

Results from two studies:

BioGaia Gastrus in *Helicobacter pylori* infected patients

BioGaia's new probiotic tablet BioGaia Gastrus has been tested in two independent clinical trials in patients with *Helicobacter pylori* infection. In one of them, performed in Bari, Italy, in 100 patients in with confirmed *Helicobacter pylori* infection, BioGaia Gastrus supplementation led to a significant reduction in infection load and symptoms.

– We have found that Gastrus was able to decrease *Helicobacter pylori* bacterial load and to decrease the antibiotic associated side effects that are very frequent and fastidious during the eradication therapy. Although the eradication rates were similar in both treatment groups, we observed a spontaneous eradication in three patients taking just Gastrus, says Dr Francavilla at the Bari University Hospital. The other study, performed in Mexico, did not show significant results.

Two independent, randomised, double blind, placebo-controlled clinical studies have been performed to determine the effects of BioGaia Gastrus on the control of *Helicobacter pylori* infection in patients with mild symptoms. The first trial was performed in Bari, Italy, and the second in Monterrey, Mexico. Both trials included 100 patients whereof 50 were given Gastrus before, during and after standard triple therapy and 50 a placebo.

The Italian study demonstrated a significant reduction in *Helicobacter pylori* load and symptoms in the pre-eradication period when BioGaia Gastrus was given alone. Moreover, during this period three of 50 subjects in the Gastrus group compared to one of 50 in the placebo group lost their infection completely. Eradication rates under triple therapy were unchanged by Gastrus use, but symptoms were again significantly improved during the therapy in the probiotic group compared to those receiving placebo.

– Our data shows that probiotics, although not indicated to eradicate *Helicobacter pylori*, have the ability to increase the well being of a patient before, during and maybe after the eradication regimen. Even when antibiotics are not indicated or not tolerated by the patients, the use of a probiotic with a well demonstrated anti *Helicobacter pylori* activity might be of great support for the patient and the physician, says Dr Ruggiero Francavilla at Bari University Hospital, Italy.

In the Mexican study, performed in 100 similar patients, no significant reductions in *Helicobacter pylori* load or in symptoms were observed in the pre-eradication period with Gastrus. However, as in the Italian study, three of 50 subjects in the Gastrus group lost their infection completely when given Gastrus alone, compared to none in the placebo group. Histopathological analysis of the gastric mucosa showed significant benefit of both BioGaia Gastrus and placebo supplementation, but there were no significant changes in mucosal cytokine patterns after supplementation. Eradication rate was unchanged by probiotic supplementation, as were symptom scores during eradication.

BioGaia is a biotechnology company that develops, markets and sells probiotic products with documented health benefits. The products are primarily based on the lactic acid bacterium *Lactobacillus reuteri* which has probiotic, health-enhancing effects. The class B share of the Parent Company BioGaia AB is quoted on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm.
www.biogaia.com

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– Our findings did not agree to those of the Bari study, although the protocols were similar, which was surprising, and we are now analysing why the results differ in the two studies. We did see spontaneous eradication of *Helicobacter pylori* infection in 6% of the subjects given Gastrus alone, and this finding alone creates great interest in the use of this probiotic in *Helicobacter pylori* infected subjects, says Dr Francisco Bosques, University Hospital J.E. González, Autonomous University of Nuevo León, Monterrey, Mexico.

– Based on earlier documentation and the new, encouraging data, we have decided to put BioGaia Gastrus on the market as we believe that Gastrus has a great role to play in the control and treatment of *Helicobacter pylori* infections. A few partners will launch already next year. There is more and more evidence that the overuse of antibiotics is causing a series of problems and we believe that Gastrus can help to reduce the use of antibiotics and also increase compliance when consumed by these patients. With these new study results, earlier studies and new on-going studies, we are creating a platform for Gastrus in the treatment of *Helicobacter pylori* infections and as a compliment to the present consensus treatment regimens, says Peter Rothschild, President at BioGaia.

There are already three published studies with *Lactobacillus reuteri* Protectis in *Helicobacter pylori* patients showing reduction of infection load and symptoms.¹ *Lactobacillus reuteri* Protectis is one of two probiotic strains in the new product BioGaia Gastrus. The other is *Lactobacillus reuteri* ATCC PTA 6475, a strain specifically chosen for its anti-inflammatory properties, which is an important factor in the treatment of *Helicobacter pylori*-infection. Apart from the newly completed trials *Lactobacillus reuteri* Gastrus is currently tested in two independent trials and further trials are planned to start next year.

BioGaia is announcing these results today, as they will now be made available to a wider circle for pre-launch and registration work. The researchers are currently working on the manuscripts of the studies, which will be submitted for publication in reputable scientific journals later this year or in the beginning of next year.

For additional information please contact

Peter Rothschild, President, BioGaia: +46 8 555 293 00 or +46 70 830 65 40

Eamonn Connolly, Senior Vice President Research, BioGaia: +46 8 555 293 00

Ruggiero Francavilla, doctor, Bari University Hospital, Italy: rfrancavilla@me.com

Francisco Bosques, doctor, University Hospital, Monterrey, Mexico: fbosques58@hotmail.com

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BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 10 November 2011, 11:00 am CET.

¹ Lionetti E et al. Aliment Pharmacol Ther. 2006;24:1461-8, Imase K et al. Kansenshogaku Zasshi, 2007;81:387-93, Francavilla R et al. Helicobacter, 2008;13:127-134.

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