

ASX RELEASE

11 December 2017

Positive Bioxyne Gut Health Clinical Trial Results

Highlights

- Initial results from the completed clinical trial examining the effects on microbiome composition, gastrointestinal symptoms, quality of life, medication use and adverse events were received.
- The substantial amount of generated data is in the process of being analysed and peer reviewed. A comprehensive analysis is expected in early 2018.
- Significant beneficial effects were observed in reductions of a range of gastric symptoms including bloating and gas, and significantly less antibiotic use during the study period.

Bioxyne Limited (ASX:BXN) is pleased to provide the preliminary findings on the outcomes of a double blind, randomised, placebo-controlled clinical trial examining the effect of taking one daily Progastrim[®] capsule containing the company's proprietary probiotic, PCC[®] (*Lactobacillus fermentum* VRI-003, minimum of 2 billion cfus) for 6 months on the microbiome composition, gut health and quality of life of healthy participants.

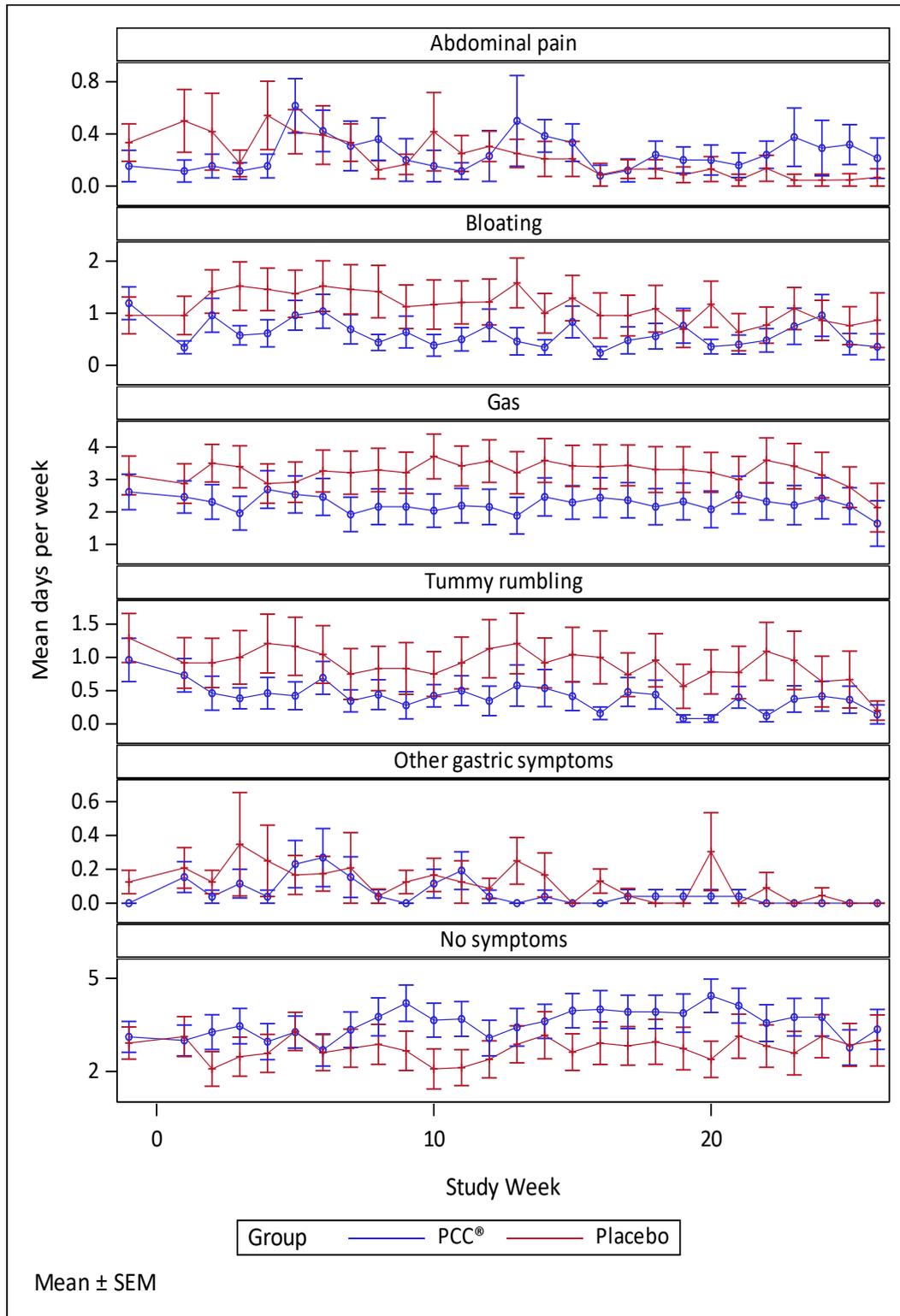
The trial has generated a substantial amount of scientific data which is currently being analysed and peer reviewed. The full analysis of the results are expected in early 2018.

Preliminary findings indicate statistically significant group differences for gastrointestinal and bowel health and consumption of antibiotics.

The table below presents some of the significant statistical findings, demonstrating differences between the active (PCC[®]) and placebo groups:

Patient reported measure	Statistically significant finding
Days where patients did not experience any gastric symptoms	Participants in the active (PCC [®]) group reported more days than the placebo group (p < 0.0001).
Bloating	Participants in the active (PCC [®]) group reported less bloating than the placebo group (p = 0.0036).
Gas	Participants in the active (PCC [®]) group reported less gas than the placebo group (p < 0.0001).
Stomach rumbling	Participants in the active (PCC [®]) group reported less stomach rumbling than the placebo group (p < 0.0001).
Other (unspecified) unpleasant gastric symptoms	Participants in the active (PCC [®]) group reported less other gastric symptoms than the placebo group (p = 0.0020).
Other (unspecified) health issues	Participants in the active (PCC [®]) group reported less other health issues than the placebo group (p < 0.0001).
Antibiotic use	Participants in the active (PCC [®]) group reported less antibiotic use than the placebo group (p < 0.0001).

A visual summary of the patient reported gastric symptom results over the study duration is presented below:



When the above measures were assessed for gender differences, it was found that women in the PCC® group experienced greater improvements than men.

There were no differences in the reporting of minor adverse events between the placebo control and active PCC[®] group. The incidence rates of adverse events in the PCC[®] were not statistically different to those in the placebo control group, suggesting that long-term (6 months) consumption of PCC[®] is safe.

Dr Peter French, Bioxyne's Science Director commented: *"The data demonstrated the positive influence of Bioxyne's probiotic, PCC to gastrointestinal health, and health in general. It is notable that a single capsule of PCC[®] taken daily could produce several significant beneficial gut health effects."*

In previous similar clinical studies, PCC[®] has also demonstrated to be a powerful immunomodulator, with effects on susceptibility to respiratory tract infections, eczema (atopic dermatitis), and boosting of the immune response to the flu vaccine.

Clinical trial details

The trial initially recruited 61 people in Sydney who had no medically diagnosed illnesses and who generally considered themselves to be healthy. They were randomised into either an 'active' PCC[®] or a placebo control group and were provided with capsules in unmarked bottles. They were asked to consume one capsule per day with water.

The active bottles contained Progastrim[®] capsules – the active ingredient in Progastrim[®] is Bioxyne's proprietary probiotic PCC[®] (a strain of *Lactobacillus fermentum*).

The average age of the participants was around 35, with even numbers of men and women in each group. A total of 47 participants completed the study.

The participants were asked to provide three stool samples for 16S RNA microbiome analysis - one prior to commencing the trial, one at 3 months and the last at 6 months, using a dedicated sample collection kit. In addition, they were asked to complete a daily diary recording gastrointestinal symptoms and bowel movements, a validated quality of life questionnaire (SF36), and a record of any adverse effects.

The information in this announcement that relates to the statistical analysis was conducted by Datapharm Australia Pty Limited (Datapharm), which is independent and a registered contract research organisation specialising in biostatistics. Datapharm consents to the statistical information included in this announcement.

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About Bioxyne

Bioxyne Limited (ASX:BXN) is an Australian life sciences and health products company (incorporated in 2000) with a focus on clinically effective health and wellness products particularly in the gut and immune health areas.

Bioxyne has a strategic investment in the consumer dietary supplements and functional foods markets through its proprietary probiotic, *Lactobacillus fermentum* VRI-003 (PCC®), and through an acquisition in New Zealand, now trading as Bioxyne International, the Company is further developing a range of functional food and beauty products containing ingredients sourced exclusively from New Zealand, for our direct sales channel.

Bioxyne's probiotic business is supported by a manufacturing and distribution agreement with Chr. Hansen (Denmark) a global leader in the manufacturing of natural food additives and supplements products for the food, health, pharmaceutical and agriculture industries.

Bioxyne has a distribution agreement for PCC® with Nu-Skin Enterprises (USA) a successful worldwide multilevel marketing company who pride themselves in offering only quality solutions to their customers.

For more information on Bioxyne, please visit www.bioxyne.com