Xenome's Xen2174 Enters Human Clinical Trials

Xenome, the Brisbane based biotechnology company on peptides, has its latest neuropathic pain drug Xen2174 entered Phase I clinical trials. The results of the trial are expected to be available by the last quarter of 2004.

Xen2174 is derived from the venom of the cone shell, a common marine shellfish on the Queensland Great Barrier Reef. Xen2174 has been shown to selectively inhibit the Norepinephrine Transporter (NET) in the central nervous system, preventing it from activating the descending inhibitory pain pathway. This kind of neuropathic pain usually found in patients with shingles, diabetic neuropathy, chronic back pain, HIV/AIDS and cancer. Xen2174 can be directly delivered into the space around the spinal cord adjacent to NET, prohibiting the pain signals from reaching the brain. In animal models of pain, Xen2174 has been shown better pain relieving effect than morphine.

The Phase I trial will involve 20 healthy male volunteers in a randomized, placebo-controlled, double blind and dose-escalating study. Dr Michael Thurn, Head of Drug Development in the company, said, “Additional information on the pharmacokinetics and potential anti-nociceptive effects of Xen2174 will also be examined during the trial.” When the Phase I trial is completed successfully, the drug will be tested on cancer patients with intractable pain later.

Xenome’s CEO and Company Director, Dr Tony Evans, said, “The trial initiation represents one of several value adding milestones recently completed by the company including the filing of an IND with the US Food and Drug Administration (FDA) and the further investment of AUD2 million (US$1.4 million) from QBF (Queensland BioCapital Fund) bring its total investment in Xenome to AUD6 million (US$4.2 million).” Xen2174 will be targeting the market of severe cancer pain treatment, which is estimated to be worth over US$4 billion.

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**Chronic Cancer Pain Fact Sheet**

Chronic cancer pain of moderate to severe intensity is typically associated with advanced stages of cancer and may be due to tumor invasion of surrounding tissues, or to chemotherapy or radiotherapy. In up to 15% of cancer patients, the pain may be intractable or refractory to management with oral opioids and adjunctive, nonopioid medication. Further, while opioids may relieve pain, they often have serious side effects, including sedation, respiratory depression, clouded thinking, constipation, nausea and fatigue. These symptoms can prevent adequate pain treatment and there is a general reluctance by both patients and clinicians to use opioids because of addiction. (Source: Xenome Ltd)
CyGenics Renewed NIH Contract on T Cell Technology

CyGenics, a biotechnology company focused on developing stem cells, has successfully renewed its contract with the US National Institutes of Health (NIH) via its US based Cytomatrix business unit. The contract, which is worth US$272,000, will continue till June 2005.

The contract, entitled “Immune Reconstitution by Thymic Organoid in Murine BMT”, includes testing to further develop CyGenics’ T cell technology and reconstitute the immune system in mice. The experiment will help to assess the T cells produced in the company’s ex vivo artificial thymus and evaluate the performance of these cells when engrafted into the immune system of an organism. Dr Michael Rosenzweig, Chief Scientific Officer of CyGenics, said, “We enjoy a long and valued relationship with the NIH. This contract serves to further validate the capabilities of our artificial thymus.”

The NIH, part of the US Department of Health and Human Services, will be supporting the T cell research, which may eventually help cancer patients recover their immune systems which has been damaged by chemotherapy, radiotherapy or disease. Currently, there are 18,000 people working for NIH in different institutes and centers for various diseases.

The contract marks the last pre-clinical work on the T cell technology, before it enters the Phase I/II clinical trial later this year. According to Dr Mark Pykett, President of CyGenics, the artificial thymus has already generated a revenue of US$17 million from the contract with the US Department of Defense for vaccine screening.

Dr Pykett said, “The intention of the artificial thymus is ultimately to deliver a simple, cost-effective and patient-specific ability to generate new human T cells. By making new, fully functional T cells, the company would be able to provide a platform with the potential for producing applications to treat a wide array of diseases, to the benefit of millions of patients around the world.”

About CyGenics
CyGenics is a biotechnology group focused on the development and commercialization of stem cell related technologies and applications covering tissue banking, tissue engineering, cell growth bio-manufacturing, biologics and cell therapy.

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NOVOGEN’S CARDIOVASCULAR DRUG ENTERS HUMAN CLINICAL TRIAL

Novogen Limited has its new cardiovascular drug, trans-NV-04, entered second human clinical trial. The drug will be tested in healthy human subjects at risk of cardiovascular disease.

Trans-NV-04, being an advanced version of the company’s experimental NV-04 compound, is more effective than the parent compound while retaining the low side effect and high safety profile, as shown in previous laboratory studies at the Baker Heart Research Institute in Melbourne. The current trial, also conducted by the Baker team, will evaluate safety and tolerability in a dose ranging study, then proceed to a randomized, crossover, placebo-controlled and double-blind study in the human subjects.

The drug’s effect on several cardiovascular risk factors, including arterial stiffness, blood pressure, plasma lipids, circulating adhesion and inflammatory molecules, insulin sensitivity and plasma cortisol will be compared between the group of subjects taking the drug and those taking placebo. This study will help to establish a dosing regime to be used on healthy people and lower their risks of having cardiovascular diseases. It will also reduce the damage in diseased arteries of people suffering from atherosclerosis, and hasten the recovery from surgical interventions, such as by-pass surgery and angioplassty, used to manage such disease.

Vascular disease like atherosclerosis, hypercholesterolaemia are prevalent in the Western society. More than 300 million individuals in the seven major pharmaceutical markets suffer from hypercholesterolaemia (high cholesterol level) and US alone has a annual amount of US$17.7 billion spent on drugs curing these diseases. Prof Alan Husband, Research Director of Novogen, said that most available drugs now used to treat cardiovascular disease have undesirable side effects. “In contrast, trans-NV-04 is expected to be sufficiently safe to be administered over long periods without side effects,” he said.

The NV-04 research was funded AUD3.7 million (US$2.6 million) through the Australian government’s research and development START program. The study will continue evaluate NV-04’s potential to promote blood vessel relaxation and inhibit smooth muscle cell growth in blood vessels, thus control and prevent atherosclerosis.

Atherosclerosis Fact Sheet

What is atherosclerosis?

Atherosclerosis comes from the Greek words athero (meaning gruel or paste) and sclerosis (hardness). It's the name of the process in which deposits of fatty substances, cholesterol, cellular waste products, calcium and other substances build up in the inner lining of an artery. This buildup is called plaque. It usually affects large and medium-sized arteries. Some hardening of arteries often occurs when people grow older.
Plaques can grow large enough to significantly reduce the blood's flow through an artery. But most of the damage occurs when they become fragile and rupture. Plaques that rupture cause blood clots to form that can block blood flow or break off and travel to another part of the body. If either happens and blocks a blood vessel that feeds the heart, it causes a heart attack. If it blocks a blood vessel that feeds the brain, it causes a stroke. And if blood supply to the arms or legs is reduced, it can cause difficulty walking and eventually gangrene.

**How does atherosclerosis start?**

Atherosclerosis is a slow, complex disease that typically starts in childhood and often progresses when people grow older. In some people it progresses rapidly, even in their third decade. Many scientists think it begins with damage to the innermost layer of the artery. This layer is called the endothelium. Causes of damage to the arterial wall include:

* elevated levels of cholesterol and triglyceride in the blood;
* high blood pressure;
* tobacco smoke; and
* diabetes.

Tobacco smoke greatly worsens atherosclerosis and speeds its growth in the coronary arteries, the aorta and arteries in the legs. (The coronary arteries bring blood to the heart muscle; the aorta is the large vessel that the heart pumps blood through to the body.)

Because of the damage to the endothelium, fats, cholesterol, platelets, cellular waste products, calcium and other substances are deposited in the artery wall. These may stimulate artery wall cells to produce other substances that result in further buildup of cells.

These cells and surrounding material thicken the endothelium significantly. The artery's diameter shrinks and blood flow decreases, reducing the oxygen supply. Often a blood clot forms near this plaque and blocks the artery, stopping the blood flow.

(Source: American Heart Association)

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Rockeby’s CANDIA5 Completed FDA 510K Trial

Rockeby Biomed (ASX: RBY) has completed the FDA 510K trial for its vaginal thrush diagnostic CANDIA5, which was part of its application to FDA to market the product in the US. CANDIA5 is currently the world’s only rapid, point of care diagnostic for the common fungal infection among women.

Under the requirements of Section 510(k) of the Food, Drug and Cosmetic Act, also known as the Premarket Notification or 510(k), FDA should determine whether the medical device intended to go on shelf is equivalent to one that has already been classified. The trial of Rockeby compared the test results of CANDIA5 with other existing means, including microbiological diagnosis and fungal culture of vaginal sample, to diagnose vulvovaginal candidiasis.

Dr Jack Sobel from the College of Medicine at Wayne State University headed the trial, which involved 200 patients from five sites, namely Wayne State University, Medical University of South Carolina, University College of Medicine, Woman & Infants Hospital and Magee Women’s Hospital. The doctors participated in the trial were from the Infectious Disease Society of Obstetrics and Gynecology (IDSOG) of the US, who are regarded as leaders in fungal infection.

The results of the trial will be lodged with the FDA by September.

About Rockeby Biomed Ltd

Rockeby biomed is an ASX-listed (ASX: RBY) biotechnology company engaged primarily in the research, development and marketing of products for the diagnosis and treatment of fungal infections in humans. The company’s main market is that of in vitro diagnostic testing which covers serology tests in hospitals as well as point-of-care products for use by consumers or health professionals operating outside hospitals.

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AustCancer’s Revisys Supplements Coming to Singapore

About Australian Cancer Technology
Australian Cancer Technology is a publicly listed oncology drug development company developing the Pentrys’ anti cancer vaccine in clinical trials and building a pipeline of oncology products through a strategic alliance with BioFocus plc (UK).

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ACT (USA), the US subsidiary of Australian Cancer Technology Limited (AustCancer), has appointed Hengzi Technology Investment Pte Ltd to exclusively distribute its revisys range of nutritional supplements in Singapore.

Revisys, already launched in the US in February this year, is an integrated, multi-level nutrient system. It supports people of different levels of health and nutritional needs, catering to patients with unique nutritional requirements due to extenuating health issues. The agreement with Hengzi Technology is the first distribution deal for the products in a market outside the US.

Lim Linbert, Director of Hengzi, said, “Most western medicine patients in Singapore would also seek complementary medicines for their conditions. There is an increasing call for complementary products that are backed by sound medical science.” The company has experience in marketing and distribution of medical devices and pharmaceutical devices in the Asia Pacific region from prominent healthcare companies like the Australian biotechnology company VRI BioMedical.

The product will be launched in Singapore in November 2004. Paul Hopper, Managing Director of AustCancer, said, “We’ve made good early progress in penetrating the United States market with revisys and we are now ready to start developing a position in other markets. Singapore intrinsically appeals as a strong potential market for us and if it meets our expectations, expansion into other Asian countries would be a logical next step.”

The product for the Singapore market will be manufactured by ACT (USA) in Australia. Both developers of revisys Prof David Felten and Prof Barry Boyd will be introducing the product to the Singapore medical and health professionals.

There are also plans to launch revisys by December 2004 in Australia. ACT (USA) has estimated that the total sales of revisys, including export and domestic, will be of US$8–10 million a year by 2006.
Life Therapeutics and UK BioProducts in Negotiation for Anti-D Product

Life Therapeutics, Australian biotechnology company, recently signed a Memorandum of Understanding with the UK based BioProducts Laboratories (BPL) to enter exclusive negotiations for the acquisitions of the latter’s recombinant Anti-D therapeutic product.

Anti-D, also known as human anti-D immunoglobulin, is particularly important to pregnant women with a blood type known as rhesus negative and bearing a baby that is rhesus positive. The blood group incompatibilities between mother and baby can be fatal, if no Anti-D is given on precaution. The worldwide market for Anti-D products is estimated at US$200 million each year.

Under the memorandum, Life Therapeutics will be given a 12-week period of exclusivity for negotiation on a final agreement of the deal and an approved schedule on the manufacturing and marketing of the product. It is expected that Life Therapeutics will be responsible for the manufacture, clinical trials and distribution of the newly developed rAnti-D.

BPL’s rAnti-D is different from conventional Anti-D in a way that it is not derived from plasma, thus carries a much lower risk of infection and higher efficiency in manufacturing. BPL, the largest Anti-D supplier in the UK, has been working on this recombinant product for 15 years, and it has already completed Phase I clinical trials.

Dr Hari Nair, CEO of Life Therapeutics, said, “An exclusive agreement with BPL to manufacture and distribute rAnti-D would give both companies a very strong position in the Anti-D market. While a precise timetable will be part of our negotiation with BPL, we expect to be ready to take rAnti-D to market within 36 months.”

According to Life Therapeutics Executive Vice-Chairman and Chief Financial Officer, John Manusu, the company is interested in this new product because it can be efficiently manufactured with the Gradiflow technology, and complement the Anti-D plasma business of the subsidiary Life Sera. He said, “Life Sera’s technical expertise, market knowledge and clinical data will significantly reduce the cost of developing this product.”

BPL was pleased about the MoU signed, leading to company to further explore the market of Anti-D. CEO Chris Hadfield of the company said, “Life Therapeutics has a novel, vertically integrable technology and the resources to manufacture and distribute rAnti-D in the US and the rest of the world. We are looking forward to working with them.”

About Life Therapeutics
Life Therapeutics is a biotechnology company dedicated to improving the health and lives of patients worldwide by providing superior products and constant innovations. Its specialty biological and diagnostic products set a new standard for the life sciences market.

Through highly sophisticated donor management, patented separation technology and innovative diagnostic offerings, Life Therapeutics enhances the complete cycle of plasma-derived products — from collection to commercialization.

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Acru Ltd has signed a commercial agreement with CSL Ltd for the distribution of Acru’s Testosterone MDTS® treatment for women. Under this agreement, CSL will have the exclusive rights to distribute the transdermal spray in Australian and New Zealand to treat women with sexual dysfunction.

Testosterone is believed to be responsible for maintaining muscle and bone strength, as well as contributing to sex drives in women. It is published in the Journal of the American Medical Association in 1999 that more than 40% of women have one form or another of sexual dysfunction, a major unmet medical need without widely approved therapy. The New England Journal of Medicine evaluated the sexuality and quality of life in women with low blood levels of testosterone. After raising their blood levels of testosterone using a medicated skin patch, health and sexuality seemed to improve.

Acru’s treatment has entered Phase 2 study in Australia with 200 patients and the result will be released by early 2005. The company has already secured partnership with VIVUS Inc for Testosterone MDTS treatment to explore the US market. Dr Igor Gonda said, “We are very pleased to have an organization of CSL’s status sign a commercial deal at this stage of the drug development. It is an endorsement of Acru’s revolutionary treatment and drug delivery system that we now have a partner for this product in Australia and New Zealand.”

Colin Armit, CSL Pharmaceutical’s President, said, “The testosterone transdermal spray offers significant growth potential to our women’s healthcare portfolio — as well as providing a more convenient method to administer the drug. We are pleased to partner home-grown technology.”

Acru will receive an upfront payment and royalties on net sales in Australia and New Zealand through its subsidiary FenPharm Pty Ltd under the agreement. Dr Gonda said, “This announcement is an important step in maximizing the value of this product in our domestic markets and CSL are to be commended for their support of Australian innovation and commitment to their local markets.”
About Acrux

Acrux is a dynamic Australian specialty pharmaceutical company with vision and skills in transdermal drug delivery systems — ways of administering drugs through the skin — for many therapeutic uses.

Acrux Limited was established in 1998 to invest in specialty pharmaceutical businesses developing products, which are intended to enable the safe and effective delivery of a broad range of drugs through the skin. The Company is a Pooled Development Fund (PDF) that has three businesses that are currently developing a range of products.

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About CSL Limited

The CSL Group of companies develops, manufactures and markets pharmaceutical products of biological origin. CSL’s Human Health business includes the operations of ZLB Behring, CSL Bioplasma and CSL Pharmaceutical, as well as our global new product development activities.

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Indian Biotech Industry Needs More Mature Funding

Kiranjit Mazumdar Shaw, Chairperson of the Vision Group of Biotechnology, said that the Indian booming biotech industry has the potential to attract US$250 million in Karnataka and create a million jobs across the country. However, the government is not backing the biotech startups as much as that in the IT industry, blocking the way to further development.

The total revenue from the biotech sector last year was US$750 million, in which over one-third comes from the state of Karnataka. The state’s biggest city, Badalagore, is also attracting attention since it is Biotech Park, Bangalore Biohelix, under construction, and will be in use within two years. Shaw said, “Around 25 companies were set up in India last year. Of these, 17 preferred to start their operation in Bangalore.”

This state of technology and science attracted a US$8 million dollars biotech VC funding in the year 2003–4. Dharam Singh, Karnaka Chief Minister, said, “With an annual revenue of Rs1,000 crore (US$215 million), Bangalore has clearly emerged as the biotech city of India, thanks to technical competence, qualified human resources and the required infrastructure being available in the city.”

Nonetheless, the incentives of the government on further developing the biotech industry do not seem too encouraging to the industry players. On the presentation of the Union Minister’s 2004–5 budgets, it is stated that science and technology, including biotechnology, “will receive priority and will be provided with additional funds.” Companies doing scientific R&D approved by the Department of Scientific and Industrial Research before April 1, 2004 may receive a specific provision, with a 100% deduction of profits for 10 years. These funds would certainly encourage small and medium biotechnology companies to further advance their R&D, as more savings could be channeled into these activities.

According to Shaw and many industry players, this was not enough. She was disappointed that the 2004 budget did nothing to remove the customs duty on research equipment. “One cannot expect young BT (biotech) companies to come up when the equipment costs are high,” said she, calling for measures like a national biotech policy and a seed-fund for startups. Shaw, though, was enthused by the response from the Union Master for Science and Technology Kapil Sibal. “We have placed a few items that need to be addressed such as regulatory issues, IPRs, seed fund, BT park and regulatory reforms for clinical trials,” said she.

On the other hand, Dr MK Bhan, Secretary of the Department of Biotechnology, said that a series of measures would soon take place and encourage the growth of the biotech industry. He said, “Two issues of concern are regulatory issues and IPRs. The industry can expect action on this front in two years.” Speaking at the inauguration of the BangaloreBio 2004 Conference series, Dr Bhan outlined a series of measure to sustain the growth of the industry.

The plans include broadening the research paradigm, building innovation centers within existing institutions after solving their conflict of interests, concentrating the investments in particular areas of the industry, and drafting up a government-endorsed policy to encourage public-private partnership. The industry may have a long way to go before meeting the expected investment sum, but these steps are essential for adding fuel to the country’s booming business.
Ocimum Biosolutions recently has its Biotracker, a Laboratory Information Management System (LIMS), licensed to the Canada biotechnology company ARIUS Research Inc. The newly adopted technology will help ARIUS in its research on cancer therapy.

Biotracker is a patented LIMS that allows laboratories to keep an accurate track of samples, reagents, instruments, processes and output from the time these resources are acquired. The system is also equipped with a multi-level user configurable security feature.

ARIUS Research, which focuses on discovery and development of anticancer monoclonal antibodies (MAbs), will implement Biotracker to manage the large volume and complexity of data generated during drug development. Biotracker’s flexibility, low-cost instrument and convenient interface can help ARIUS Research to integrate numerous complex data and support its corporate growth.

Anuradha Acharya, CEO of Ocimum Biosolutions, said, “We expect that Biotracker will be vastly beneficial to ARIUS Research in integrating, maintaining and enhancing data management.”

About Ocimum Biosolutions

Ocimum Biosolutions is a life sciences contract research and development company with competencies in Bioinformatics, LIMS, Genomics, Proteomics and custom contract research services, with operations in USA and India. Our team comprises experts from Life Sciences / Computer Sciences backgrounds. Additionally cross-trained within Ocimum for a period of 9-12 months in association with the University of Alabama in Huntsville, these consultants can complement a biotech/pharma company’s IT needs, or execute contracts both on-site and off-site.

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Lupin to Shut Down Its South African Subsidiary

Lupin Ltd, India’s tuberculosis drug manufacturer, has announced that it plans to close down its South African subsidiary Lupin Laboratories South Africa (Pty) Ltd, which was started seven years ago as part of a joint venture with local partner Quottromed.

It was reported that Lupin would be looking to liquidate the South African subsidiary, which operates essentially as a marketing outfit, and the process of closing down the company will likely be completed by this year. Apparently there had been too little business taking place out of the subsidiary for about two years now, and Lupin’s joint-venture partner is facing financial problems. Employees from Lupin working under the subsidiary will return to the parent company, which has subsidiary companies elsewhere in countries such as Thailand, Hong Kong and the US.

Lupin’s decision to pull out its South African operations may seem like a step backwards for the company especially in a time where many Indian companies are making news for their business ventures and activities in the competitive global markets. But through institutional sales, Lupin will probably still be able to facilitate the sales of its tuberculosis drugs to a region that had been badly afflicted with the disease. African nations account for the highest HIV/AIDS incidence in the world, and a strong presence in the regional markets æ via a subsidiary or not æ would still be extremely important for a company like Lupin which specialize in the manufacturing of TB drugs.

About Lupin Ltd

Lupin is one of the world’s largest manufacturers of drugs that combat tuberculosis, bacterial infections, and cardiovascular diseases. Lupin’s products reach more than 50 countries, with significant presence in, besides India, US, Europe and Southeast Asia.

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www.drugdisc.com
Researchers from the Institute of Environmental Science and Engineering, Nanyang Technological University (NTU), Singapore, in a collaborative effort with Sinomem Technology Ltd, have succeeded in developing cost-effective, durable membranes* for purifying water and producing medicines, food and drinks.

At the institute’s Advanced Membrane Technology Center, a process using hollow fiber membranes to separate oil emulsions from water-based lubricants has already been patented. This is regarded as a major breakthrough since delicate conventional membranes are usually damaged by oil.

In addition, the researchers have also managed to produce more durable membranes which can withstand the acidic conditions especially during the production of traditional Chinese medicines.

According to Prof Tay Joo Hwa, Director of the institute, the research efforts aim to replace distillation and evaporation, commonly used techniques for purification or concentration of active ingredients, with membranes that can do the same job at a fraction of the cost.

The institute hopes that the tie-up with Sinomem will help them grab a chunk of the billion-dollar global market, which is growing at between 10% and 15% annually. In China alone (the world’s largest market), the membrane market is worth several hundred million dollars a year.

According to Dr Lan Wei Guang, Sinomem’s Managing Director, the partnership would allow Sinomem to develop customized solutions for companies, to help them increase production yields and use raw materials and energy more efficiently. He added that not only will these companies be able to lower their overall costs, they can also focus on preserving the environment thus minimizing pollution and wastewater discharge.

The collaboration would bring together the institute’s membrane-related research with Sinomem’s ample market and industry experience, to meet the needs for cheaper and cleaner water here and in the region.

* Membranes are thin films of porous material, whose tiny pores act as a barrier to unwanted materials, such as salt, bacteria and viruses.
About Sinomem Technology Ltd

Established in 1996 and headquartered in Singapore, Sinomem Technology Ltd, provides integrated process and engineering solutions for separation, purification and cleaner production purpose in diverse industries by the use of their advanced membrane technology.

The company’s breakthrough technology allows companies in the pharmaceutical, chemical and dyestuff, food and beverage, water and wastewater treatment industries to enjoy benefits such as:

1. improved quality and desired product,
2. increased production yield,
3. lower consumption of raw materials and energy, and
4. minimization of pollution and waste discharges.

Sinomem has completed more than 50 projects in China, and has recently made it to No. 28 on the list of the 250 fastest-growing technology companies in the Asia Pacific in a recent ranking exercise.

In 2004, the company achieved a 27% growth in net earnings and 24% growth in revenue.

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SciGen to Market SciLin in India

About SciGen
In view of the strong government support for the biotechnology sector in Singapore, SciGen has adopted an approach to its product development which, in keeping with government initiatives, endeavors to supply competitively priced, state-of-the-art products to the markets it serves. SciGen’s major strength lies in its ability to recognize the potential of new products in their early and late stages of development. Through joint collaboration with its partners, SciGen utilizes its extensive expertise in regulatory and clinical environments, in conjunction with marketing and promotional abilities, to bring products to market. SciGen’s primary focus is on the development of innovative products that address serious conditions.

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Striking a deal with India’s largest generic drugs producer Ranbaxy Laboratories, the biopharmaceutical firm SciGen Ltd will be selling its human insulin product, known as SciLin, in India. The Singapore-based company has also obtained approval from the India’s drug controlling agency for its product’s commercialization.

SciGen’s managing director and CEO Mark Compton described the approval of SciLin as a key milestone for the company as India is one of the fastest growing economies in Asia and has a large insulin market. The incidence of diabetes in the country is estimated to be at around 8% and the rate is rising. SciGen is also in collaboration with Indian marketing and sales company Shreya Life Sciences for this major venture, with the objective being to introduce the insulin product to the Indian market soon — especially at a time where medical treatment is becoming more affordable in India. The combined sales force available to SciGen approximates 3,500 medical sales representatives, visiting about two million doctors in total, the company noted.

The registration of human insulin in India represented a very important success for the track record of SciGen’s regulatory affairs team. SciLin is ideal for treating patients suffering from diabetes. These people lack insulin, a protein hormone secreted in the pancreas that maintains the balance of glucose metabolism. In addition to the approval for marketing insulin in India, SciGen has recently received approval in India for its human growth hormone, SciTropin™, and steps are being taken to launch the product within the next few months.

“The registration of biological pharmaceuticals in particular is a highly specialist area and SciGen’s team has demonstrated again that the company has these skills and can use them to the benefit of its stakeholders,” Compton said.