

Giaconda's Phase II Study on Heliconda published – over 90 % eradication in patients with resistant *Helicobacter*

Sydney, NSW, January 30, 2006 Giaconda Limited (ASX: GIA), announced today that the results of the Phase II Clinical study of its *Helicobacter pylori* (*H. pylori*) eradication therapy Heliconda have been published in the February, 2006 issue of *Alimentary Pharmacology and Therapeutics*. In the study, Heliconda achieved eradication in 90.8% of 130 patients who had failed one or more eradication attempts using standard triple therapy. Side effects were mild and the presence of clarithromycin or metronidazole resistant strains had no significant impact on the eradication rates.

Prof. Tom Borody, Giaconda's Chief Medical Officer said, "In light of the increasing resistance to antibiotics used in the present standard of care therapy, this study proves that Heliconda can be an important addition to the armamentarium of the physician who actively treats *H. pylori*. It reduces the concern about resistant strains of *H. pylori* and this is especially important for the Primary Care Physician who does not normally test for resistance. To date there have been no reported strains of rifabutin resistant *H. pylori* so Heliconda can safely be used as rescue therapy. It may even be used as first line therapy in patients with a history of frequent antibiotic use with less concern about the resistance issue."

About *Helicobacter pylori*

Helicobacter pylori (*H. pylori*) is known to be the major contributing cause of chronic histological gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. Around 50% of the world population is believed to be infected with *H. pylori*. It is estimated that in clinical practice, eradication failure after primary treatment outside clinical trials is between 20-40%. *H. pylori* eradication is the key to curing most peptic ulcer disease. Its eradication may also aid in the prevention of gastric cancer. In the last few years, *H. pylori* has been found to be increasingly difficult to eradicate using known, marketed antibiotic agents. This is particularly so using regimens containing metronidazole or clarithromycin due to the progressive development of *H. pylori* resistance. It is also known that, though many antibiotics can suppress *H. pylori* growth in vitro, the activity of the same antibiotics in vivo may be quite ineffective. Hence, the development of effective in vivo eradication combinations for *H. pylori* infection can be difficult to achieve and requires human clinical trials in addition to knowledge of microbiological sensitivity. Furthermore, single antibiotics have not eradicated *H. pylori* effectively and double antibiotic combinations have also resulted in poor eradication rates in most studies. The recommended current primary treatment regime is triple therapy, consisting of a proton pump inhibitor (PPI) and two antimicrobial agents; clarithromycin with either nitromidazole or amoxicillin. Clarithromycin resistance is not common in the general population, but can subsequently occur in up to 67% of strains isolated from patients who failed eradication therapy. In Australia the proportion of *H. pylori* infections resistant to clarithromycin is increasing, from 3-5% in 1996 to 11-17% currently. Resistance appears to be developing faster in countries where clarithromycin is being used frequently, particularly in the US and in Europe.



About Heliconda

Heliconda is positioned as a therapeutic rescue therapy similar to the currently available triple therapies on the market for primary treatment. This product consists of rifabutin in conjunction with a proton pump inhibitor and an antibiotic (usually amoxicillin). Heliconda's targeted disease indication will be patients who have developed resistance to currently marketed *H. pylori* treatments

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. Both of these products are ready for Phase III clinical trials, with a Phase IIIa already complete for Myoconda.

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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