disease and its symptoms.

The need therefore remains high to provide an effective solution for the treatment of gastrointestinal disorders, in particular functional gastrointestinal disorders, more in particular for irritable bowel syndrome (IBS), small bowel constipation, small bowel diarrhoea, alternating constipation and diarrhoea and unclassified IBS.
Furthermore, there is a need to provide an effective solution for the treatment of inflammatory gastrointestinal disorders, such as, for example, chronic inflammatory bowel diseases (IBD).

Following an extensive research and development activity, the Applicant addresses and solves the aforementioned needs by providing: novel strains of isolated bacteria, such as, (I.i) *Bifidobacterium breve* BbIBS01 (DSM 33231), (I.ii) *Bifidobacterium breve* BbIBS02 (DSM 33232), (I.iii) *Bifidobacterium animalis subsp. lactis* BIIBS01 (DSM 33233) and (I.iv) *Lactobacillus plantarum* LpIBS01 (DSM 33234) (in short, novel bacterial strains (I.i-I.iv) of the invention or (I.i-I.iv)); mixtures (M) comprising at least one or more of said bacterial strains (I.i-I.iv) and, optionally, at least one further bacterial strain selected from the group comprising or, alternatively, consisting of: *Lactobacillus casei* DG® (CNCM I-1572) and *Lactobacillus paracasei* LPC-S01™ (DSM 26760) (in short, mixtures (M) of the invention); compositions comprising said mixtures (M) (in short, compositions of the invention); the use of said bacterial strains, mixtures or compositions for the preventive and/or curative treatment of gastrointestinal disorders, preferably functional gastrointestinal disorders, more preferably of the irritable bowel syndrome (IBS) (IBS with diarrhoea, IBS with constipation, IBS with alternating constipation and diarrhoea and unclassified IBS), and/or inflammatory gastrointestinal disorders, more preferably chronic inflammatory bowel diseases (IBD), as reported in the present description and in the claims.

SUMMARY

In one aspect, provided herein is a composition comprising a mixture M comprising, or alternatively, consisting of at least one bacterial strain selected from the group A comprising, or alternatively, consisting of: a bacterial strain belonging to the species Bifidobacterium breve identified as Bifidobacterium breve BbIBS01 and having deposit number DSM 33231, a bacterial strain belonging to the species Bifidobacterium breve identified as Bifidobacterium breve BbIBS02 and having deposit number DSM 33232, a bacterial strain belonging to the species Bifidobacterium animalis identified as Bifidobacterium animalis subsp. lactis BIIBS01 and having deposit number DSM 33233, a bacterial strain belonging to the species Lactobacillus plantarum identified as Lactobacillus plantarum LpIBS01 and having deposit number DSM 33234, and mixtures thereof, wherein all said bacterial strains were deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) on 31 July 2019 by SOFAR S.p.A.; and wherein, optionally, said composition comprises at least one food or pharmaceutical grade additive and/or excipient.

In another aspect, provided herein is the composition as described herein for use as a medicament.

In another aspect, provided herein is use of the composition as described herein in the manufacture of a medicament for the preventive and/or curative treatment of functional gastrointestinal diseases, disorders and/or symptoms.

In another aspect, provided herein is use of the composition as described herein in the manufacture of a medicament for preventive and/or curative treatment of inflammatory gastrointestinal diseases, disorders and/or symptoms.

In another aspect, provided herein is a bacterial strain belonging to the species Bifidobacterium breve species identified as Bifidobacterium breve BbIBS01, wherein said bacterial strain was deposited, according to the Budapest Treaty, at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33231 on 31 July 2019 by SOFAR S.p.A.

In another aspect, provided herein is a bacterial strain belonging to the species Bifidobacterium breve identified as Bifidobacterium breve BbIBS02, wherein said bacterial strain was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33232 on 31 July 2019 by Sofar S.p.A.

In another aspect, provided herein is a bacterial strain belonging to the species Bifidobacterium animalis identified as Bifidobacterium animalis subsp. lactis BIIBS01, wherein said bacterial strain was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33233 on 31 July 2019 by SOFAR S.p.A.

In another aspect, provided herein is a bacterial strain belonging to the species *Lactobacillus plantarum* identified as *Lactobacillus plantarum* LpIBS01, wherein said bacterial strain was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33234 on 31 July 2019 by SOFAR S.p.A.

Lactobacillus plantarum LpIBS01 (DSM 33234) was isolated from the human gastrointestinal tract. The Bifidobacteria in question, such as *Bifidobacterium breve* BbIBS01 (DSM 33231), (I.ii) *Bifidobacterium breve* BbIBS02 (DSM 33232), (I.iii) *Bifidobacterium animalis subsp. lactis* BIIBS01 (DSM 33233), are of human origin and they are naturally found in the human intestine.

Specifically, said novel bacterial strains of the invention (I.i-I.iv) or derivatives thereof, mixtures (M) of bacterial strains of the present invention and compositions comprising said mixtures (M) of the present invention, are effective in the preventive and/or curative treatment of gastrointestinal disorders, in particular with regard to functional gastrointestinal disorders, such as for example IBS, given that they determine:

- at the level of the gut microbiota, a positive modulation of the microbial populations present, such as for

CLAIMS

1. A composition comprising a mixture M comprising, or alternatively, consisting of at least one bacterial strain selected from the group A comprising, or alternatively, consisting of:
- a bacterial strain belonging to the species *Bifidobacterium breve* identified as *Bifidobacterium breve* BbIBS01 and having deposit number DSM 33231,
- a bacterial strain belonging to the species *Bifidobacterium breve* identified as *Bifidobacterium breve* BbIBS02 and having deposit number DSM 33232,
- a bacterial strain belonging to the species *Bifidobacterium animalis* identified as *Bifidobacterium animalis subsp. lactis* BIIBS01 and having deposit number DSM 33233,
- a bacterial strain belonging to the species *Lactobacillus plantarum* identified as *Lactobacillus plantarum* LpIBS01 and having deposit number DSM 33234, and mixtures thereof,
wherein all said bacterial strains were deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) on 31 July 2019 by SOFAR S.p.A.;
and wherein, optionally, said composition comprises at least one food or pharmaceutical grade additive and/or excipient.

2. The composition according to claim 1, wherein said mixture M comprises or, alternatively consists of bacterial strains:
- *Bifidobacterium breve* BbIBS01 DSM 33231,
- *Bifidobacterium breve* BbIBS02 DSM 33232,
- *Bifidobacterium animalis subsp. lactis* BIIBS01 DSM 33233, and
- *Lactobacillus plantarum* LpIBS01 DSM 33234.

3. The composition according to claim 1 or 2, wherein said mixture M further comprises at least one further bacterial strain selected from the group B comprising or, alternatively, consisting of: a bacterial strain identified as *Lactobacillus casei* DG® deposited at the National Collection of Cultures of Microorganisms Pasteur Institute in Paris under accession number CNCM I-1572 on 05 May 1995 by SOFAR S.p.A.,
a bacterial strain identified as *Lactobacillus paracasei* LPC-S01™ deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under accession number DSM 26760 on 15 May 2017 by SOFAR S.p.A. and a mixture thereof.

4. The composition according to claim 3, wherein said mixture M comprises or, alternatively consists of bacterial strains:
- *Bifidobacterium breve* BbIBS01 DSM 33231,

- *Bifidobacterium breve* BbIBS02 DSM 33232,
- *Bifidobacterium animalis subsp. lactis* BIIBS01 DSM 33233,
- *Lactobacillus plantarum* LpIBS01 DSM 33234, and
- *Lactobacillus casei* DG® CNCM I-1572.

5. The composition according to claim 3, wherein said mixture M comprises or, alternatively consists of bacterial strains:
- *Bifidobacterium breve* BbIBS01 DSM 33231,
- *Bifidobacterium breve* BbIBS02 DSM 33232,
- *Bifidobacterium animalis subsp. lactis* BIIBS01 DSM 33233,
- *Lactobacillus plantarum* LpIBS01 DSM 33234, and
- *Lactobacillus paracasei* LPC-S01™ DSM 26760.

6. The composition according to any one of claims 1 to 5, wherein said composition is formulated for oral, sublingual or buccal, transmucosal, topical, rectal, topical cutaneous or topical vaginal use; preferably said composition is formulated for oral use.

7. The composition according to any one of claims 1 to 6 for use as a medicament.

8. ~~The~~ Use of the composition according to any one of claims 1 ~~a~~ to 6 ~~for use~~ in ~~a~~ the ~~method~~ manufacture of a medicament for the preventive and/or curative treatment of functional gastrointestinal diseases, disorders and/or symptoms.

9. The ~~composition~~ use according to claim 8, wherein said ~~composition is for use in a method for the preventive and/or curative treatment of~~ functional gastrointestinal diseases, disorders and/or symptoms is selected from the group comprising or, alternatively, consisting of: irritable bowel syndrome (IBS), dyspepsia, pyrosis, esophageal disorders, stomach disorders and duodenum disorders, small intestinal bacterial overgrowth (SIBO), gastrointestinal disorders with sub-inflammatory conditions; preferably the irritable bowel syndrome (IBS) constipated bowel or irritable bowel syndrome (IBS) diarrhoeic bowel or irritable bowel syndrome (IBS) with alternating constipation and diarrhoea.

10. ~~The~~ Use of the composition according to any one of claims 1 to 6 ~~for use~~ in the~~a~~ ~~method~~ manufacture of a medicament for preventive and/or curative treatment of inflammatory gastrointestinal diseases, disorders and/or symptoms.

11. The ~~composition~~ use according to claim 10, wherein said ~~composition is for use in a method for the preventive or curative treatment of~~ inflammatory gastrointestinal disorders is selected from the group comprising or, alternatively, consisting of: chronic inflammatory bowel diseases (IBD), Crohn's disease, ulcerative colitis, microscopic colitis, diverticular disease, diverticulitis, Helicobacter pylori, peptic or gastric ulcer, and duodenal ulcers; preferably selected from chronic inflammatory bowel diseases (IBD), Crohn's disease, ulcerative colitis, microscopic colitis, diverticular disease, and diverticulitis.

12. A bacterial strain belonging to the species *Bifidobacterium breve* species identified as *Bifidobacterium breve* BbIBS01, wherein said bacterial strain was deposited, according to the Budapest Treaty, at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33231 on 31 July 2019 by SOFAR S.p.A.

13. A bacterial strain belonging to the species *Bifidobacterium breve* identified as *Bifidobacterium breve* BbIBS02, wherein said bacterial strain was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33232 on 31 July 2019 by Sofar S.p.A.

14. A bacterial strain belonging to the species *Bifidobacterium animalis* identified as *Bifidobacterium animalis subsp. lactis* BIIBS01, wherein said bacterial strain was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33233 on 31 July 2019 by SOFAR S.p.A.

15. A bacterial strain belonging to the species *Lactobacillus plantarum* identified as *Lactobacillus plantarum* LpIBS01, wherein said bacterial strain was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under deposit number DSM 33234 on 31 July 2019 by SOFAR S.p.A.