



## Major Government Clinical Study Approved for Anadis' AIDS therapy

Wednesday 22 October 2008

New York and Melbourne, Australia---Anadis Ltd. ([ANX.AX](#) ; [ANDIY.PK](#); [CUSIP: 032517104](#)) announces today that it has been informed by the [Australian National Center in HIV Epidemiology and Clinical Research \(NCHECR\)](#) and the University of New South Wales (UNSW), both in Sydney, that their Institutional Review Board has approved a major, phase IV multi-site randomized double-blind placebo controlled study of Anadis' newest product, [BioGard™](#). In the study, Anadis' BioGard will be used alone and in combination with the new Merck ([NYSE: MRK](#)) anti-AIDS drug [Isentress™ \(raltegravir\)](#) This investigator initiated "CORAL" study is sponsored by NCHECR.

BioGard is Anadis' novel oral therapy contains high affinity anti-LPS antibodies and was recently approved for use by the Australian Therapeutic Goods Administration (TGA). HIV/AIDS continues to be one of the most devastating global diseases. [According to recent estimates](#), 33 million people worldwide have HIV and 25 million have died of it since it was first recognized on December 1, 1981. In the U.S., more than 1.1 million persons are living with HIV and there are 56,000 new cases annually.

The study protocol steering committee and principal investigators include many of Australia's leading AIDS clinical investigators, including Dr. Sean Emery, NCHECR; Dr. Damian Purcell, Head, Molecular Virology Laboratory, University of Melbourne; Dr. Anthony Kelleher, Center for Immunology and Professor David Cooper, St. Vincent's Hospital, Sydney and the NCHECR.

During this past year, thanks in part to groundbreaking science sponsored by the [U.S. National Institutes of Health \(NIH\)](#), there has been renewed recognition that the gastrointestinal system plays a critical role in early infection and later development of HIV/AIDS. In particular, the chronic immune activation in the GI tract is now a recognized cause of immune depletion, leading to treatment failure.

The CORAL study is designed to demonstrate that Anadis' BioGard, supplementing Merck's newest anti-viral drug raltegravir (which is the first of a new class of HIV drugs to receive FDA approval, the [integrase inhibitors](#)), together and separately, can reduce GI immune activation and allow rebuilding of immune competence in those HIV patients with continuing HIV viral replication.

**AUSTRALIA**  
L1 39 Levenson St,  
North Melbourne, VICTORIA, 3051  
Tel (61) 3 9018 4880 Fax (61) 3 9018 4881

**USA**  
The Empire State Building  
350 Fifth Avenue 59th Floor  
New York, N.Y. 10118  
Tel 646 402 5289 Fax 646 390 3238



Dr. Zeil Rosenberg, Anadis CEO, noted “This important clinical study will hopefully show that BioGard, the only approved oral, high affinity, anti-LPS antibody formulation in the world today, can directly impact HIV disease progression by enhancing immune function and reducing local immune activation. Study data will hopefully show that [BioGard](#) is a safe and effective adjunctive treatment for all HIV/AIDS patients to enhance [combination antiretroviral therapy](#).”

Anadis is in advanced discussion with leading researchers from the US National Institutes of Health and their collaborating clinical partners for additional, complementary studies of BioGard in patients with newly diagnosed disease.

Dr. Oren Fuerst, VP Business Development of Anadis stated: “BioGard could potentially be used in both the developed and the developing world, and as an adjunct to all current antiretroviral treatments. While we could market BioGard on our own, we are in discussion with commercialization partners, and we expect to announce such deals after we obtain the results of the CORAL study, expected during calendar year 2009.”

[Anadis Limited](#) ([ANX.AX](#); [ANDIY.PK](#); CUSIP: 032517104) is a biopharmaceutical company focused on antigen-primed, dairy-derived health products. Anadis’ proprietary and low-cost antibody manufacturing technology enables it to rapidly develop polyclonal antibody and other protein-based oral therapies to a range of important infectious and immune-mediated diseases.

Contact:

Dr. Oren Fuerst- VP, Business Development  
Email: [oren@anadis.com](mailto:oren@anadis.com)  
Tel +1 646 259 3321

Gran Rawlin – VP, Research and Development  
Email: [grant@anadis.com](mailto:grant@anadis.com)  
Tel: +61 3 9018 4880

Arie Nudel- Investor Relations  
Email: [arie@anadis.com](mailto:arie@anadis.com)  
Tel: +61 3 9014 4880

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