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Innovation: Intelligent bacteria demonstrate high efficacy in the treatment of widespread disease irritable bowel syndrome with typical symptoms of recurrent diarrhoea, abdominal pain, bloating and constipation



Gräfelfing/Munich (ots) -

- New therapy with unique bacterial strain *B. bifidum* HI-MIMBb75 promises help for approximately 80 million Europeans suffering from irritable bowel syndrome(1)
- World's largest clinical OTC irritable bowel syndrome trial investigating the efficacy of this particular strain published in the renowned medical journal *The Lancet Gastroenterology & Hepatology*(2)
- Results show significant efficacy for all predominant irritable bowel syndrome symptoms and all subtypes while simultaneously improving patients' quality of life(2)

The world's largest OTC irritable bowel syndrome (IBS) trial comes up with remarkable results, which were recently published in the renowned medical journal *The Lancet Gastroenterology & Hepatology*. For the first time, leading German scientists around Prof. Dr. Peter Layer (Israelitic Hospital Hamburg) were able to prove the significant efficacy of a heat-inactivated bacterial strain on patients with IBS. Trial results show that *B. bifidum* HI-MIMBb75 significantly alleviates all predominant IBS symptoms including diarrhoea, abdominal pain, bloating and constipation in all IBS subtypes with a simultaneous improvement in quality of life compared to placebo. The assessed bacterial strain *B. bifidum* HI-MIMBb75 is exclusively contained in Kijimea® Reizdarm PRO (available in pharmacies only).

Irritable bowel syndrome - a widespread disease

Approximately 15 % of the European population and thus up to 80 million people suffer from IBS¹ with the predominant symptoms of recurrent diarrhoea, abdominal pain, bloating and constipation. In this context, these new scientific findings are of great importance as they promise relief for patients who often face a long ordeal before diagnosis: It can take up to eight years before IBS is identified.⁽³⁾ Patients are found across all age groups and often experience a severe impairment of everyday life.

The results of the trial have already triggered a broad echo among experts. "Remarkable about this trial is that the examined heat-inactivated bacterial strain has shown its broad applicability across all predominant IBS symptoms and IBS subtypes. Thereby, previous results of a trial examining the corresponding viable bacterial strain were reproduced - which is an essential quality indicator in clinical research.", comments Professor Dr. Joachim Labenz, Director of Internal Medicine and Medical Director at the Diakonie Klinikum Jung-Stilling in Siegen, Germany.

Damaged intestinal barrier - a frequent cause of irritable bowel syndrome

The causes of IBS are manifold. Genetic factors, changes in the intestinal flora, stress or environmental influences are discussed as triggers. Today it is assumed that these factors can lead to a malfunctioning intestinal barrier possibly resulting in an increased intestinal permeability ("leaky gut"). Thus, toxins as well as pathogenic bacteria can penetrate the intestinal barrier and cause micro-inflammations. As a result, irritation of the intestinal nervous system and the typical irritable bowel symptoms such as recurrent diarrhoea, abdominal pain, bloating and constipation occur.

Bacteria form a protective shield

The heat-inactivated bacterial strain *B. bifidum* HI-MIMBb75 exclusively used in Kijimea® Reizdarm PRO adheres to the damaged areas of the intestinal barrier like a band aid ("Plaster Effect PRO"). Through this physical adhesion to the intestinal barrier, the bacterial strain appears to prevent further bacterial penetration. The intestinal barrier can recover below this "band aid" - typical intestinal conditions such as recurrent diarrhoea, abdominal pain, flatulence, or constipation can thus subside.

Innovative product development by Synformulas, Munich, Germany

The medical device Kijimea® Reizdarm PRO is the advancement of the previous market leader in Germany, Kijimea® Reizdarm. The innovative OTC product is available only in pharmacies and has been developed by Synformulas, a leading international probiotics company based in Munich, Germany. "As 'Global Leader in Probiotics' it is our mission to improve the health of as many people as possible. To succeed, we continuously develop innovative products according to the latest scientific findings and have been able to demonstrate our products' efficacy in clinical trials at the highest level," says Dr. Clemens Fischer, physician and founder of Synformulas GmbH.

About Synformulas GmbH

Synformulas is a global leader in probiotics and specializes in the research of intelligent bacteria and innovative therapies. The company sells pharmacy-exclusive products under the umbrella brand Kijimea® with a focus on the gastrointestinal area.

Holding company Futrue GmbH

The healthcare group Futrue, based in Gräfelfing near Munich (Germany), is an incubator of global health trends and innovations. Futrue has numerous medical device and drug approvals in the areas of intelligent bacteria, innovative pain therapies and medical cannabis.

Sources:

(1) Quigley E et al. Irritable bowel syndrome: The burden and unmet needs in Europe. Digestive and Liver Disease. 2006; 38; 717-723; Eurostat: Europäische Union & Euro-Zone: Gesamtbevölkerung von 2009 bis 2019 (in Millionen Einwohner). Accessed on 02.06.20 at: <http://ots.de/SC4rSY>.

Based on 15 % prevalence in Europe.

(2) Andresen V et al. Heat-inactivated Bifidobacterium bifidum MIMBb75 (SYN-HI-001) in the treatment of irritable bowel syndrome: a multicentre, randomised, double-blind, placebo-controlled clinical trial. Lancet Gastroenterol Hepatol. 2020. <http://ots.de/q37VOB>

Multi-centre, double-blind, randomized, placebo-controlled, clinical intervention trial with 443 patients throughout Germany. Particularities: All IBS subtypes were specifically included in the recruitment of subjects. The trial design was carried out according to EMA guidelines for the treatment of IBS. Quality of life was assessed via mental health vs. placebo.

(3) All data: Arztreport Barmer Ersatzkasse 2019.

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