



## **Australian study of anti-MAP treatment in Crohn's Disease published showing highest ever remission rates**

**Sydney, Australia 18 July 2007. Giaconda Ltd (ASX: GIA)** announced that the results of the first large-scale, randomized, placebo-controlled clinical study using anti-MAP therapy have been published in the journal *Gastroenterology*. The clinical study, undertaken in 1999, was conducted prior to Giaconda acquiring the intellectual property for the anti-MAP therapy, which has now been further developed and is known as Myoconda<sup>®</sup>. The publication, titled "Two-Year Combination Antibiotic Therapy with Clarithromycin, Rifabutin and Clofazimine for Crohn's Disease", presents the results of this Phase III trial. These three active ingredients are atypical anti-mycobacterial antibiotics with unique modes of action that work on an intracellular basis and are thus referred to as anti-MAP therapy.

As stated in the Company's 2005 IPO prospectus, Giaconda's conclusion concerning this study is that despite under dosing and a study design that did not reflect the current understanding of how anti-MAP therapy works; the results represent some of the highest remission rates ever published for Crohn's Disease. Giaconda's interpretation of the results of the 2 year clinical study is that the anti-MAP therapy provided a more effective treatment with a more favourable side effect profile than current conventional therapies.

While the trial did not meet its endpoint which was to cure Crohn's Disease, it did provide some very positive data that has been used in the further development of Myoconda<sup>®</sup>. The current indication being sought for Myoconda<sup>®</sup> is to specifically treat patients with Crohn's Disease infected with *Mycobacterium avium spp paratuberculosis* (MAP). The positive data from the published trial relates to the anti-MAP arm of the trial which performed significantly better than the placebo arm while patients were on active therapy. Two thirds of the patients (66%) being treated with anti-MAP therapy were in full remission at 16 weeks versus the placebo arm of 50%. This was a highly significant difference (p 0.0189). At 52 and 104 weeks the remission rates were 41% and 33% respectively. As a point of reference, although not an anti-MAP therapy, the Crohn's Disease treatment Infliximab (commercially branded Remicade) received FDA approval with 39% remission at twelve weeks.

It should be noted that both active and placebo groups maintained use of the therapies they were on at the time of initiation in addition to study induction doses of prednisolone, a commonly used steroid treatment for Crohn's Disease. The active treatment of the placebo group would tend to increase the remission rates for that group.

As the trial demonstrated, the significant benefit of the treatment stops once active therapy ceases. On the basis of this knowledge and published clinical results of Prof. Borody's treatment in his practice, Giaconda has developed Myoconda<sup>®</sup> as a long term therapy which will require an ongoing, correctly formulated maintenance dose to secure disease remission.

There are significant dosage and formulation differences between the anti-MAP therapy used in this trial and the current formulation of Myoconda<sup>®</sup>. The dose of clofazimine used in the trial was half the dose used in the current formulation of Myoconda<sup>®</sup>. The use of antibiotics at low doses is problematic not only in terms of short-term effectiveness, but also leads to a greater chance of antibiotic resistance in the long term. The current formulation of Myoconda<sup>®</sup> has been altered to address these issues with a higher dose of clofazimine being used. The active ingredients have also been combined in a single Myoconda<sup>®</sup> capsule to reduce pill burden for the patients.

It should also be noted that the published study did not test for MAP and therefore may have included patients suffering from Crohn's Disease unrelated to MAP, diluting the results for those with MAP-related Crohn's. As stated above, the indication being sought for Myoconda<sup>®</sup> is to treat patients with Crohn's Disease infected with MAP. The next trial on Myoconda<sup>®</sup> will screen for MAP infection so that only MAP infected patients will be included in the trial, which will provide more accurate and targeted data with which to carry the development of Myoconda<sup>®</sup> forward.

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### **About Giaconda Limited**

Giaconda Limited is a biotechnology company involved in developing and licensing 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<sup>®</sup> for the treatment of Crohn's Disease and Heliconda<sup>®</sup> for the treatment of resistant *Helicobacter pylori* infection.

For more information please visit [www.giacondalimited.com](http://www.giacondalimited.com)

### **About Myoconda<sup>®</sup> – A Combination Anti-mycobacterial Therapy for the Treatment of MAP in Crohn's Disease Patients**

Myoconda<sup>®</sup>, the Company's Anti-MAP therapy for the treatment of MAP in Crohn's Disease is a combination 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<sup>®</sup> presents these three compounds in a specific patented combination.

Myoconda<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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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