

SE Press Release
HD **Clinical trial will look at role of kiwifruit extract in IBS**

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New clinical trial will look at role of kiwifruit extract in IBS

New Zealand natural pharmaceutical **company** Vital Food Processors Ltd today announced the launch of a trans-Tasman clinical trial targeting treatment of irritable bowel syndrome.

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The 10-centre trial will investigate the efficacy of the kiwifruit extract Kivia in patients diagnosed with irritable bowel syndrome (IBS) with constipation.

Vital Foods already markets the same product under the brand name Phloe in the over-the-counter market in New Zealand.

Irritable bowel syndrome is regarded as a major women's health issue affecting about one in 10 people, mostly women aged between 20 and 50 years. There are limited treatment options for the condition, which presents as recurring abdominal pain or discomfort associated with either constipation or diarrhoea that lasts for at least six months.

The double-blind, randomised, placebo-controlled Phase III clinical trial, to establish the efficacy of Kivia, will recruit 180 patients who will be monitored and treated over a three-month period. Recruitment will take place at 10 sites across New Zealand and Australia. Patients are already being admitted to the trial in Auckland, Melbourne, Sydney, Brisbane, and Adelaide. Two other New Zealand centres will start recruiting patients this month. Results are expected before the end of this year and if successful, will **lead** to entry of the product into international markets with a specific health indication for the treatment of IBS.

Vital Foods' chief executive Justus Homburg said Phloe is one of the most extensively investigated natural products for digestive health.

"This clinical trial is designed to build on the results of previous studies that focussed on relief of constipation and showed that Phloe relieved abdominal bloating, pain and flatulence in people with some of the symptoms also associated with IBS," said Mr Homburg. "These included four randomised, double-blind, placebo-controlled trials conducted in the United States and in **China** and three randomised open-label trials conducted in Japan."

Gastroenterologist Dr Alasdair Patrick, who is managing the trial site at Auckland's MacMurray Centre, says the new study is a significant step in identifying a successful treatment for the estimated 2.7 **million** people in New Zealand and Australia that suffer from IBS.

"Dietary intervention is already a mainstay of our treatment of IBS. Adjusting the intake of fibre, carbohydrate and fat in the diet can be effective, but IBS remains difficult to treat and is an ongoing burden for many people that impacts on their daily quality of life. This trial is a step towards identifying an effective treatment."

Dr Iona Weir, Vital Foods' chief scientific officer, says international investigations into the cause of IBS to date have yielded no clear results.

"However, while the causes of IBS have not been clearly identified, we do know what factors can contribute to symptoms. In earlier studies, Phloe has been shown to relieve some of those symptoms and what is most exciting is that it appears the proprietary kiwifruit extract in the product, zylactinase, may actually modify some of the contributing factors in the gut.

"We now have an extensive body of clinical data that supports the efficacy of Phloe."

Anyone who is interested in further information about this clinical trial or who is interested in participating in the trial should go to: www.theideastudy.com

About IBS

Irritable Bowel Syndrome is a chronic gastrointestinal disorder estimated to affect between 9 and 23% of the population worldwide. Although it affects approximately one in 10 people, the International Federation for Functional Gastrointestinal Disorders reports that most IBS sufferers do not seek medical help. Nevertheless, in the United States between 2.4 and 3.5 million annual physician visits are for patients diagnosed with IBS, and it has become a major women's health issue.

About Phloe

One of the most effective, gentle laxative over-the-counter therapies currently available, Phloe is made from green kiwifruit using Vital Foods' proprietary processing technology. Studies have confirmed that Phloe improves general digestive health, minimises episodes of occasional constipation, and assists in reducing abdominal discomfort. Phloe has few, if any, of the side effects commonly associated with harsher laxatives. It has been recently made a standard preparation for many patients undergoing radiation therapy for prostate and bowel cancer in New Zealand.

About Kivia

Kivia is the same formulation as Phloe but, if this trial confirms expected efficacy, it will be marketed internationally with a specific claim for treatment of IBS.

About Vital Foods

Vital Foods' was established to provide the digestive health benefits of kiwifruit through easy to consume digestive health products for all ages. The company's first product on the market was Kiwi Crush, a frozen kiwifruit drink that is sold as a digestive aid in supermarkets in New Zealand. Research into its therapeutic effects led to the development of Phloe, also based on kiwifruit, which was launched in 2007 and is now available in pharmacy, healthfood and grocery outlets in New Zealand and is about to be launched globally through www.digestivephloe.com. Together, the two products currently make up the highest-selling digestive health product family sold in New Zealand.

The new clinical study is a key step towards confirming Kivia as a treatment of a clinically diagnosed disease internationally, and, in turn, growing opportunities in the global consumer healthcare market.

In mid 2011 Nestle took at 18.2% stake in the company through its wholly-owned Health Sciences Company. Other shareholders are New Zealand's largest kiwifruit company Seeka Kiwifruit Industries, the venture funds BioPacific Ventures and Inventages, and private interests.

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