CyGenics Ltd announced with the Murdoch Children’s Research Institute (MCRI) that they will together carry out CyGenics’ stem cell expansion clinical trials. In the collaboration, CyGenics’ subsidiary Cytomatrix will provide the technology to MCRI.

The trials are expected to show that stem cells derived from umbilical cord blood can retain the full functionality and effectiveness after expansion. Previously, the technology has been proven and published with expansion of human bone marrow stem cells, cord blood stem cells and peripheral blood stem cells. If these trials are successful, CyGenics will be able to offer safe, efficacious and cost effective means of multiplying human stem cells. This will help to meet the huge demand of stem cell transplants, estimated US$7.8 billion by 2012, around the world.

Associate Professor David Ashley, Head of the Children’s Cancer Center of MCRI and Royal Children’s Hospital, said, “In Australia, one in every 600 children will develop cancer. The potential of stem cell therapy for many diseases, in particular many cancers, is enormous. The primary limitation today in the use of such therapy has been the quantity. There simply aren’t enough stem cells available. We are excited to be working on trials that may well put an end to this limitation.”

The technology, if successful, will contribute to the recovery of patients with hematological malignancies and metabolic disorders, like leukemia, thalassemia and anemia. Steven Fang, Group CEO of CyGenics, said, “Stem cell expansion is the “holy grail” of the stem cell research community and could open the door to not only many more stem cell transplants, but also the development of more medical applications using stem cells.”

These collaborative trials have gained full support from the Australian Government. AUD50,000 (US$36,260) has already been granted to the company for the development of the stem cell technology. The technology transfer is also supported by the International Science Linkages Program, organized by the Australian Government.
The Louisiana State University Health Sciences Center in Shreveport (LSUHSC-S) and Bionomics will cooperate under agreement to study the cancer treating gene, BNO69. The gene delivery system from LSUHSC-S will be combined with Bionomics’ gene discovery platform (Angene) to develop a new cancer therapy.

Dr J Michael Mathis, Associate Professor of Cellular Biology and Anatomy and Director of the LSUHSC-S Gene Therapy Center, Louisiana Gene Therapy Research Consortium Inc, said, “The grouping of the Bionomics gene discovery platform with our delivery technology and preclinical testing expertise offers great potential for turning new therapeutic genes into clinical applications.”

Tumors require oxygen and nutrients for their survival and are usually located close to blood vessels. In order for tumors to increase in size, they must be able to recruit new blood vessels by a process known as angiogenesis. Bionomics has developed Angene, a drug discovery platform, which combines several genomics tools to identify and characterize novel angiogenesis targets. Dr Mathis's gene delivery technology will help to deliver the gene expression silencing molecules developed from Bionomics’ Angene platform to solid tumors. The combined technology may disrupt blood vessel formation and prohibit tumor growth in cancer patients.

Earlier this year, the US FDA has approved the use of anti-angiogenesis therapeutics to treat colorectal cancer. Dr Deborah Rathjen, CEO and Managing Director of Bionomics, said, “Bionomics has strong expertise in angiogenesis, which is captured in our comprehensive Angene platform and can be used to identify new ways to approach the treatment of cancer and ultimately develop new therapeutics.”

According to Dr Gabriel Kremmidiotis, Director of Cancer Research at Bionomics, over 600 genes have been identified in the Angene platform that could be used to develop new treatments for cancer and other diseases, where anti-angiogenic therapies can be applied. Dr Kremmidiotis said, “This collaboration is exciting for Bionomics as it provides an additional opportunity for us to progress our proprietary angiogenesis genes and gene silencing molecules towards the clinic.”

Dr Mathis added, “Stopping malignant cancer growth has always been the greatest hurdle to increase survival for our patients. Treating malignancies with anti-angiogenic therapies may be particularly useful in those involving the breast, head and neck, and prostate.”
Concerns over Impact of FTA on Pharma Industry

While US President George W Bush signed the free trade agreement (FTA) with Australia at the White House without hesitation and opposition, the Australian Federal Government faced the strong demand from the Labor Party to amend the agreement and protect the Pharmaceutical Benefits Scheme (PBS) in the country.

The PBS subsidizes around 80% of all prescription medicines available in Australia. Australians have to pay up to AUD23.70 (US$16.92) for most PBS medicines, while those who have a concession card pay only AUD3.80 (US$2.71). In 2003, the scheme covered about 161 million prescriptions. The cost of the scheme is more than AUD5.1 billion (US$3.64 billion) per year.

However, as the Opposition Leader Mark Latham suggested, the new FTA with the US may pose threat to the system by preventing generic drug to enter the market. US drug firms often use the “evergreening” ploy, i.e. to extend the patent of their drugs by constantly claim a new use or make slight changes. The prices of the drugs are thus maintained at high prices.

Prof David Henry, former member of the Pharmaceutical Benefits Advisory Committee (PBAC) responsible for recommending new drugs for PBS, said the FTA introduced a more commercialized environment for companies to exploit evergreening. The prices the Government agrees to pay in PBS for every brand is the same amount — up to the cost of the lowest priced brand. The US industry was trying to destroy this “reference pricing” method.

Latham demanded the government to make amendments on the agreement to penalize “bogus” patents. “We won’t be giving an inch. We will be insisting on our amendments.” However, the Federal Cabinet refused to capitulate the demands and the agreement is now at risk. Australia and the US must exchange letters by 1 October, otherwise the agreement will not come into effect on January 1 as scheduled.

Prime Minister John Howard said, “We are quite willing to accommodate them on something that is sensible but we are not going to accommodate them on something that will produce a bad law, the will unsettle the existing intellectual property laws in this country.” He said the amendment, which creates fines for any company try to stop less expensive generic drugs to be used, would undermine the deal and send the public the message that it adversely affected the scheme. “If a spurious claim is made for an extension of a patent then the court will deal with that,” said Prime Minister.

The government insisted that it would not have signed the agreement in the first place if it diminished the benefits scheme in any way. Howard said, “There’s nothing in the FTA that gives the big American companies anything. They wanted something that would have delayed the coming onto the market of generics and I knocked that back.”

Latham said Labor Party would fight for what it believed in and the fate of the deal was up to the government. He said, “This is in Mr Howard’s hands. If he wants to knock back our amendments, we won’t be budging an inch.”

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ANTISENSE THERAPEUTICS’ MS DRUG ENTERS PHASE 2 CLINICAL TRIALS

Antisense Therapeutics Limited, the Australian pharmaceutical company specialized in the development and commercialization of novel antisense therapeutics, and the US-based Isis Pharmaceuticals announced the success of their joint Phase I study for the multiple sclerosis (MS) drug ATL-1102. A Phase 2 clinical trial is expected to begin in the second half of the year for ATL-1102, a second-generation antisense inhibitor of VLA-4 (Very Late Antigen-4). Inhibitors of VLA-4 has been shown to have positive effects in multiple animal models of inflammatory diseases including MS.

Multiple Sclerosis is a lifelong chronic disease that slowly destroy the central nervous system, commonly diagnosed in patients aging from 20 to 40 years old. Based on results, 6mg/kg/week of ATL-1102 appeared well tolerant and had been selected as the proposed dose for Phase 2 development.

ATL-1102 is an inhibitor of CD49d, a sub-unit of VLA-4. The inhibition of VLA-4 may prevent white blood cells from entering the nervous system to stop the progression of MS. The double-blind, randomized, dose-escalated, placebo-controlled Phase 1 study evaluated the pharmacokinetic and safety profile of ATL-1102 in 54 healthy volunteers, ATL-1102 was either delivered in an intravenous (IV) or subcutaneous (SQ) formulation. The drug was found to be well tolerant, while the most commonly reported side effects were mild conditions such as flu-like symptoms and occasional injection site reactions. The trial was conducted at the Charterhouse Clinical Research Unit of the Ravenscourt Park Hospital in London.

Antisense Therapeutics is in the process of preparing an application to conduct a Phase 2a clinical trial in MS patients. The trial is to be conducted in Europe and the clinical trial application will be filed with an appropriate European regulatory authority. Mark Diamond, CEO of Antisense, said, “We are pleased with the favorable results of this trial which, along with preclinical data, gives us critical dose information allowing us to move confidently to the next stage of clinical development.”

Antisense Therapeutics’ technological partnership with Isis Pharmaceuticals consists of Isis granting Antisense Therapeutics rights to use Isis technology to commercialize antisense drugs to a number of drug targets. Isis scientists have produced over 400 scientific publications on antisense, and have several partnerships with major pharmaceutical companies.

The collaboration agreement with Isis provides access to and assistance in expanding Antisense Therapeutics’ drug pipeline, including access to the rapid generation of antisense lead compounds to our potential therapeutic targets. Antisense Therapeutics have also agreed a list of potentially exciting research targets with Isis and can, during the R&D phase, select those with the most commercial potential to exclusively market and sell. This includes
an exclusive license to a drug in Isis’ pre-clinical pipeline, ISIS 107248 (under the new code name ATL1102), which ATL will take through clinical development for multiple sclerosis, and access to Isis manufacturing for provision of bulk quantities of antisense compounds for clinical trials.

“These data are consistent with the results of other second-generation antisense drugs demonstrating the predictability of the antisense platform,” added Dr Stanley T Cooke, Chairman and CEO of Isis Pharmaceuticals. “We continue to make excellent progress with our second-generation antisense drugs with results announced from three trials so far this year and we expect to continue that clinical momentum throughout 2004.”

About Antisense Therapeutics

Antisense Therapeutics’ strategy is to gain access to the best enabling antisense technologies through partnerships with key antisense technology leaders, to create antisense drugs for diseases where there are large and/or poorly met markets, in collaboration with Antisense Therapeutics’ technology and research partners, to out-source preclinical and clinical testing of the candidate drugs to expert contractors, and to commercialize the drugs that are shown to be successful in pre-clinical and/or clinical testing by entering into licensing deals or other partnerships with major pharmaceutical companies.

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About Isis Pharmaceuticals

Isis Pharmaceuticals, Inc. is a genomic drug discovery and development company focused exclusively on the untapped therapeutic target, RNA. The goal of Isis is to develop new medicines that will improve patients’ lives. Isis will strive to accomplish this goal using the technologies the company has invented to discover drugs. Isis’ novel approaches also enhance the drug discovery and development productivity of their pharmaceutical company partners.

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Cancer Vac Ltd, subsidiary of Prima BioMed Ltd, has begun the Phase II trial of its immunotherapy technology on patients with ovarian cancer. The treatment is unique that it is patient-specific — they are treated with their own cells after being modified in the laboratory.

The cancer treatment consists of two elements: the Mannan Fusion Protein (MFP) product and the Dendritic Cell Therapy process. The principal behind this technology is to increase the body’s response to cancer cells by manipulating specialized cells of the immune system called dendritic cells (DC). These cells are isolated from the patient’s blood and then are exposed to the MFP in the process.

Dr Paul Mitchell, Principal Investigator of Austin Hospital, explained further, “Once treated in the laboratory, these cells are returned to the patient to activate the immune system against Mucin-1, a cancer protein expressed in a number of different cancers including ovarian tumors.” DC returned to the patient’s immune system will interact with T-cells, which are responsible for setting up an immune attack. It has been found that, in early trials, the strength of the T-cell attacks increases after the process.

The Phase II trial will recruit up to 20 ovarian cancer patients referred by gynecological oncologists from Mercy Hospital, Monash Medical Center and the Royal Women’s Hospital. Seven treatments will be given to the patients within 12 months of the study. During the period, patients’ blood level of CA125, which is a sensitive measure of tumor size, will be monitored.

Dr Mitchell said, “A major advantage of Cancer Vac’s technology is that relatively long term treatment with this proposed therapeutic approach appears to have no, or minimal, side effects.” It is reported that 20% of the patients from the Phase I trial have remained on treatment for over 2.5 years and both are still doing well. “Due to the nature of the therapy we believe there is no reason why it cannot be continued indefinitely as long as proving beneficial to the patient,” Dr Mitchell added.

(Corporate URL: www.primabiomed.com.au)
Regenera Receives Human Ethics Approval for Visagen Phase III Trial

Regenera Limited has received the first human ethics committee approval to start its Phase III human clinical trials on Visagen. The study will be conducted at the Singapore Eye Research Institute to help treat patients with diseases at the back of their eyes.

Regenera has been developing treatments for diseases of the back of the eye, such as age-related macular degeneration (AMD) and diabetes-related (D-R) eye diseases. In Australia, there are about 800,000 people suffer from macular degeneration, while a 15 million in the US. On the other hand, WHO estimated there are 150 million people have diabetes world wide, among which 75% have D-R eye diseases.

Visagen, Regenera’s main product, is a formulation of the synthetic steroid, triamcinolone acetonide (TA), a proven treatment of AMD. The effectiveness of TA in treating these eye diseases has been shown in previous clinical study. Dr William Ardrey, CEO of Regenera, said, “We are pleased to receive the ethics approval for our first clinical trial, for indication of Cystoid Macular Edema to be treated with Visagen.”

The Phase III trials in Singapore will expand soon and further recruit 30 patients for three other indications, including AMD, Uveitis, Diabetic Macular Edema, which makes the total participants be 120.

About Regenera Ltd

Regenera targets opportunities in eye diseases with an inflammatory component involving the “back of the eye” — a rapidly developing, lucrative multi-billion dollar healthcare marketplace.

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Relenza Dispute between Biota & GSK

GlaxoSmithKline was ordered by the Victorian Supreme Court on 10 August 2004 to hand over a suite of internal documents, the first batch of discovery documents, to Biota Holdings Limited (ASX:BTA) concerning the latter’s product, Relenza. The trial judge ordered the documents to be made available by 15 October, while some have to be handed in within two to three weeks.

On 5 May 2004, Biota issued a writ in the Victorian Supreme Court claiming breaches of contract and fiduciary duties by the worldwide GSK group for failing to promote and support Relenza. The drug, discovered by Biota scientists in 1989 with CSIRO and Victorian College of Pharmacy, was the first in a new class of broad-spectrum anti-flu drugs, known as neuraminidase inhibitors* (NAI).

GSK have to provide documents related to the its level of marketing and promotional support provided to Relenza, conduct of the trials of Relenza, and the conduct of the worldwide launch of Relenza. Minutes and papers of board meetings, corporate executive committee meetings, and product development committee meetings will be revealed to the UK based pharmaceutical company.

Peter Molloy, Biota’s CEO, said, “Biota is pleased that the litigation is proceeding at a good pace and that we have obtained access to GSK’s internal materials at this early stage. We continue to believe that our case is very strong and now look forward to deepening our understanding of what happened to Relenza in the light of GSK’s own documents.”

The trial judge expected completion of full discovery by GSK by approximately February to March next year, already a speedy timetable in a case involving such a large volume of documents.

* NAI are effective against both “A” and “B” strains of influenza. It is estimated that the sales of NAI have grown to AUD500 million in 2003/04. Nonetheless, Relenza only have 2% of the market share since GSK’s withdrawal of support.
Rockeby Biomed Test
SysCan3 on Newborns in US

Rockeby Biomed Ltd (ASX:RBY) and Duke University together is studying Rockeby’s SYSCAN3, a diagnostic for fungal infections, on newborn infants with the sponsorship from the National Institute of Child Health and Human Development in the US.

The studying is conducted at 16 major research hospitals in the US, testing the blood samples from 1,750 babies with birthweight 1,000g or less. Systemic candidiasis, invasive infection caused by Candida in organs like liver, spleen and kidney, is the fourth highest incidence of hospital-acquired blood infection in the US. This fungal infection usually occurs in patients with their immunology suppressed.

The current diagnosis method of the infection is with repeated culture of a normally sterile body fluid like blood. This culture technique can identify about 50% of the cases. The mortality rate of Candida infection in very premature babies is high, due to the delay or even absence of diagnosis. SYSCAN3 is more convenient to use than the traditional diagnosis methods as it can be used in a standard serology laboratory without extra equipment or training beforehand.

Dr Sze-Wee Tan, Managing Director of Rockeby, said, “This trial provides an excellent testing ground for SYSCAN3. The diagnosis of Candida infection in extremely low birthweight babies in the hospital environment has traditionally presented major challenges.” With the evaluation of the new diagnostic tests, it is hoped that the early diagnosis of neonatal candidiasis can be improved.

SYSCAN3 will be compared with three other tests for candidiasis, which are based on different technologies to that used by Rockeby, for the detection of candida in the blood samples collected.

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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AstraZeneca Outlines Plan for Expansion of India-based Operations

Global pharmaceutical giant AstraZeneca has outlined its ambitious plans to increase its operations in India, having taken account of the impending changes in the country’s patent laws that would put India on par with developed countries on these areas. This push is announced by the company chairman, Percy Barnevik, on a recent trip — he said that India has great promise in the areas of research and development and clinical trials.

The announcement came in spite of recent developments in the stock markets, where AstraZeneca had recently de-listed its shares from the Indian stock exchanges. Also, AstraZeneca had been rocked by Indian generic manufacturer Dr Reddy’s lodging of a drug master file to create a generic version of gastric ulcer drug Nexium, one of AstraZeneca’s flagship product.

AstraZeneca India, which runs the conglomerate’s Indian pharmaceutical business, has been operating a new research center in Bangalore last year and Barnevik noted that the Bangalore R&D unit was promising. The Bangalore R&D center had started with a focus on tuberculosis research, one of four R&D laboratories run by AstraZeneca that focuses exclusively on drug discovery. The other three labs are located in the United States, Canada and France.

The plans for expansion in India is part of the grand scheme of things at AstraZeneca, where the company seek development potentials in countries such as Egypt, Mexico and India. Having played a role in AstraZeneca’s push in the developing world and being involved with various Indian companies for four decades, Barnevik now wants his company to capitalize on the eventual growth of the developing world markets.

About AstraZeneca

Employing 58,000 people across the globe, AstraZeneca is focused on providing new and effective prescription medicines that make a real difference for patients. The global conglomerate concentrates on important areas of medical need — cancer, cardiovascular, central nervous system, gastrointestinal, infection, pain control, and respiratory and inflammation. Backed by a strong research base and extensive commercial skills, AstraZeneca manufactures in 20 countries and sell in over 100.

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Ranbaxy Seeking New CRO for Generic AIDS Drugs

Following World Health Organization (WHO) announcement on three of Ranbaxy’s generic HIV products may not be biologically equivalent to the original patented products, the Indian pharmaceutical company is putting the blame for the debacle on the contract research organization (CRO) that had carried out the bio-equivalence studies.

Hence Ranbaxy has announced that it will be working with a new CRO, and Ramesh L Adige, Ranbaxy’s Vice President of Corporate Affairs, added that it will take a few months for the new results to be submitted to the WHO. Ranbaxy does not rule out the possibility of not involving a laboratory from outside for its future research projects, noting that laboratory tests can be done in-house by the company.

Basically, CROs are accredited labs that are appointed by pharmaceutical companies for the relevant outsourcing purposes. As the WHO clearly states that the drugs were being dropped because the lab which had conducted the bio-equivalence tests did not meet international specifications on the handling of data, Ranbaxy has cause to believe that it was not entirely their fault that the generic drugs had fell out of favor with the regulatory authorities.

Ranbaxy isn’t the only pharmaceutical company from India facing the problem. Cipla suffered a similar fate when an action was taken a few months ago for two of its generic AIDS drugs — incidentally, both Cipla and Ranbaxy had been heavily involved in the supply of cheap generic AIDS drugs to poor countries.

A recent audit was carried out by the WHO on an independent CRO in India, which has been tapped to conduct bio-equivalence studies for many international pharmaceutical companies. The audit found several anomalies in data handling, and a lack of compliance with the good clinical and laboratory practices related to bio-equivalence studies carried out by this CRO on three of Ranbaxy’s HIV/AIDS medicine, or anti-retrovirals* (ARVs).

While the reputation of Ranbaxy may have been salvaged, the company is expected to face some apprehensions still, the doubts raised by experts on whether these cheap generic alternatives produced in India are genuinely of the same standards as the original products.

* Anti-retrovirals are a triple fixed-dose combination pill containing lamivudine, stavudine and nevirapine in two different strengths, and a lamivudine plus zidovudine tablets.
Indian Drug Exports Likely to be Affected by New US Initiatives

With the US FDA having taken steps to promote authorized generics that are produced under license from patent holders, Indian pharmaceutical companies who are making headway into the American generic markets could well be adversely affected in the near future.

The FDA initiatives clearly showed that the American authorities now consider prices of generic drugs to be ruling high during the 180-day exclusivity period, granted to the company which gets the first FDA approval to launch a particular generic medicine. Hence, making it more favorable for authorized generics to be launched during the exclusivity period.

The FDA's official take on these issues is that the marketing of authorized generics helps increase the level of competition and therefore promotes lower prices for pharmaceuticals, particularly during the 180-day exclusivity period. During this period, the prices for generic drugs are often substantially higher than after other generic products are able to enter the market. Allowing eligible generic applicants to waive the exclusivity will enable other generic applicants to market their products sooner.

Previously, the lack of competition allows prices to rule high during this period, whereby leading pharmaceutical firms from India had been focused on being the first to file with the FDA for a range of drugs scheduled to go off patent over the next few years. Now these companies have to settle for a new environment in the US markets, which may or may not have an impact on their businesses.

Recent signs certainly haven not been too encouraging. The FDA had denied petitions submitted by Mylan Pharmaceuticals and Teva Pharmaceuticals, US, seeking to prohibit the marketing and distribution of authorized generic versions of branded products during the period of exclusivity. Another recent petition filed by Pfizer, seeking to prevent generic applicants' waiver of the 180-day exclusivity, was also turned down.

Indian pharmaceutical companies remain confident that the rulings will not have a huge impact on their business, citing the fact that generic prices on the whole are not likely to be affected — and the fact that few companies could compete with the low prices of generic medicine produced by India.
Japan

Takeda Withdraws from Five Joint Ventures

Takeda Pharmaceutical Co announced that it will withdraw from its five joint ventures with companies from different countries and concentrate on new drug development.

The leading drugmaker will sell its stakes in the five joint ventures between 2005 and 2007 to its business partners with a total gain of more than ¥50 billion (US$450 million). The amount acquired will be used to develop new drugs. Takeda hopes to concentrate its financial and human resources in its pharmaceutical business and survive in the increasingly competitive global market.

According to the company officials, the five ventures are a food firm operated with Kirin Brewery Co, an agrochemical venture with Sumitomo Chemical Co, an animal drug firm with US-based Schering-Plough Corp, a vitamin venture with German-owned BASF Japan Ltd and a composite materials firm with Mitsui Chemicals Inc.

Australia

Acyte and Serono Working on Cell Expression Technology

Acyte Biotechnology, a Sydney based company on mammalian cell expression system, will collaborate with Swiss biopharmaceutical giant Serono to develop recombinant proteins. Serono will test the production of pharmacologically active proteins with Acyte's Chinese hamster ovary cell (CHO).

Acyte will provide cell expression systems and engineered host cell lines. Its patented technology for autocrine to grow well in the absence of serum provides for significantly easier and more cost effective purification of different protein from the culture medium. It is suitable for safe and economic production of recombinant biopharmaceuticals and glycoproteins.
Kyowa Hakko Kogyo Co Ltd (KHK), a Tokyo-based pharmaceutical and biotechnology company, has joined hands with the German specialist AnalytiCon Discovery GmbH to search for active molecules from natural products since 2002. After 18 months of hard work, the first biologically active semi-synthetic substance for development of drugs has been identified.

Under the collaboration, KHK provided small natural products including cis-3-hydroxy-proline and trans-4-hydroxy-proline using its microbial technology. AnalytiCon then utilizes the bulk amount of starting material from KHK to develop new compounds by means of their NatDiverse technology, a combination of natural product and combinatorial chemistry. KHK’s pharmaceutical division screens the impressively large amount of compounds resulted from NatDiverse and has found the novel compound that can contribute to the pharmaceutical industry.

Dr Hirofumi Nakano, Director of Kyowa Hakko’s BioFrontier Laboratories, said, “The milestones — thanks to AnalytiCon’s technology — have been reached in a very short time, are a strong incentive to continue our cooperation in this promising sector applying our technology and capacity.”

With the encouraging discovery of the new semi-synthetic compound, the two companies will further combine their microbial strain collections and produce unique natural metabolites for drug developments. Dr Lutz Müller-Kuhrt, CEO of AnalytiCon, is optimistic about the prospects of the collaboration and the possibility of delivering the products they found to the pharmaceutical industry.

About Kyowa Hakko Kogyo Co Ltd

Kyowa Hakko consists of four in-house companies (the Pharmaceuticals Company, Bio-Chemicals Company, Kyowa Hakko Chemical Co Ltd, and Food Company) and the Liquor and Alcohol Division. The Pharmaceuticals Company is involved in the production and sale of pharmaceuticals for medical professionals. It handles more than 50 drugs, such as cardiovascular agents to control blood pressure, antiallergic agents, anticancer agents, G-CSF preparations which reverse leukopenia caused by chemotherapy, agents to increase the activity of the digestive system, and central nervous system (CNS) drugs for the treatment of Parkinson’s disease and epilepsy. At the same time, the Company is involved in research for healthcare worthy of the 21st century and is exploring new drugs distinguishable from any other.

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Lion Takes On Chugai’s OTC Drugs Business

About Chugai Pharmaceutical
The social responsibility of the Chugai Group is to provide the medical community around the world with innovative, high-value-added products and services that treat patient and consumer illnesses, improve quality of life and reduce medical costs, as well as generating a reasonable profit. This is the only way for the Group to make a long-term contribution to society.

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About Lion Corporation
In October 1891, founder Tomijiro Kobayashi established T Kobayashi & Co in Kanda, Tokyo, to trade in the raw materials for soap and matches. Thereafter, T Kobayashi & Co began manufacturing soap and toothpaste, taking the first steps to becoming a manufacturer. However, the toothpaste and soap businesses were to present differences that gradually became more pronounced, while the two companies continued to expand their businesses independently, and merged in 1980 to give rise to Lion Corporation.

Lion Corporation is slated to take over Chugai Pharmaceutical’s business portfolio of over-the-counter (OTC) drugs, which includes health tonic drinks and insecticides, while the insecticide manufacturing business of Chugai’s wholly owned subsidiary Eiko Kasei Co will be handed over to Lion Packaging Co Ltd.

The announcement made by the two companies came in the wake of Chugai Pharmaceutical’s decision to maximize the value of its OTC business by transferring it to a company which places this business as its core strategic area with complementary synergies with other brands — and Lion Corporation is reckoned to be just the right company. By divesting the two companies’ OTC business, Lion’s industry position will be greatly strengthened.

It’s characteristic that Chugai’s OTC business has little duplications with Lion’s existing business, thereby enabling a complementary integration in both technology and marketing areas, and synergistic effects from each party’s resources are expected. Other than transferring its non-prescription products to Lion, it was earlier reported too that Chugai will sell a pesticide manufacturing facility based in the Fukushima Prefecture to a Lion subsidiary in the Chiba Prefecture.

Chugai officials had said that business for its OTC unit had been less profitable than its core prescription drug business, while the pharmaceutical business is also one of the key operations at Lion, a major household and health-care products maker that boasts its own OTC drug division. Japan’s OTC pharmaceutical sector took a beating during the economic recession, which prompted manufacturers to cut prices to survive competition. The recession also left this particular sector in the midst of realignment. Yamanouchi Pharmaceutical Co and Fujisawa Pharmaceutical Co have been making plans to integrate their OTC drug operations under a joint venture, Zepharma Inc, in October.

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The announcement made by the two companies came in the wake of Chugai Pharmaceutical’s decision to maximize the value of its OTC business by transferring it to a company which places this business as its core strategic area with complementary synergies with other brands — and Lion Corporation is reckoned to be just the right company. By divesting the two companies’ OTC business, Lion’s industry position will be greatly strengthened.

It’s characteristic that Chugai’s OTC business has little duplications with Lion’s existing business, thereby enabling a complementary integration in both technology and marketing areas, and synergistic effects from each party’s resources are expected. Other than transferring its non-prescription products to Lion, it was earlier reported too that Chugai will sell a pesticide manufacturing facility based in the Fukushima Prefecture to a Lion subsidiary in the Chiba Prefecture.

Chugai officials had said that business for its OTC unit had been less profitable than its core prescription drug business, while the pharmaceutical business is also one of the key operations at Lion, a major household and health-care products maker that boasts its own OTC drug division. Japan’s OTC pharmaceutical sector took a beating during the economic recession, which prompted manufacturers to cut prices to survive competition. The recession also left this particular sector in the midst of realignment. Yamanouchi Pharmaceutical Co and Fujisawa Pharmaceutical Co have been making plans to integrate their OTC drug operations under a joint venture, Zepharma Inc, in October.
Kyorin and Merck

Collaborate in Antibiotics Research

In an exclusive patent license and collaborative R&D agreement, global pharmaceutical research company Merck will collaborate with Japan’s Kyorin Pharmaceutical Co Ltd in researching infectious diseases. The two companies have been in collaboration since 1998, conducting collaborative research synthetic antibacterial agents for the treatment of community-acquired pneumonia and nosocomial infections. The new agreement extends the current partnership by three years and will provide for future development and licensing of any products that may result from the collaboration.

Under the terms executed by this latest agreement focusing on antibiotics research, Kyorin grants Merck an exclusive worldwide license, excluding Japan, for the development, manufacture and sale of any products that result from the collaboration, while Merck will make milestone payments and pay royalties based on product sales to Kyorin.

In Japan, Kyorin will continue to jointly develop a compound with Banyu Pharmaceutical Co Ltd, a 100%-owned Japanese subsidiary of Merck, under the exclusive license from Merck, and Banyu will co-promote the product with Kyorin. In addition, the two companies will establish a joint steering committee to manage the collaborative research, and to jointly assess and select candidate compounds for further development.

About Kyorin Pharmaceutical Co

Kyorin establish a firm, trusting relationship by concentrating mainly in three medical fields, also through promoting a Franchise Customer (FC) strategy. It places emphasis on the three medical fields with which our products are closely related: respiratory internal medicine, otorhinolaryngology and urology.

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About Merck

Merck & Co, Inc is a global research-driven pharmaceutical products company. Merck discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through its joint ventures.

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Fujisawa’s New Formulation Facilities Completed

Fujisawa Pharmaceutical Co Ltd has completed the construction of its new formulation facilities for micafungin (generic name), a novel candid antifungal agent developed by Fujisawa, on the premise of the Takaoka Plant of Fujisawa Toyama Co Ltd, a wholly owned subsidiary of the company.

Taking into account the brisk sales of the antifungal agent in Japan, Fujisawa decided the construction of new formulation facilities in the Takaoka Plant, with the construction work beginning in October 2003 and its completion in August 2004. The commercial supply is scheduled to start in March 2005.

With the addition of the new formulation facilities, Fujisawa will now be able to fulfill domestic demands on micafungin, or even a possible future increase in demands from overseas. Since its launch, micafungin had been contributing to the treatment of serious fungal infections and is a drug product that’s highly regarded by the medical society in Japan. A sNDA (supplemental New Drug Application) for pediatric use was recently filed in Japan, and the agent was filed in the US, Canada and Europe between 2002 and 2003, currently being reviewed by the authorities for approval.

From now on, the manufacturing process of micafungin would be split between three plants: fermentation in the Nagoya Plant, synthesis in the Toyama Plant of Fujisawa Toyama, and formulation and packaging in the Takaoka Plant of Fujisawa Toyama.

About Fujisawa Pharmaceutical Company Limited

Fujisawa Pharmaceuticals produces and markets pharmaceuticals, medical equipment and supplies, home care business, chemicals and animal health products. The company is one of Japan’s largest drug makers, with its main strength in antibiotics. About 35% of sales come from overseas, much of which is from sales of its immunosuppressive agent Prograf.

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Singapore-headquartered stem cell biotechnology specialist, CordLife, has recently announced that its Boston-based subsidiary, Cytomatrix LLC, has successfully secured a contract with the US Department of Defense (DOD). Worth up to US$1.7 million, the contract concerns the use of CordLife’s patented artificial T cell production technology, in which its 3D cell growth scaffold is configured to produce T cells from stem cells outside the human body for the first time. The contract is expected to run to December 2005.

DOD will utilize this unique system to screen vaccine prototypes under development, thereby understand how the human immune system responds to proposed vaccines, thus determining which are most likely to be effective.

This approach to vaccine screening is expected to reduce both the cost and the time taken to bring vaccines to market. In particular, this vaccine screening system could reduce or eliminate the use of animals in the early stages of vaccine testing, as well as often laborious assays using donated human samples. The development of a standardized, in vitro cellular assay for assessing vaccine efficacy, such as CordLife’s artificial T cell system, could result in savings of years of effort and millions of dollars.

“To the best of our knowledge, this is the first time such an approach is being used anywhere in the world,” said Dr Mark Pykett, President of Cytomatrix. “It is a recognition of the enormous and growing possibilities of our technology. The deployment of the Cytomatrix® in another commercial setting further demonstrates our technology’s potential and bodes well for this company as we develop more applications for use by companies around the world.”

About CordLife Pte Ltd
CordLife Pte Ltd is a leading stem cell biotechnology company. It operates American Association of Blood Banks (AABB) compliant umbilical cord blood and peripheral blood stem cell banking facilities in Singapore and Malaysia.

From its Singapore headquarters, and from its Cytomatrix R&D Division in Boston USA, the company engages in cutting edge adult stem cell research in conjunction with leading institutions.

One of the company’s core technologies is a unique cell growth platform called, “The Cytomatrix®,” a platform that enables cells to grow in three dimensions. Utilizing this platform, the company is working on stem cell expansion, and provides R&D products to researchers around the world.

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