has proposed to acquire San Francisco-based Abunda Nutrition. Evolva had colloborated with Abunda in 2009 in order to develop the latter's next-generation nutritional ingredients.

The collaboration will also concentrate on advancing highly purified forms of Stevia, which is a natural high intensity sweetener that is manufactured by the fermentation of yeast. The fermentation methodology helps in processing and refining of Stevia plants and allows pure Stevia components to be produced. Evolva has proposed to obtain full ownership of certain additional development-stage compounds that are useful in cardiovascular health along with Stevia.

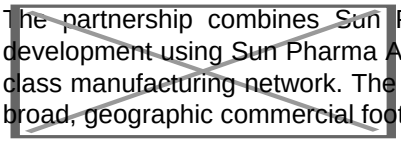
Venus Remedies wins TQM award

Venus Remedies, a leading research-based pharma company, recently bagged the prestigious international award, QC-100 TQM (Total Quality Management), in Gold Category. The award has come in recognition of the company's commitment to

quality, system efficiency, leadership, technology and innovation. Venus is the only pharma company from India to have won this prestigious award, which was given by Business Initiative Directions (BID) International Quality Convention 2011 held in Geneva on March 7, 2011. Around 59 countries from around the globe participated in different categories in these awards.

Sun Pharma, Merck in joint venture

US-based drug major, Merck, and India-based, Sun Pharma, have entered into a collaboration to jointly develop, manufacture and commercialize new combinations of innovative branded generics in the emerging markets.



The partnership combines Sun Pharma's proven track record of leadership and expertise in rapid, innovative product development using Sun Pharma Advanced Research Company's proprietary platform technologies, and Sun Pharma's world-class manufacturing network. The venture will also benefit from Merck's clinical development and registration expertise and a broad, geographic commercial footprint.

Indo-Spain JV to make enzymes

Kilpest India has come forward for a joint venture with two Spainish firms, Biotools B & M Labs and its Madrid-based spin-off company, 2B Blackbio Biotech, in order to manufacture enzymes and reagents that are important in the field of molecular biology.

Kilpest is one of India's oldest pesticide formulating company that started operations in Madhya Pradesh during the 1970s. This venture will also manufacture molecular diagnostic kits based on Spanish patented technology for several diseases, including tuberculosis diagnostic, malaria and dengue among others.

DRL technology center in UK opens

Indian drug major Dr Reddy's Laboratories announced the opening of its newly expanded Chirotech Technology Center, at Cambridge Science Park, UK where Chirotech has been based for the last 20 years. The new 33,000 sq ft facility is purpose built for laboratories and offices and has been fitted to Dr Reddy's specific requirements for chemistry, biology and analytics.

The additional capacity will help facilitate an initial doubling of scientific staff in Chirotech while providing additional capacity in the future. It will help strengthen core capabilities in biocatalysis and chemocatalysis, build capabilities in fast growing segments like Activated mPEGs and peptides, and allow development of other areas of expertise in chemistry.

Takeda sues DRL for Dexilant

Dr Reddy's Laboratories has been sued by global pharma giant, Takeda Pharmaceutical, in the US for allegedly infringing upon its patent coverage of gastroesophageal reflux disease drug Dexilant (dexlansoprazole delayed release capsules).

Takeda alleged that Dr Reddy's and its US subsidiary have infringed US patent numbers through the submission of an abbreviated new drug application seeking approval to market generic versions of Dexilant, a patented drug of Takeda.

US sales of dexilant is estimated to be worth $261 million (1,161.97 crore).

Calyx Chemicals files DRHP for IPO

Calyx Chemicals and Pharmaceuticals has filed the Draft Red Herring Prospectus with Securities and Exchange Board of India and the stock exchanges for an IPO of 68,30,000 equity shares at face value of 10 for each equity share. The issue also includes an employee reservation portion of 50,000 equity shares. The IPO, will be made through the book building process wherein not more than 50 percent of the issue shall be allocated on a proportionate basis to qualified institutional buyers, not less than 15 percent of the Issue shall be available for allocation to non-institutional bidders and not less than 35 percent of the Issue shall be available for allocation to retail individual bidders

Gene Logic offers academic price for ASCENTA

Gene Logic, the leading provider of reference gene expression database solutions, based at Gaithersburg, Maryland, and an Ocimum Biosolutions company, announced that user licenses of its award-winning ASCENTA System are now offered at

special academic pricing to all academic and non-profit organizations to encourage innovation in the industry. ASCENTA is web-based and was developed to simplify access and information retrieval from BioExpress, Gene Logic's proprietary database. ASCENTA makes it possible for researchers to quickly identify and prioritize drug targets and biomarkers.

Suven Life Sciences gets US FDA approval

Suven Life Sciences announced that it received the US health regulator approval for its manufacturing facility at Pashamylaram, in Andhra Pradesh. It had undergone US FDA renewal inspection at its Unit III, the facility at Pashamylaram, near Hyderabad.

The unit manufactures and supplies active pharmaceutical ingredients (bulk drugs) and intermediates under current good manufacturing practice (CGMP). Based on the inspection and the review, the US FDA classified the Suven facility as acceptable for manufacture and supply of active pharmaceutical ingredients and intermediates.

₹300 crore allocated by DBT for GM crops

The department of biotechnology (DBT) has allocated ₹300 crore for conducting research on genetically-modified (GM) crops. India presently boasts of around 400 research centers that are conducting research, of which 200 are part of the DBT grant.

The effort is to improve the productivity of a variety of GM crops, according to S R Rao, advisor, DBT, Government of India.

DBT is spearheading several policy-related developments, which would shape the future of GM foods in India, including Food Safety and Standard Act. However, there is a lot of debate on the labelling policy of GM foods and inclusion of GM food trade issues in the foreign trade policy.

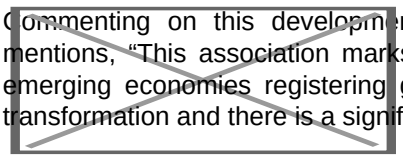
GM technology only an option: Experts

To address the challenges on food security, DuPont, convened a panel of experts to discuss solutions on feeding India. The 'Global Collaboratory' event was held on April 8, 2011. The panel included emminent personalities such as Dr M S Swaminathan, chairman, M S Swaminathan Research Foundation, Dr Swapan Kumar Datta , deputy director general (crop science), Indian Council of Agricultural Research, Pradip Mazumdar, CEO & director, CropLife India and Ajay Jakhar, agriculturalist and chairman, Bharat Krishak Samaj among others.

Glenmark Pharma in distribution pact with Canada's IDC

Glenmark Pharmaceuticals, a leading player in dermatology and drug discovery, has entered into an exclusive arrangement with Immanence-IDC, a leading Canadian company for the distribution of their high-end anti-aging cosmeceutical range of products.

The agreement will span across eight operating countries for Glenmark. The countries are India, Brazil, Mexico, South Africa, Egypt, Vietnam, Malaysia and Thailand. This will mark Glenmark's presence in this fast growing specialized dermatology segment which is growing at a rapid pace across emerging economies.



Commenting on this development, Mr Arvind Vasudeva, Chief Operating Officer, Glenmark Pharmaceuticals Limited mentions, "This association marks a new beginning for us in one of the fastest growing segments in dermatology. With emerging economies registering good economic growth in the past decade, this niche segment has been witnessing a transformation and there is a significant need for these high-end products across our operating countries"

He added "The IDC cosmeceutical range of products are based on a solid scientific foundation and have been successfully launched in few countries. This association will enable us to consolidate our leadership position in dermatology across operating branded generic markets"