

CBio Secures Another Clinical Trial Milestone

- **Milestone triggers \$1 million payment from Novo Nordisk A/S**
- **Payment follows earlier milestone approvals for clinical trial sites in Central and Eastern Europe**

BRISBANE, 11 March 2010: Australian drug development company CBio Limited (ASX: CBZ) today announced the achievement of a clinical trial milestone under its option agreement with global pharmaceutical leader Novo Nordisk A/S. The agreement relates to the development of XToll, the potential new-generation drug therapy which could provide safer and more effective treatment of autoimmune diseases such as rheumatoid arthritis (RA).

The clinical trial milestone was triggered by the recruitment of the 75th patient into the current 150 patient phase II clinical trial.

“We remain greatly encouraged by progress in the trial and feedback from clinical investigators, and are focussed on completing the trial and receiving the final results,” said CBio Managing Director Jason Yeates.

“We believe that CBio holds an attractive pharmaceutical asset in XToll and that the drug has the potential to address the unmet needs of patients and participate in what is currently a US\$17 billion global market,” Mr Yeates said.

“Many patients are only partial responders to existing therapies and adverse effects from these therapies are a real issue being faced by RA patients every day. Safer and more effective treatments are needed,” he said.

Under the terms of the agreement, Novo Nordisk will make a milestone payment to CBio of US\$1 million.

The agreement was signed in May 2008 and grants Novo Nordisk an exclusive option to negotiate an exclusive licence to CBio’s intellectual property surrounding XToll which is currently in phase II clinical trials at sites across Australia and New Zealand. Additional clinical trial sites in Serbia, Bosnia and Georgia are expected to commence recruitment this month.

Novo Nordisk is a world leader in diabetes care and has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy.

Headquartered in Denmark, Novo Nordisk employs more than 29,000 people in 81 countries and markets its products in 179 countries.

“There is a global search underway by major pharma companies for new RA therapies that are proven to be safer and more effective than therapies now available. We believe XToll has the potential to be a part of this demand pipeline and, most importantly, improve the lives of RA sufferers,” Mr Yeates said.

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ABOUT THE POTENTIAL MARKET FOR XTOLL

While CBio will initially target XToll as a potential RA therapy, the Company believes it may be used to treat a number of other diseases. Global sales for biological therapies for RA were US\$8.6 billion in 2005, rising to an estimated US\$12 billion-plus in 2009 and are forecast to reach over US\$18.5 billion by 2013.

This RA market is currently dominated by three drugs: the “blockbuster” anti-TNF therapies Remicade, Enbrel and Humira. While the primary market for these drugs is in the treatment of RA, they are used as therapies for other autoimmune diseases including Crohn’s disease, ulcerative colitis, psoriaticarthritis and ankylosing spondylitis. It is estimated that one-quarter of Remicade revenues come from indications other than RA; roughly one-sixth of Enbrel revenues come from indications other than RA; and one-eighth of Humira revenues come from indications other than RA.

In 2008 sales of these top three drugs for the treatment of RA were US\$10.9 billion. However, the total global sales of these three drugs in all disease states were in excess of US\$17 billion.

Biological disease modifying anti-rheumatic drugs (bDMARD) have essentially revolutionised the treatment of RA throughout the world, although they are also the most expensive of all available RA treatments. Between 2009 and 2013, the value of the biologic market for the treatment of RA is estimated to grow by a compound annual growth rate of around 11%. Fuelling growth in this market will be a general increase in the uptake of biologics for the treatment of RA as they gain greater acceptance from physicians, the higher levels of patient disease education, and the ageing American and European populations. Apart from patent expirations facing current bDMARD leaders (two leading RA therapies have patent expiry dates in the coming seven years: Enbrel - 2012; Humira – 2016) and new product launches, it is expected that few other factors will slow the growth in this market for the foreseeable future.

Yet there remains a significant unmet need for new, clinically efficacious therapies for RA. The pipeline for rheumatoid arthritis therapies therefore remains strong.