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Press Release

Probiotic Effects Within and Beyond the Gut

Alimentary Health (AH) Limited announces the results of the first report to demonstrate the ability of a specific probiotic, *B. infantis* 35624, to reduce systemic inflammatory tone in both gastrointestinal and non-gastrointestinal related disorders in three separate randomized double-blind placebo controlled intervention studies. These results have been published in the leading peer-reviewed journal, *Gut Microbes* (4:4, 1-5; July/August 2013).

There is persuasive evidence from several sources indicating that the gut microbiota has an influence on the development and maintenance not only of the mucosal but also the systemic immune response.

Scientists from Alimentary Health Ltd. and the Alimentary Pharmabiotic Centre, University College Cork fed *B. infantis* 35624 for 6-8 weeks to patients with the gastrointestinal disorder ulcerative colitis (UC; n=22) and also to patients suffering from two common non-gastrointestinal inflammatory diseases: the skin condition psoriasis (n=26) and chronic fatigue syndrome (CFS; n=48). At baseline, both gastrointestinal (UC) and non-gastrointestinal (CFS and psoriasis) patients had significantly increased blood levels of C-reactive protein (CRP) and the pro-inflammatory cytokines, tumor necrosis factor α (TNF- α) and interleukin-6 (IL-6), compared with healthy volunteers. CRP and cytokines are proteins found in the blood that act as inflammatory markers; levels of both rise in response to inflammation.

Compared to the placebo control, the researchers found that across all three inflammatory disorders patients experienced significantly reduced levels of inflammatory markers: in particular, patients who received *B. infantis* 35624 had significantly lower CRP levels in their blood compared with placebo while TNF- α was reduced in CFS and psoriasis and IL-6 was reduced in UC and CFS. In general, reductions in inflammatory markers, such as those seen in this study, would be indicative of clinical remission and a lower risk of relapse. This is the first paper to show that a probiotic consistently reduced inflammation markers across multiple conditions and comprehensively shows, the immune modulating potential of the probiotic strain *B. infantis* 35624 in humans.

Commenting on the results Professor Eamonn Quigley Chief, Division of Gastroenterology and Hepatology, Houston Methodist Hospital and Weill Cornell College of Medicine, Houston, Texas, said:

“Some probiotics alter the immune system in animal studies but few translate the effects to humans. What is impressive about these results is that not only are they from human subjects, but from individuals with common inflammatory conditions. In these results we are clearly seeing the impact of a probiotic organism in human disease; this raises the exciting prospect of new

strategies using specific probiotics to modify the body's systemic immune response from within the gut.”

Professor Fergus Shanahan, Professor of Medicine and Director of the Alimentary Pharmabiotic Centre, University College Cork commented:

“This work shows the ability of a single microbe to reduce systemic pro-inflammatory biomarkers in both gastrointestinal and non-gastrointestinal conditions and demonstrates the ability of certain probiotics to act beyond the gut.”

This study is further confirmation of the therapeutic versatility of AH's proprietary strain *B. infantis* 35624, already commercialized in the USA, as the active ingredient in the Align® brand, the most highly recommended probiotic by US gastroenterologists for Irritable Bowel Syndrome.

AH CEO Barry Kiely comments:

“These results show the potential for carefully selected probiotics to manage the underlying inflammation across a number of chronic conditions; and we are proud of AH's pioneering contribution to the field. Underlining our core capability in strain discovery and application, this work is another significant milestone in AH's strategy of developing clinically-validated nutrition-based products for dietary management of selected conditions which are regulated through medical foods and food for special medical purposes.”