Corporate Office • 600 North Bridge Road • # 12-09/10 Parkview Square • Singapore 188778
Phone (65) 6238 0808 • Facsimile (65) 6295 1108 • info@cordlife.com • www.cordlife.com
Laboratory • 1 Orchard Boulevard • # 08-08 Camden Medical Centre • Singapore 248649
Phone (65) 6238 0820 • Facsimile (65) 62381108

Media	Asia Pacific Bio Tech	Date	15 May 2005
Section	Industry Watch		

Australia

CyGenics Files Investigational New Drug Application

About CyGenics

CyGenics Ltd is a biotechnology and immunotherapy company focused on the development and commercialization of stem cell-related products, services, applications and technologies.

From its headquarters in Australia, CyGenics operates three divisions: Singapore-based CordLife (tissue banking services, in particular, cord blood banking) and Cell Sciences (consumable cell culture products), and Cytomatrix (cell therapeutics and technology development) based in the US.

Leading stem cell biotechnology and immunotherapy company, CyGenics Ltd announced that it had filed an Investigational New Drug Application (IND) with the US Food and Drug Administration (FDA). This IND filing is for its Phase I/II clinical trials, using T-cells produced in its T-cell growth platform, to restore the damaged immune systems of patients. The Phase I/II trials will specifically examine the safety and potential efficacy of this growth platform in reconstituting the immune system of patients with certain cancers of the blood system.

This filing follows on from the announcement made on 18 November 2005 on CyGenics' collaboration with Cell Therapies Pty Ltd, the commercial manager of the Cell Processing Centre within the Centre for Blood Cell Therapies at Peter MacCallum Cancer Centre in Australia. Using CyGenics' patented T-cell production technology which generates T-immune cells from stem cells outside the body, Cell Therapies Pty Ltd will produce the T-cells using the technology for patients enrolled in the planned clinical trials.

The IND is a comprehensive document outlining the technology platform and methodology, how the cell therapy product is manufactured, and the nature of the trial. By filing the clinical trial documents though the US FDA, and adhering to the highest standards in clinical trials, CyGenics ensures that the data derived from the trials will be as widely applicable as possible.

The target patient group for these clinical trials will be patients with lymphoma and leukemia and related diseases, for whom chemotherapy treatment has damaged their immune system. Under the protocol, blood stem cells and skin cells will be extracted from the patients, and grown in the scaffold to produce new T-cells that will be transfused back into the patients. These trials will demonstrate the safety and efficacy of T-cells produced, and are anticipated to commence in Australia in 2005. CyGenics sees these Phase I/II trials as on track for completion by mid-2006.

A successful completion of these trials will place CyGenics among the first in the world to offer safe, efficacious and cost-effective means of producing T-cells for therapeutic uses, addressing a key limitation in the treatment of patients whose immune systems have been damaged. The technology is expected to be applicable to a wide range of malignant diseases, infectious diseases and autoimmune disorders, including patients who have HIV or who have received chemotherapy and/or radiation treatment. Should the initial Phase I/II trials prove successful, CyGenics will move ahead to complete Phase III trials, alone and with partners, to move the product toward commercialization for multiple applications. As these trials near completion, CyGenics intends to develop T-cell production kits for immunotherapy for some diseases, as well as license this technology to research and pharmaceutical companies involved in developing treatments for other diseases.

"We anticipate we will be able to begin work early next year," said Dr. Mark Pykett, chairman of CyGenics' Scientific Advisory Board. "Once all the regulatory processes are complete, we believe we will be able to quickly develop this new technology and help patients around the world who today have few, if any, alternatives. We are proud to be the first company in the world to enter into clinical trials in this field."

cygenics

Contact Details:

CyGenics Ltd

Address: Level 4, 414 Lonsdale St, Melbourne 3000, Australia

URL: www.cygenics.com

cordlife

Contact Details:

CordLife Pte Ltd

Contact person: Paula Sengupta

Address: Room 126, Building 404, Bio21 Molecular Science & Biotechnology Institute, The University of Melbourne, 2 Park Drive, Parkville 3010, Australia

Tel: +1800 333 050

Fax : +61 3 9445 9224

Email: Ausinfo@cygenics.com