

Press release

Innovation: Intelligent bacteria prove to be effective against the widespread irritable bowel syndrome (IBS) with typical symptoms such as chronic diarrhea, abdominal pain, flatulence, and constipation

- A new therapy with the specific bacterial strain B. bifidum HI-MIMBb75 promises help for up to 80 million patients with irritable bowel syndrome in Europe¹
- The world's largest clinical IBS-OTC study on the efficacy of the bacterial strain was published in the renowned journal The Lancet Gastroenterology & Hepatology²
- The bacterial strain proves to be significantly effective against all leading symptoms of IBS and all IBS subtypes, while improving the patients' quality of life²

Gräfelfing, 4th June 2020. One of the largest OTC studies regarding IBS³ published in the renowned medical journal The Lancet Gastroenterology & Hepatology produced sensational results. For the first time, leading German scientists and study leader Prof. Dr. Peter Layer from the Israelite Hospital Hamburg were able to prove the significant efficacy of a heat-inactivated bacterial strain for patients with irritable bowel syndrome. A significant reduction of all IBS symptoms, such as diarrhea, abdominal pain, flatulence, and constipation for all IBS subtypes, as well as an improvement of the patients' quality of life in comparison to placebo were shown in the study results with the specific bacterial strain B. bifidum HI-MIMBb75. This bacterial strain is used in the pharmacy-exclusive preparation Kijimea® Irritable Bowel PRO.

Irritable bowel syndrome - a widespread disease

In Germany alone, about 11 million people suffer from IBS with typical symptoms such as chronic diarrhea, abdominal pain, flatulence, and constipation - in Europe, up to 80 million people are affected.¹ Therefore, the new scientific findings are of great importance, as they promise relief from what is often a long path of suffering: up to eight years can pass before IBS is diagnosed.⁴ Affected people of all ages are often severely impaired in their everyday lives.

Damaged intestinal wall – a common cause for irritable bowel syndrome

The causes of irritable bowel syndrome are manifold. Genetic factors, changes in the intestinal flora, stress or environmental influences are being discussed as triggers. Today, it is assumed that these factors can lead to a disturbed intestinal barrier, which can result in increased intestinal permeability ("leaky gut"). Thus, harmful substances as well as pathogenic germs can penetrate the intestinal wall and cause micro-inflammations. This results in irritations of the intestinal nervous system and typical irritable bowel symptoms such as chronic diarrhea, abdominal pain, flatulence, and constipation.

Bacteria form a protective shield

The heat-inactivated bacterial strain B. bifidum HI-MIMBb75, which is only contained in the medical product Kijimea® Irritable Bowel PRO, figuratively attaches itself protectively like a plaster on the damaged areas of the intestinal wall ("plaster effect PRO"). Through this physical adhesion to the intestinal wall, the bacterial strain appears to prevent further bacterial penetration. Under this "plaster" the intestinal wall can recover - typical intestinal complaints such as recurrent diarrhea, abdominal pain, flatulence, or constipation can therefore subside.

Innovative product development by SYNformulas, Munich

The medical product Kijimea® IBS PRO is a progression of the previous market leader in Germany Kijimea® IBS and is exclusively available in pharmacies. SYNformulas, a leading international probiotics company based in Munich, developed the innovative OTC product. "Our goal as 'a global leader in probiotics' is to help as many people as possible with innovative preparations, which are developed according to the latest scientific findings and have been able to demonstrate their efficacy in clinical studies at the highest level," says Dr. med. Clemens Fischer, medical doctor and founder of SYNformulas GmbH.

¹Quigley E et al. Irritable bowel syndrome: The burden and unmet needs in Europe. *Digestive and Liver Disease*. 2006; 38; 717-723; Eurostat: European Union & euro area: total population from 2009 to 2019 (in millions of inhabitants). Retrieved 02.06.20 from: <http://ots.de/Dw1iWw>. Based on 15% prevalence in Europe.

²Andresen, V. et al. Heat-inactivated *Bifidobacterium bifidum* MIMBb75 (SYN-HI-001) in the treatment of irritable bowel syndrome: a multicentre, randomized, double-blind, placebo-controlled clinical trial. *Lancet Gastroenterol Hepatol*. 2020. <http://ots.de/q37VOB>Multizentrische, double-blind, randomised, placebo-controlled, clinical intervention trial involving 443 patients nationwide. Special features: All different RDS subtypes were specifically included in the selection of subjects. The EMA guidelines for the treatment of IBS were taken into account in the study design. Quality of life measured by mental health vs. placebo.

³Comparison considers studies with probiotic strains only.

⁴All data: Barmer Ersatzkasse Physician Report 2019