



CLINICAL PHASE PILOT STUDY RESULTS

SINGLE CAPSULE MYOCONDA® DEMONSTRATES A GOOD SAFETY PROFILE

Sydney, Australia, 18 February 2008. **Giaconda Ltd (ASX: GIA)** today announces the results of a study investigating the predicted effectiveness and safety of Myoconda® for the treatment of *Mycobacterium avium paratuberculosis* (MAP) infection in Crohn's Disease. The components, Rifabutin, Clarithromycin and Clofazimine, are all approved for use in humans as separate agents. This pilot pharmacokinetic study was designed to optimize the formulation of Myoconda® by combining the three components into a single capsule following discussions with the US Food and Drug Administration (FDA). The study was included as part of the IND (Investigational New Drug Application) that was approved by the FDA last year.

The study design used 24 normal, healthy, non-smoking male and female subjects under a randomized, open-label, single-dose, 1-way 2-arm, parallel design. There were no significant or serious adverse events reported in either arm.

The significant finding was that in the 'all-in-one' formulation the blood concentrations of Rifabutin and Clarithromycin achieved were more optimal, for both components causing no significant adverse effects with potentially increased efficacy. Previous studies indicated that concomitant use of these two agents can elevate the levels of Rifabutin in the blood, increasing the potential for side effects and reduce the levels of Clarithromycin, thus potentially reducing the efficacy of this important active ingredient. The new formulation has improved both the pharmacokinetic availability of both ingredients and reduced the side effect potential, providing a novel and significant improvement on previous formulations. A patent application has been filed by Giaconda Ltd to protect the novel formulation technique.

"This study is an important step in the development of a solid safety and efficacy profile for Myoconda in the treatment of MAP infection in Crohn's Disease, and reflects the resourceful and innovative support we have received from our formulation consultants," said Patrick McLean, CEO of Giaconda.

"The metabolic benefits of the new formulation add value to an already promising product. This result bolsters Myoconda®'s already impressive record in the clinic, which, with the new formulation patent, will help support our ongoing negotiations with potential distribution and marketing partners and in our fundraising efforts," Mr McLean added.

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About Giaconda Limited

Giaconda Limited is a life sciences company involved in developing and commercialising innovative and cost effective medical therapies in the field of gastroenterology. Giaconda's products are targeted towards the treatment of serious conditions that are not adequately addressed by any existing therapy. In this way, Giaconda's products are intended to satisfy these significant unmet medical needs of the gastrointestinal market. The Giaconda portfolio consists of five products, all of which are novel combinations of known compounds. Giaconda has two lead products, Myoconda® for the treatment of Crohn's Disease and Heliconda® for the treatment of resistant *Helicobacter pylori* infection.

For more information please visit www.giacondalimited.com

About Myoconda® – A Combination Antibiotic Therapy for the Treatment of Crohn's Disease

Myoconda®, the Company's Anti-MAP therapy for the treatment of Crohn's Disease is a combination

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of three registered anti-mycobacterial drugs - rifabutin, clarithromycin and clofazimine. These three drugs are widely marketed world-wide for the treatment of mycobacterial and other infections. Myoconda[®] presents these three compounds in a specific patented combination in a unique format. The combination has undergone a Phase III trial in Australia across 22 centres and has demonstrated the highest remission rates of any major trial published to date with fully 66% of all patients in remission at 16 weeks. Giaconda has completed formulation development, manufactured clinical trial product material under cGMP conditions and has just completed a pharmacokinetic study in healthy humans. The FDA has approved a Phase II/III clinical study as part of the regulatory path toward registration in the US.

Myoconda[®] is based on the proposition that MAP infection is a significant factor in Crohn's Disease. Prof. Borody has long been at the forefront of this approach, which is gaining increasing acceptance among gastrointestinal specialists worldwide. Prof. Borody has published significant data demonstrating that patients treated with anti-MAP combination therapy such as that found in Myoconda[®] experience long-term remission of clinical symptoms and inflammation, some for up to nine years.

About Crohn's Disease

Crohn's Disease is a chronic inflammatory disease of the gastrointestinal tract. The disease most commonly affects the lower small intestine and the large intestine. Symptoms of Crohn's Disease include abdominal pain, diarrhoea, fever and weight loss. In severe cases, the intestine can become blocked or obstructed, requiring surgery. Young patients with Crohn's Disease may also suffer growth retardation. Patients suffering Crohn's Disease are conventionally treated with drugs aimed at reducing inflammation and other associated symptoms. The cause of Crohn's Disease is unknown, thus the standard treatments aim to treat symptoms rather than the cause of the disease. The bacterium *Mycobacterium avium* ss. *paratuberculosis* (MAP) is the lead candidate as an infectious cause of Crohn's Disease. By targeting the MAP infection, Myoconda[®] is designed to address a possible source of the disease, rather than attempting to merely alleviate its symptoms.

Except for historical information, this news release may contain forward-looking statements that reflect the Company's current expectation regarding future events. These forward looking statements involve risk and uncertainties, which may cause but are not limited to, changing market conditions, the successful and timely completion of clinical studies, the establishment of corporate alliances, the impact of competitive products and pricing, new product development, uncertainties related to the regulatory approval process, and other risks detailed from time to time in the Company's ongoing quarterly and annual reporting.

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