GIACONDA ANNOUNCES POSITIVE PHASE II DATA FOR PICOCONDA® PRESENTED AT AUSTRALIAN GASTROENTEROLOGY WEEK

Sydney, Australia 18 October 2006. Giaconda Ltd (ASX: GIA) announced that the results of a Phase II clinical study involving Picoconda®, a bowel preparation for gastrointestinal procedures, have been presented at the Australian Gastroenterology Week conference in Adelaide and published in the *Journal of Gastroenterology and Hepatology*.

The use of colonoscopic surveillance has increased significantly in recent times as an effective method for detecting colonic polyps and bowel cancer. The effectiveness of this screening relies on an adequately prepared bowel. Preparation of the bowel has been the most poorly tolerated aspect of colonoscopic procedures. The key problems with the standard bowel preparation for patients are the volume of the preparation that needs to be consumed, its unpalatability and the effects of purgative solutions administered on the day prior to the procedure which include nausea, vomiting, abdominal pain and headache. This has led to poor patient compliance with the standard pre-screening bowel preparations which in turn leads to a poor cleansing result.

Giaconda seeks to provide a product that will be acceptable to both doctors and patients. In order to increase patient compliance Giaconda and Pharmatel Ltd developed Picoconda®, a bowel preparation in a capsule form. In order to further reduce the side effect profile a hypertonic salt solution which reduces gas, bloating, nausea and headaches was combined with Picoconda® capsules in this study.

The aim of this randomised, single-blinded, comparative Phase II clinical study was to assess the efficacy and safety of the combination of the hypertonic solution and Picoconda® capsules as a bowel preparation, compared to standard Glycoprep, standard Picosulphate preparations and Picoconda® capsules alone. The primary objective was to test the hypothesis that the combination of the hypertonic solution and Picoconda® capsules would be as effective and safe as these other preparations. The secondary objective was to assess side effects, patient compliance and tolerance.

Significantly for Giaconda, one outcome of the trial was that the Picoconda® capsules, with or without the hypertonic solution, were found to be the most favoured bowel preparation by patients and in general, resulted in a lower number of mild adverse events than the other preparations.

“We are very pleased with the results of this study,” said Professor Tom Borody, Chief Medical Officer of Giaconda. “Our aim is to provide a product that is more readily acceptable to patients, resulting in a higher rate of patient compliance, which will assist in delivering a higher standard of medical care. This trial gives us an excellent guide to the future development of a second generation product in this area” he added.

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

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APPENDIX 1

Picoconda® Phase II trial – Protocol

Title	A phase II, comparative, single-blinded, randomised study to evaluate the efficacy and safety of Hypertonic Solution combined with Picoconda® capsules compared with Picoconda® capsules alone, standard Glycoprep, and standard Picosulphate as a bowel preparation
Principal Investigator	Dr Sanjay Ramrakha
Co-Investigators	Dr Thomas J Borody, Dr Antony Wettstein and Dr John Saxon
Study Site	Centre for Digestive Diseases, Five Dock NSW AUSTRALIA
Design	Randomised, single blinded, comparative study
Objectives	Primary Objective: To evaluate the efficacy and safety of Hypertonic Solution combined with Picoconda® capsules compared with Picoconda® capsules alone, standard Glycoprep, and standard Picosulphate powder sachets as a bowel preparation Secondary Objective: To assess the side effects and compliance of the hypertonic solution combined with Picoconda® capsules compared with Picoconda® capsules alone, and those of standard Glycoprep and standard Picosulphate powder sachets.
Patient Population	Male and female subjects aged 18 to 70 years undergoing colonoscopy and with no other major concomitant illness that may interfere with subject's ability to enter the trial.
Patient Sample Size	It was planned that 60 subjects were to fully complete the study (15 per arm). Sixty two subjects enrolled, with 59 subjects completing the study as per protocol. Due to subject withdrawals and randomisation the subject disposition was 15 subjects in Arm 1, 16 subjects in Arm 2, and 14 subjects in each of Arms 3 and 4.
Treatment and dosage	Treatment Arm 1 Hypertonic Solution combined with Picoconda® capsules - 1 bottle of hypertonic solution and 20 Picoconda® capsules Treatment Arm 2 30 Picoconda® Capsules Treatment Arm 3 Glycoprep – 1 sachet Treatment Arm 4 Picosulphate – 2 sachets
Efficacy Data	Patient Evaluation Form to assess the compliance and tolerance using score rating. Doctor Evaluation Form to assess efficiency of colonic cleansing. Sedationist Evaluation Form to assess efficiency of colonic cleansing.
Safety Data	Adverse event (AE) assessment, compliance, urinalysis, physical examination and blood testing.

Statistical Methods:

Fisher's test was used due to small sample size (n=62) with an expected number of subjects in each cell of 15 to look for significant difference between the proportions (the number of subjects actually benefited from each treatment). For example, if the proportions are close together the power is small or large if the proportions are far apart. Wilcoxon signed rank test is used for paired groups which are randomly selected from the population. The Mann-Whitney non-parametric test was used to compare two mean scores. A p value of less than 0.05 is considered significant.

Good Clinical Practice

This clinical trial was 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).

APPENDIX 2

Picoconda® Phase II trial – Trial Results

Safety

There were no Serious Adverse Advents (SAE's) in the trial and no abnormal biochemistry results were observed in any of the patient groups.

The safety data suggests that while approximately half of the subjects in the arm treated with Hypertonic solution and Picoconda® capsules experienced side effects that were possibly related to the bowel preparation, these adverse events were mostly mild. However the data suggests that the arm treated with the standard Picosulphate sachets suffered fewer side effects, but that the arm treated with Picoconda® capsules suffered milder side effects. The most common side effect reported was headache.

As part of the safety analyses, the number, type and severity of adverse events were separated according to the bowel preparation taken by the subject and compared with the other bowel preparations. Several significant differences between the bowel preparations in terms of the number, type and severity of adverse events reported was observed. Of particular note, treatment with Hypertonic solution combined with Picoconda® capsules resulted in no nausea, vomiting, bloating, and faint/light headedness in any subject. Patients in the Glycoprep treatment group reported a statistically significant greater number of nausea and vomiting effects (p=0.0001). In addition, while the Picoconda® capsule and Picosulphate sachet arms had a similar adverse event profile in the moderate/severe AE's, there was a marked difference in the number of headaches experienced in the mild AE's. 28.57% of Picosulphate sachet subjects experienced mild headaches, whereas only 6.25% of Picoconda® capsule subjects did (p=0.17).

Efficacy

Hypertonic solution combined with Picoconda® capsules (p=0.03) and Picosulphate sachets (p=0.003) were superior to Picoconda® capsules alone or Glycoprep sachets. However, there were no significant differences in colonoscopic visualisation between specific areas of the colon, with the exception of the Hypertonic solution combined with Picoconda® capsules capsule being significantly more effective than Picoconda® capsule alone in the caecum (p=0.03) and the transverse colon (p= 0.03).

Patient satisfaction was greater in the Picoconda® capsule group compared to the Picosulphate sachet group (p=0.03).

The Picoconda® capsule (87.5%) was also found to be better tasting than standard Glycoprep (0%), Picosulphate sachet (20%) (p=0.0001) or Hypertonic solution combined with Picoconda® capsules (20%) (p=0.0002). Additionally, significantly more subjects in the Glycoprep arm (57.14%) rated their preparation as barely tolerable compared to subjects in the Picoconda® capsule only arm (0/17, $p < 0.0008$), and significantly more subjects in the Picosulphate sachet arm (64.29%) rated their preparation as not good but tolerable, compared to those in the Picoconda® capsule only arm (114.76%, $p < 0.021$).
In terms of "ease of completion" compared to the other arms, more subjects in the Picoconda® Capsule arm (70.58%) rated this bowel preparation as easy to complete. This was significantly different from the Glycoprep arm, in which only 35.71% of subjects rated the preparation as easy to complete ($p < 0.03$).

Conclusions

The efficacy data demonstrated that while doctors and sedationists did not significantly differentiate between the different bowel preparations in the overall adequacy of bowel cleansing, when rating the cleanliness of the bowel according to specific bowel areas (i.e. rectum, transverse colon, caecum and terminal ileum), both agreed that Hypertonic solution combined with Picoconda® capsules were more effective in cleansing the transverse colon than the other bowel preparations. Doctors rated this preparation as significantly more effective than Picoconda® capsules alone, and sedationists rated this preparation as more effective than Glycoprep or Picosulphate sachets in cleansing the transverse colon. Additionally, doctors rated both Hypertonic solution combined with Picoconda®

capsules and Picosulphate sachets as being more effective in cleansing the caecum than Picoconda® capsules alone. While the ratings given to the efficacy of different bowel preparations varied slightly between doctors and sedationists, overall, doctors and sedationists agreed on the efficacy of the different preparations in cleansing various areas of the bowel. In general, both doctors and sedationists rated the efficacy of Picosulphate sachets and Hypertonic solution combined with Picoconda® capsules as superior to Picoconda® capsules alone and Glycoprep.

Hypertonic solution combined with Picoconda® capsules was equal or superior in efficacy, as assessed by the doctors and sedationists, compared to the other bowel preparations. When rating the preparations for tolerability, subjects reported that the Picoconda® capsules alone preparation was the most tolerable preparation to take prior to colonoscopy. Subjects appear to have found this preparation easier to complete than the Glycoprep preparation, and they stated that they preferred the taste of Picoconda® capsules alone to the taste of Glycoprep, Picosulphate sachets, and Hypertonic solution combined with Picoconda® capsules.

Overall, the most efficacious bowel preparation would be Hypertonic solution combined with Picoconda® capsules followed by Picosulphate sachets. The most efficacious in subject tolerability is Picoconda® capsules alone.