



GIACONDA ANNOUNCES COMMENCEMENT OF CLINICAL TRIAL FOR HEPACONDA[®] IN HEPATITIS C

Sydney, Australia 25 June 2007. Giaconda Ltd (ASX: GIA) announced that a Phase IIa clinical trial of Hepaconda[®] for the treatment of Hepatitis C virus (HCV) genotype 1 refractory to current therapy has commenced. The study is being carried out by the Centre for Digestive Diseases and the first patient has been enrolled in the trial and begun treatment.

The current standard treatment for chronic HCV has limited efficacy, especially in genotype 1 and poor tolerability with the result that many patients cease treatment. Genotype 1 Hepatitis C virus has the lowest response rate to standard treatment compared to other genotypes and carries a higher risk of post-treatment relapses and progression to liver cirrhosis and liver cancer.

Hepaconda[®] is a combination of bezafibrate and chenodeoxycholic acid, both of which have demonstrated activity against HCV as single compounds. Giaconda believes that the combination of bezafibrate, with chenodeoxycholic acid may offer a synergistic advantage over current treatment.

The clinical trial is a two centre, open label, prospective study of the efficacy and safety of the combination of chenodeoxycholic acid and bezafibrate in the treatment of subjects diagnosed with Hepatitis C Virus genotype 1, who have failed standard therapy (peg-interferon and Ribavirin combination therapy).

The primary endpoints of the trial are to obtain a virological response and a reduction in viral load at 3 months and 6 months. The secondary objectives are to obtain clinically significant improvements in elevated liver function tests at 3 and 6 months and to obtain an acceptable safety profile. Subject to recruitment, it is anticipated that the trial will finish by the end of 2007 and that results will be made available in 2008. (Further details in the Appendix 1)

"Hepatitis C is a significant health issue across the globe and a significant number of patients fail conventional treatment," said Professor Tom Borody, Chief Medical Officer of Giaconda.

"We are committed to developing an alternative for these patients and we believe that Hepaconda[®] may offer such an alternative."

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[®].

For more information please visit www.giacondalimited.com

GIACONDA LIMITED

Suite 1307, Level 13, 370 Pitt Street, Sydney NSW 2000 Phone: [612] 9266 0440 Fax: [612] 9266 0441
email: info@giacondalimited.com ABN 68 108 088 517 www.giacondalimited.com

About the Centre for Digestive Diseases

The Centre for Digestive Diseases (CDD) under the leadership of founder and Medical Director, Prof Thomas Borody, has distinguished itself as a unique medical institution offering novel approaches in researching, diagnosing, and treating Gastrointestinal (GI) conditions. CDD offers a range of services in the day-procedure unit. Patients undergo a range of gastrointestinal procedures in its well equipped facilities, supported by an ISO:9001 accredited organisation consisting of 35 staff. CDD also houses a Department of Research and Innovation responsible for conducting clinical trials as approved by a Human Research Ethics Committee (HREC).

Giaconda's products were sourced from Professor Borody at the CDD. Giaconda has several agreements with the CDD that cover research services and Professor Borody's role as Giaconda's Chief Medical Officer.

About Hepatitis C Virus

Hepatitis C Virus affects 3.1% of the world's population and is currently the number one cause for liver transplantation in the United States. In Australia, current numbers of individuals diagnosed with newly acquired HCV infections have been estimated to be in excess of 242,000 with over 50% of cases located in NSW alone. There are six primary genotypes of HCV and studies show that 70-75% of all infections are of the genotype one variety. Currently the most effective treatment for chronic HCV includes a combination of the drugs interferon alpha and ribavirin. This treatment is associated with a number of side effects and is only effective for 42 – 46% of patients, leaving a large portion with no effective therapy.

About Hepaconda® – A combination therapy for the treatment of Hepatitis C Virus

Hepaconda® is a combination of bezafibrate and chenodeoxycholic acid. It has been demonstrated in clinical trials that chenodeoxycholic acid, when used as a single compound, reduced Hepatitis C infection (HCV) and improved liver function in patients who have failed existing therapy. The combination of bezafibrate, which has been shown to eliminate HCV, with chenodeoxycholic acid, therefore appears to offer an advantage over current treatment.

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.

CONTACTS:

Company	Media & Investor Relations
Tom Borody – Chief Medical Officer	Fay Weston – Talk Biotech
T: (02) 9370 0050	T: +61 422 206036
E: tborody@giacondalimited.com	E: fayweston@talkbiotech.com.au

For information on patient participation in the Hepaconda Ph IIa clinical study please contact:

Centre for Digestive Diseases – Research Department

(02) 9713 4011 (prompt #3)

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APPENDIX 1

Hepaconda[®] Phase IIa trial – Protocol

Title	Phase IIa, proof-of-concept, open label study to evaluate the efficacy and safety of the combination of Chenodeoxycholic acid and Bezafibrate in the treatment of chronic Hepatitis C Virus genotype 1 (HCV-1).
Principal Investigator	Dr Simon Benstock, BSc, MBBS, FRACP
Co-Investigators	Prof. Thomas J. Borody, MBBS, PhD, FRACP, FAGC, FACP A. Prof Martin Weltman, MBBS, PhD, FRACP, FACH AM Dr Antony Wettstein, MBBS(Hons), FRACP
Study Sites	Centre for Digestive Diseases Level 1, 229 Great North Road Five Dock, NSW 2046 Eastern Suburbs Endoscopy Centre 1903, Westfield Tower 1 520 Oxford Street Bondi Junction, NSW 2022
Design	Open prospective study
Objectives	<u>Primary Objective:</u> To evaluate the efficacy of Chenodeoxycholic acid (CDCA) and Bezafibrate in the treatment of HCV-1 by measurement of Virologic Response (VR) during (3 month) and post treatment (6 month EOT). <u>Secondary Objectives:</u> To evaluate efficacy of the combination of Chenodeoxycholic acid and Bezafibrate in the lowering of elevated liver function tests. To evaluate the safety of the combination of Chenodeoxycholic acid and Bezafibrate in the treatment of chronic HCV-1.
Patient Population	Patients presenting to the Centre for Digestive Diseases who have been diagnosed with chronic HCV-1, with detectable HCV-RNA, anti-HCV and who have failed previous therapy with pegylated interferon and ribavirin combination therapy.
Patient Sample Size	10 subjects who complete study participation
Treatment and dosage	Chenodeoxycholic acid (CDCA) morning - 500mg and evening - 750mg Bezafibrate 1x 200mg bd
Efficacy Data	Virologic Response through a decrease in quantitative HCV-RNA (Viral Load). Changes in anti-HCV levels and abnormal alanine aminotransferase (ALT), aspartate aminotransferase (AST) levels, γ -glutamyl transpeptidase (GGT), other liver function parameters, leukocyte levels, platelet levels, cholesterol (lipoprotein breakdown), INR, and eGFR.
Safety Data	Blood analysis / laboratory abnormalities (FBC, full biochemistry, pregnancy), physical examination, vital signs, adverse event (AE) assessment, withdrawals and compliance.

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Statistical Procedures

Interim analysis at 3 months of entire cohort. Efficacy analysis will be performed on an intention-to-treat basis. Summary statistics (n, medians and ranges, means + SEMs) will be generated for continuous variables in the data analysis for primary and secondary objectives. NOVA will be used to compare continuous variables at different time points. Categorical variables will be analysed by the Fisher's exact test. Wilcoxon rank sum test will be used to compare change in continuous variables from baseline. Alpha will be set at 0.05.

Study Duration

Study participation will be 24 weeks

Good Clinical Practice

This clinical trial will be conducted according to the principles of the good clinical practice (GCP) guidelines of the ICH and the ethical principles laid down in the current revision of the Declaration of Helsinki amended 2000 (Edinburgh, Scotland).

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