FDA approves Myoconda® IND for MAP in Crohn’s Disease

Sydney, Australia 24 April 2007. Giaconda Ltd (ASX: GIA) today announced that the US Food and Drug Administration (FDA) has approved the Company’s Investigational New Drug application (IND) for the clinical development of Myoconda® to treat patients with Crohn’s Disease infected with Mycobacterium avium spp paratuberculosis (MAP).

The Company understands that its lead product, Myoconda®, is the first therapy to be submitted to the FDA for this indication. There are no anti-MAP therapies approved for use in Crohn's Disease.

MAP is considered as the most likely infectious cause of Crohn’s Disease. Current treatments on the market are indicated for symptomatic treatment of the disease. On the basis of clinical experience, Giaconda believes that by treating and controlling the underlying MAP infection, Myoconda® will offer a valuable therapy to patients who do not respond to currently available therapies. Current research indicates that between 40 – 50% of Crohn’s patients are MAP positive. Patients can be diagnosed with MAP infection using a blood test.

The IND approval allows the Company to commence the next clinical trial of Myoconda® in the USA. The Company is continuing preparations for the multi-centre, double blind, placebo controlled, Phase II/III trial. Before the trial commences the Company will conduct pharmacokinetics investigations, test the drug manufacturing for the trial and make ethics submissions to the various clinical trial centres. It is anticipated that the trial will commence by the end of 2007.

Since the previous Phase III trial, which was undertaken prior to Giaconda acquiring Myoconda®, an alternative development program, substantially different from its predecessor, has been undertaken based on further understanding of the mechanism of action of Myoconda®. This has resulted in a new product based on the original research. The Phase II/III trial is necessary due to the changes in the drug format which will now be an all-in-one oral capsule, the increased dosages and the new indication being sought.

“We are very pleased to have reached this key milestone in the development of Myoconda®. There is clearly a need for this type of therapy for the substantial subset of Crohn's Disease patients infected with MAP who are not well served by current therapies,” said Patrick McLean, CEO of Giaconda

“Giaconda is now another step closer to achieving its aim of bringing this product to market as soon as possible for the benefit of patients who are infected with MAP. The development of Myoconda® is supported by a significant number of opinion leaders in the field”.

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® 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 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.

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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