

For Immediate Release

CyGenics T cell Clinical Trials Update

Key points:

- FDA consultant appointed – Joyce Lea Frey-Vasconcells, PhD
- A thymus-derived stem cell GVHD study has been completed, with satisfactory results – No GVHD
- A bone marrow-derived stem cell GVHD study will be conducted in early 2006

23 November 2005 – Leading cell therapy company CyGenics Ltd (ASX: CYN) today updated the market on the status of the clinical program for the company's *Ex-Vivo* T cell Production (Artificial Thymus).

CyGenics is pleased to announce the appointment of Joyce Lea Frey-Vasconcells, PhD, Executive Director, PharmaNet Consulting, as FDA consultant. Dr. Frey-Vasconcells has more than 18 years of experience with biologics and pharmaceuticals. Prior to joining PharmaNet, she served more than 12 years at the FDA, most recently as Deputy Director, Office of Cellular, Tissue, and Gene Therapies (OCTGT) with the Center for Biologics Evaluation and Research (CBER). During her tenure at FDA, Dr. Frey-Vasconcells helped develop many of CBER's science and public health policies regarding the regulation of biologic therapies and is considered one of the foremost regulatory experts regarding these therapies.

The company's patented innovative cell production technology generates new T cells from autologous (patient's own) skin cells and bone marrow stem cells, resulting in a broad spectrum of patient-matched T cells for clinical transplantation. The T cells produced may be used to restore the balance, diversity and coverage of a patient's T cell immune system that has been destroyed or altered by disease or treatment.

The company is working towards commencing clinical trials to demonstrate the safety and efficacy of the technology in humans. The trials are targeted at restoring the immune system of immuno-compromised patients.

CyGenics has completed an *in vivo* pre-clinical animal study aimed at assessing the presence or absence of Graft Versus Host Disease (GVHD) using thymus-derived stem cells cultured on skin cells. The study did not demonstrate any GVHD. The company has commenced a further *in vivo* pre-clinical animal study aimed at assessing the presence or absence of GVHD using bone marrow-derived stem cells cultured on skin cells. These studies are necessary to closely mimic the system that will be used in humans.

The company recognises that these further studies will result in the commencement of the clinical trials taking longer than anticipated. However, the *in vivo* pre-clinical animal GVHD studies will provide critical safety data prior to commencing studies in humans.

On receipt of regulatory and ethical approvals, the Phase I/II clinical trials are planned to commence at the Peter MacCallum Cancer Centre in Melbourne.



“The company cannot trade off the significant commercial upside of this technology by rushing into Phase I clinical trial. The additional time and costs related to our decisions now are relatively small.” said Ian Brown, Chief Operating Officer of CyGenics.

About CyGenics

CyGenics is a cell therapy company focused on the development and commercialisation of adult stem cell-related products, services, applications and technologies. From its headquarters in Australia, CyGenics operates four subsidiaries: 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 Boston, USA, and CytoVations (new product development) based in New Jersey, USA. CyGenics is listed on the Australian Stock Exchange, under the symbol CYN. For more information, please visit www.cygenics.com.

For more information, please contact:

General Inquiries

Steven Fang, CEO, CyGenics Ltd Mob: +61 (0)400 933 243 Email: steven.fang@cygenics.com	Ian Brown, COO, CyGenics Ltd Mob: +61 (0)438 565 212 Email: ian.brown@cygenics.com
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Media Inquiries

Rebecca Piercy, Buchan Consulting Ph: +61 (0)3 9866 4722 Mob: +61 (0)422 916 422 Email: rpiercy@bcg.com.au	Ronald Hee, CyGenics Ltd Ph: +65 6238 0808 Mob: +65 9061 9098 Email: ronald.hee@cygenics.com
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