SUMMARY

Broadly, the present disclosure relates to therapies and methods for treating or preventing diseases and disorders related to excess body weight. More specifically, the discosure is based on the surprising finding that the combination of the use of an amylin analogue and a GIPR / GLP-1R dual agonist results in greater treatment efficacy as compared with treatment of either agent alone.

Thus, the disclosure provides a combination of an amylin analogue and a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist for use in treating or preventing a disease in a subject, wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

In one example, the disclosure provides a combination of an amylin analogue and a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist for use in treating or preventing a disease in a subject, wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes; wherein the amylin analogue and the gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist are administered by any one of separately, simultaneously, consecutively, concomitantly, together, or in the same formulation to a subject.

The disclosure also provides a combination of an amylin analogue and a GIPR / GLP-1R dual agonist for use in a method of inhibiting weight gain and/or reducing body weight in a subject.

In one example, the disclosure provides a combination of an amylin analogue and a GIPR / GLP-1R dual agonist for use in a method of inhibiting weight gain and/or reducing body weight in a subject; wherein the amylin analogue and the GIPR / GLP-1R dual agonist are administered by any one of separately, simultaneously, consecutively, concomitantly, together, or in the same formulation to a subject.

The disclosure also provides a kit comprising an amylin analogue and a GIPR / GLP-1R dual agonist.

In one aspect, the present disclosure refers to use of an amylin analogue and a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual

agonist in the manufacture of a medicament for combination therapy for treating or preventing a disease in a subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

In another aspect, the present disclosure refers to use of an amylin analogue in the manufacture of a first medicament and use of a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy for treating or preventing a disease in a subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

In another aspect, the present disclosure refers to use of an amylin analogue in the manufacture of a medicament for use in combinatorial therapy for treating or preventing a disease in a subject, wherein the medicament is to be administered in combination with a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

In another aspect, the present disclosure refers to use of a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist in the manufacture of a medicament for use in combinatorial therapy for treating or preventing a disease in a subject, wherein the medicament is to be administered in combination with an amylin analogue, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

In another aspect, the present disclosure refers to use of an amylin analogue and a GIPR / GLP-1R dual agonist in the manufacture of a medicament for combination therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the amylin analogue

is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

In another aspect, the present disclosure refers to use of an amylin analogue in the manufacture of a first medicament and use of a GIPR / GLP-1R dual agonist in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

In another aspect, the present disclosure refers to use of an amylin analogue in the manufacture of a medicament for use in combinatorial therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the medicament is to be administered in combination with a GIPR / GLP-1R dual agonist, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

In another aspect, the present disclosure refers to use of a GIPR / GLP-1R dual agonist in the manufacture of a medicament for use in combinatorial therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the medicament is to be administered in combination with an amylin analogue, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

In another aspect, the present disclosure refers to a non-therapeutic method of inhibiting weight gain and/or reducing body weight in a subject, the method comprises that an amylin analogue and a GIPR / GLP-1R dual agonist is to be administered to the subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof, and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

In another aspect, the present disclosure refers to a kit comprising an amylin analogue and a GIPR / GLP-1R dual agonist, wherein the amylin analogue and the GIPR / GLP-1R dual agonist are as defined herein.

Preferably, the amylin analogue is petrelintide

CLAIMS

1. Use of an amylin analogue and a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist in the manufacture of a medicament for combination therapy for treating or preventing a disease in a subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and
wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

2. Use of an amylin analogue in the manufacture of a first medicament and use of a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy for treating or preventing a disease in a subject,
wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and
wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

3. Use of an amylin analogue in the manufacture of a medicament for use in combinatorial therapy for treating or preventing a disease in a subject, wherein the medicament is to be administered in combination with a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist,
wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and
wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

4. Use of a gastric inhibitory polypeptide receptor (GIPR) / glucagon-like peptide-1 receptor (GLP-1R) dual agonist in the manufacture of a medicament for use in combinatorial therapy for treating or preventing a disease in a subject, wherein the medicament is to be administered in combination with an amylin analogue,

wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof, and
wherein the disease is overweight, obesity, morbid obesity, diabetes, or a disease linked to obesity or to diabetes.

5. The use according to any one of claims 1-4, wherein the disease linked to obesity or to diabetes is selected from the group consisting of: obesity-linked inflammation, obesity-linked gallbladder disease, obesity-induced sleep apnea, obesity-linked respiratory problems, degeneration of cartilage, osteoarthritis, infertility, Alzheimer's disease, pre-diabetes, gestational diabetes, insulin resistance syndrome, inadequate glucose control, impaired glucose tolerance (IGT), disease states associated with elevated blood glucose levels, metabolic disease, metabolic syndrome, hyperglycemia, hypertension, dyslipidaemia, atherogenic dyslipidemia, kidney failure, arteriosclerosis, atherosclerosis, macrovascular disease, microvascular disease, diabetic heart disease, diabetic cardiomyopathy, heart failure as a diabetic complication, coronary heart disease, peripheral artery disease and stroke.

6. Use of an amylin analogue and a GIPR / GLP-1R dual agonist in the manufacture of a medicament for combination therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

7. Use of an amylin analogue in the manufacture of a first medicament and use of a GIPR / GLP-1R dual agonist in the manufacture of a second medicament, wherein the first and second medicaments are to be used in combination therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

8. Use of an amylin analogue in the manufacture of a medicament for use in combinatorial therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the medicament is to be administered in combination with a GIPR / GLP-1R dual agonist, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

9. Use of a GIPR / GLP-1R dual agonist in the manufacture of a medicament for use in combinatorial therapy for inhibiting weight gain and/or reducing body weight in a subject, wherein the medicament is to be administered in combination with an amylin analogue, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

10. A non-therapeutic method of inhibiting weight gain and/or reducing body weight in a subject, the method comprises that an amylin analogue and a GIPR / GLP-1R dual agonist is to be administered to the subject, wherein the amylin analogue is petrelintide or a pharmaceutically acceptable salt or solvate thereof, and the GIPR/GLP-1R dual agonist is tirzepatide or a pharmaceutically acceptable salt or solvate thereof.

11. The use according to any one of claims 1 to 9, or the method according to claim 10, wherein:
a) the amylin analogue is to be administered to the subject at a dose of up to about 10 mg, preferably a dose selected from any one of about 1 mg, about 2 mg, about 3 mg, about 4 mg, about 5 mg, about 6 mg, about 7 mg, about 8 mg, about 9 mg and about 10 mg; and/or .
b) the GIPR / GLP-1R dual agonist is to be administered to the subject at a dose of up to 15 mg, preferably a dose selected from any one of about 2.5 mg, about 5 mg, about 7.5 mg, about 10 mg, about 12.5 mg and about 15 mg.

12. The use according to any one of claims 1 to 9 or 11, or the method according to claim 10 or claim 11, wherein:
a) the amylin analogue is to be administered to the subject once a week; and/or
b) the GIPR / GLP-1R dual agonist is to be administered to the subject once a week.

13. The use according to any one of claims 1 to 9 or 11 or 12, or the method according to any one of claims 10 to 12, wherein:
a) the amylin analogue is formulated as an amylin analogue pharmaceutical composition; and/or
b) the GIPR / GLP-1R dual agonist, is formulated as a GIPR / GLP-1R dual agonist pharmaceutical composition.

14. The use according to any one of claims 1 to 9 or 11 to 13, or the method according to any one of claims 10 to 13, wherein the amylin analogue and GIPR / GLP-1R dual agonist are to be administered to the subject by injection, preferably by subcutaneous injection.

15. A kit comprising an amylin analogue and a GIPR / GLP-1R dual agonist, wherein the amylin analogue and the GIPR / GLP-1R dual agonist are as defined in any one of claims 1 to 14.