



14 December 2005

## Giaconda presents Myoconda<sup>®</sup> to FDA & MHRA supported by a BioBusiness Program Grant

Giaconda Limited (ASX: GIA), made presentations to the US Food and Drug Administration (FDA) and UK Medicines and Healthcare products and Regulatory Agency (MHRA) for pre-IND meeting / Scientific Advice discussion regarding Myoconda<sup>®</sup>, the company's lead compound. The presentations were made on December 6<sup>th</sup> and 7<sup>th</sup> respectively and were done with the assistance of an international regulatory consulting company CanReg Inc located in Dundas, Ontario, Canada. The pre-IND meeting / Scientific Advice discussion were supported by a matching fund BioBusiness Program Grant for assistance in regulatory efforts to obtain approvals for a Phase IIIb clinical study. This clinical study on the Myoconda<sup>®</sup> triple therapy for Crohn's Disease patients is in development.

An IND (Investigative New Drug) application is an application for approval for the use of an investigative new drug in a clinical study and is an important step in the regulatory approval process in the US. The Scientific Advice discussion with the MHRA forms the basis of the clinical development plan for Myoconda<sup>®</sup> in Europe.

In relation to the BioBusiness Program Grant, Ms Rosa Surace, Giaconda's COO said "The grant is a very welcome contribution to our work and demonstrates the confidence that the NSW Government has in the future of Giaconda and our ability to commercialise our products around the world. More fundamentally, I believe it reflects the State Government's desire to help many of the 30,000 Crohn's patients here in Australia who have exhausted their therapeutic options and have no where else to go for help."

### **About the BioBusiness Program**

The BioBusiness Program is sponsored by the Small Business Development Division of the NSW Department of State & Regional Development under the BioFirst banner. BioFirst is the New South Wales biotechnology strategy, which aims to position NSW as a leader in biotechnology and to maximise the social, environmental and economic benefits of this sector for the people of NSW.

One element of this strategy is the BioBusiness Program, which recognises that while this industry is technology driven, there are business challenges to be met in growing the individual enterprises that make up the industry.

A key driver is the need to close the gap between basic research and commercialisation. The BioBusiness Program will, in many instances, involve an enterprise improvement process, covering a number of projects over a period of two or more years, drawing assistance from one or more of the components of the Program described below. The objectives of the BioBusiness Program are to:

- help develop world class export-oriented products, services and businesses;
- support the biotechnology pipeline to take basic research through development to commercialisation; and
- promote leadership and training.

GIACONDA LIMITED

Suite 1307, Level 13, 370 Pitt Street, Sydney NSW 2000 Phone: [612] 9266 0440 Fax: [612] 9266 0441

email: [info@giaconda.net.au](mailto:info@giaconda.net.au)

[www.giaconda.net.au](http://www.giaconda.net.au)



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

For more information, please visit [www.giaconda.net.au](http://www.giaconda.net.au)

*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.*

ISSUED FOR : GIACONDA LIMITED  
FOR FURTHER INFORMATION : MS ROSA SURACE, CHIEF OPERATING OFFICER, GIACONDA LIMITED  
TEL: (02) 9266 0440 (BUS): [www.giaconda.net.au](http://www.giaconda.net.au)

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