



SYNformulas

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PARTNERING WITH SYNFORMULAS
A Global Leader in Probiotics

SYNformulas



Why partner with Synformulas?

As **part of the FUTRUE group, Synformulas is a global leader in probiotics.** We are focused on developing novel therapies through the use of intelligent bacteria. We are committed to pioneer treatments, which address demands unmet at present. To that end, we invest heavily in our research and development activities and cooperate with leading universities and institutions.

We have a broad range of innovative products: the commercially most successful are our IBS products Kijimea® IBS and Kijimea® IBS PRO.

Our newest clinically proven product is Kijimea® K53, an innovative treatment for allergic rhinoconjunctivitis.

Our bacterial strains and formulas are patented and have been proven clinically to significantly alleviate the specific symptoms.

We continuously look out for **strategic partnerships** that can reach more people:

- **As licensing partner with one of our patented bacterial strains or formulas**
- **As part of an ecosystem with a pharmacy and/or physician sales force**
- **By assuming end-to-end responsibility for a specific market or region**



PARTNERING TO ADVANCE GLOBAL HEALTH

OUR KEY PRODUCTS AND RESEARCH AREAS



CONSTIPATION

ALLERGY

ANTIBIOTIC-ASSOCIATED DIARRHEA

DIARRHEA, FLATULENCE, ABDOMINAL PAIN, CONSTIPATION

PATENTED

PATENT PENDING

PATENTED

PATENTED



IRRITABLE BOWEL SYNDROME

Among industrialized countries, irritable bowel syndrome (IBS) is one of the most widespread gastrointestinal disorders: About 11 % of people worldwide suffer from IBS and its symptoms such as diarrhea, flatulence, abdominal pain and constipation (Canavan et al., 2014 in Clinical Epidemiology, 6: 71-80).



Kijimea® IBS & IBS PRO

UNRIVALLED SCIENTIFIC BASE WITH TWO INDEPENDENT STUDIES CONFIRMING EFFICACY AGAINST IBS

- In 2011 it was shown that *B. bifidum* MIMBb75 significantly alleviates all IBS symptoms.
- Just recently, the **largest OTC IBS study worldwide** considering studies with probiotic strains confirmed the effectiveness of *B. bifidum* MIMBb75 in treating IBS and its symptoms (Guglielmetti, S. et al., 2011 in Aliment. Pharmacol. Ther. 33, 1123–1132), also in its heat-inactivated, non-viable form (Andresen et al., 2020 in The Lancet Gastroenterology and Hepatology).
- **Kijimea® IBS** contains *B. bifidum* MIMBb75.
- **Kijimea® IBS PRO** contains **heat-inactivated *B. bifidum* HI-MIMBb75**.
- The bacterial strain *B. bifidum* MIMBb75 is **part of the “S3-Leitlinie Reizdarmsyndrom”**, a German guideline for medical practitioners advising appropriate treatment options for IBS. It is the only bacterial strain included, which is effective against **all leading symptoms of IBS (diarrhea, abdominal pain, flatulence, constipation)**.
- **Kijimea® IBS** and **Kijimea® IBS PRO** are classified as medical devices in Europe

KIJIMEA® IBS AND KIJIMEA® IBS PRO ARE THE BLOCKBUSTERS IN THE IBS MARKET

- **Strong presence** in key European markets
- Consistent **price premium** realized vs. competitors
- Heat-inactivated *B. bifidum* HI-MIMBb75 is **unique** in terms of **stability** and **processing** capabilities – making it ideal for further processing

Kijimea® IBS PRO with heat-inactivated bacteria

THE LANCET GASTROENTEROLOGY & HEPATOLOGY

Andresen et al. (2020)



Study design

METHOD

Multicentre, prospective, randomized, double-blind, placebo-controlled trial

NUMBER OF PARTICIPANTS

443 patients, randomized to receive either a placebo or B. bifidum HI-MIMBb75

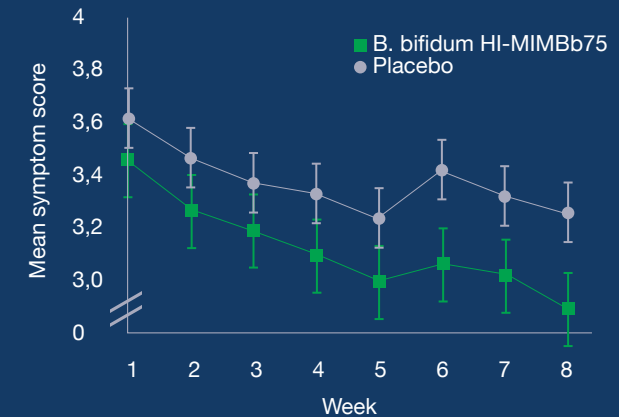
PRIMARY STUDY ENDPOINT

At least 30 % improvement of abdominal pain and adequate relief of overall IBS symptoms (combined)

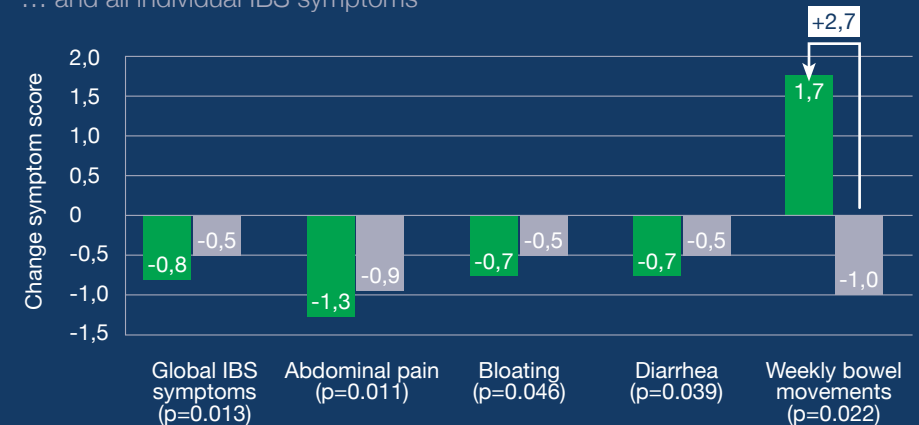
Results

RESULTS FOR IBS SYMPTOM RELIEF

Significant improvement of global IBS symptoms ...



... and all individual IBS symptoms



FURTHER FINDINGS

- Significant reduction of discomfort (p=0.0015) and pain associated with bowel movement (p=0.023)
- Significant improvement of health-related quality of life sum score (p=0.038)

Kijimea® IBS with active bacteria

ALIMENTARY PHARMACOLOGY & THERAPEUTICS

S. Guglielmetti et al. (2011)



Study design

METHOD

Multicentre, prospective, randomized, double-blind, placebo-controlled trial

NUMBER OF PARTICIPANTS

122 patients, randomized to receive either a placebo or B. bifidum MIMBb75

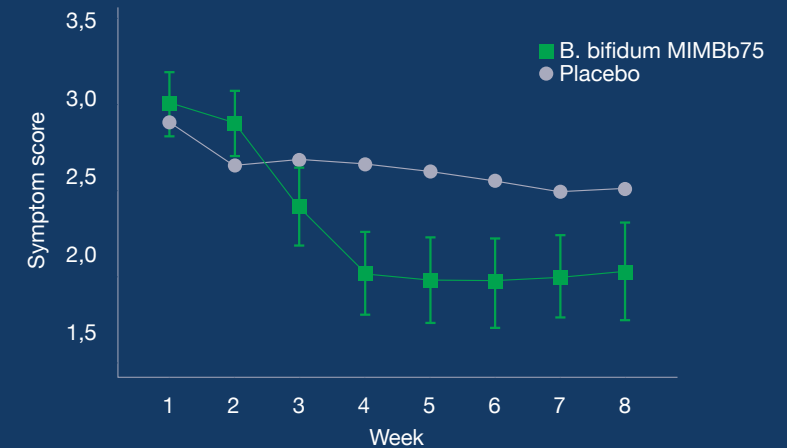
PRIMARY STUDY ENDPOINT

Subject's global assessment of IBS symptoms on 7-point Likert scale

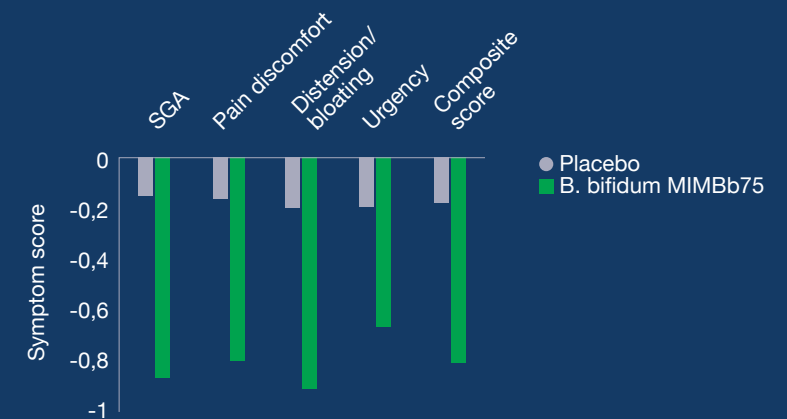
Results

RESULTS FOR IBS SYMPTOM RELIEF

Significant improvement of global IBS symptoms...



... and all individual IBS symptoms



FURTHER FINDINGS

Significant improvement of health-related quality of life sum scores, both regarding physical ($p=0.0185$) and mental health ($p=0.0083$)



Kijimea® K53

PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF ALLERGIES

Kijimea® K53 is a unique approach to tackle allergic rhinoconjunctivitis by addressing the underlying cause of allergies – which, according to latest research, is rooted in the intestinal microbiome.

- Kijimea® K53 imitates the diversity of the human microbiota through its **unique composition of 53 specifically selected probiotic strains** and its **unparalleled dosage**.
- Kijimea® K53 **rebalances the intestinal microbiome**.
- The effectiveness of Kijimea® K53 in the treatment of all rhinoconjunctivitis has recently been shown in a **clinical study**



ALLERGY

Over the last fifty years the incidence of allergic diseases has increased dramatically, particularly in the Western world.

Allergies are characterized by an exaggerated immune reaction to typically harmless substances in the environment. This often results in common allergy symptoms such as runny/itching nose and/or itching/watering eyes.

Kijimea® K53 with 53 bacterial strains



Study design

METHOD

Monocentric, randomized, double-blind, placebo-controlled clinical trial

NUMBER OF PARTICIPANTS

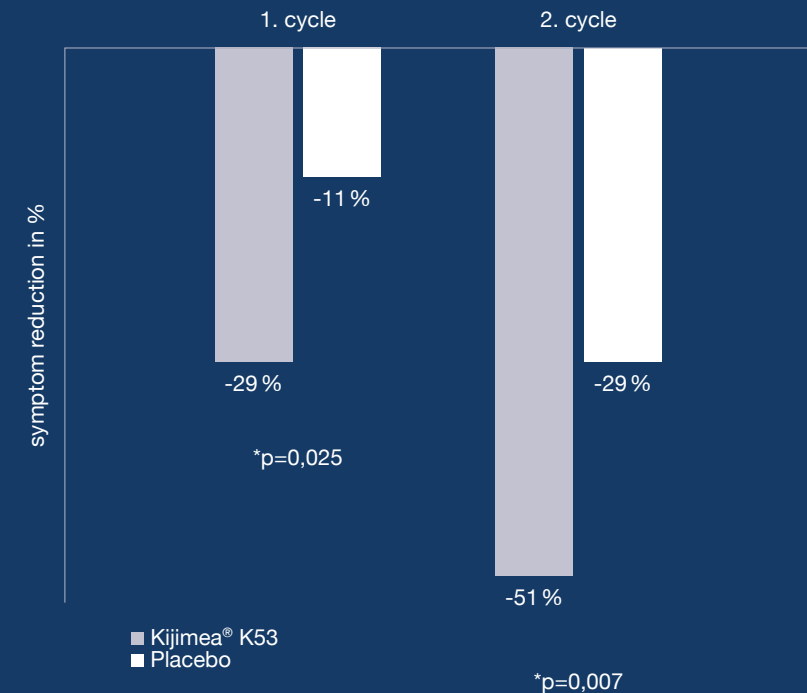
90 patients, randomized to receive either a placebo or Kijimea® K53

OUTCOME PARAMETERS

Significant improvement in the SYN-53 treatment group $TSS_{MAX} \geq 6$ during exposure compared to baseline and placebo

Results

RESULTS FOR ALLERGY SYMPTOMS RELIEF

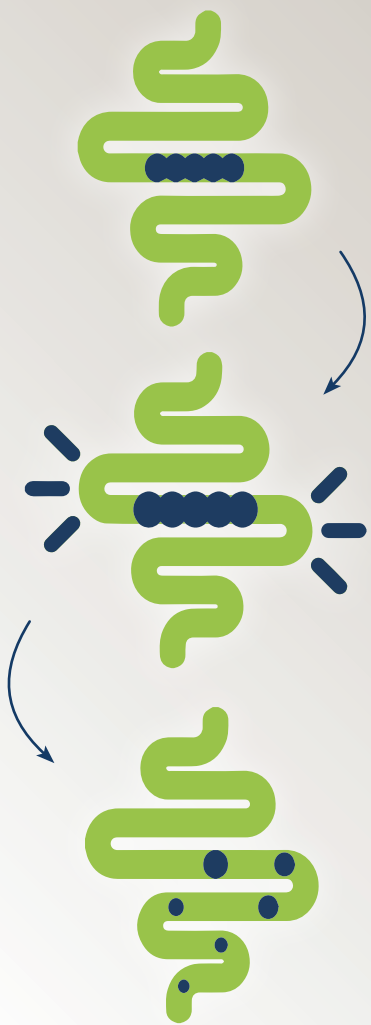


SIGNIFICANT IMPROVEMENT OF ALL ALLERGY SYMPTOMS AND THEIR SEVERITY

- -29 % after the first treatment cycle
- -51 % after the second treatment cycle
- 2/3 responder rate

CONCLUSION

- First high dose, multi-strain probiotic with short-term treatment regimen
- Comparable efficacy to conventional allergy treatment options
- Superior tolerability compared to antiallergic agents or immunotherapy



Kijimea® Regularis

PATENTED PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF CONSTIPATION AND BLOATING

Kijimea® Regularis offers effective remedy for patients with constipation and slow digestion. It consists of two main ingredients, which effectively reduce constipation and bloating:

- The **unique and patented Synformularis2 fiber complex** supports natural intestinal motility and the digestive system.
- The fibres of natural origin swell in the gut. This gently stretches the gut and **activates the intestinal muscles to contract and relax in a normal way**. It enables digestion to speed up naturally and relieves constipation – reliably and predictably.
- Simeicone: An **active agent against flatulence and bloating**, which dissolves gas bubbles and prevents the formation of new ones.
- The effectiveness of both ingredients has been intensely investigated in several clinical trials.



CONSTIPATION AND BLOATING

In Europe, about 77 million people suffer from constipation and its symptoms, such as irregular bowel movements and lumpy/hard stool (Peppas G. Et al. Epidemiology of constipation in Europe and Oceania: a systematic review. BMC Gastroenterol. 2008 Feb 12;8:5.). Further symptoms include flatulence and a bloated abdomen. Affected patients experience a significant restriction in their quality of life.

Product Overview

	Active Ingredients	Application	Daily Dosage	AI Concentration	Pack Sizes
	B. bifidum HI-MIMBb75 (heat-inactivated)	Irritable Bowel Syndrome	2 capsules per day	1 x 10 ⁹ CFU per day	14 caps 28 caps 84 caps
	B. bifidum MIMBb75 (live bacteria)	Irritable Bowel Syndrome	2 capsules per day	1 x 10 ⁹ CFU per day	14 caps 28 caps 84 caps
	53 selected bacteria strains	Allergic Rhinconjunctivitis	1 cycle = 3 capsules per day on 3 consecutive days	4.5 x 10 ¹¹ CFU per 3-day cycle	9 caps 18 caps 27 caps
	Methylcellulose and Simeticone	Constipation Bloating	2-3 servings per day	2g Methylcellulose 0,125g Simethicone	250 gram 500 gram

