

GLP/GLP1 co-agonists for treating diabetes, obesity, and other conditions. US9474780 describes and claims tirzepatide. Tirzepatide is approved by the U.S. Food and Drug Agency for use in treating type 2 diabetes, as an adjunct to diet and exercise.

5 Dulaglutide, the active ingredient in Trulicity®, is a GLP-1 RA that is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 diabetes (T2D). Dulaglutide has been used to treat many patients with T2D, resulting in significant reductions in HbA1c with low risk of hypoglycemia, and reductions in body weight. Dulaglutide is a well known GLP-1 RA.

10 Semaglutide, the active ingredient in Ozempic®, Rybelsis®, and Wegovy®, respectively, is a GLP-1 RA that is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with T2D. Likewise, semaglutide is a well known GLP-1 RA.

15 Despite improvements provided by GLP-1 RA treatment, certain patients continue to be unable to attain their HbA1c treatment goals. There is a need for additional treatment options to provide desired glycemic control, as evidenced for example, by further reductions of HbA1c, and/or weight loss, while maintaining an acceptable profile of safety and adverse events. Also, there is a need for a treatment option for a patient unable to achieve their metabolic syndrome goals using a GLP-1 RA comprising administering tirzepatide for a condition selected from chronic kidney disease, atherosclerosis, NAFLD, and NASH.

Summary

25 In an aspect, there is provided use of a tirzepatide, or pharmaceutically acceptable salt thereof in the manufacture of a medicament for improving glycemic control in a patient in need thereof, wherein the patient is receiving GLP-1 RA treatment and wherein the tirzepatide, or pharmaceutically acceptable salt thereof is to be administered once weekly.

30 In another aspect, there is provided use of a tirzepatide, or pharmaceutically acceptable salt thereof in the manufacture of a medicament for improving chronic weight management in a patient in need thereof, wherein said patient is unable to achieve their weight management treatment goal with GLP-1 RA treatment and wherein the tirzepatide, or pharmaceutically acceptable salt thereof is to be administered once weekly.

Description

In another embodiment, is a method for treating a patient unable to reach their HbA1c goal despite receiving GLP-1 RA treatment, comprising administering tirzepatide, or a pharmaceutically acceptable salt thereof. In an embodiment, tirzepatide is
5 administered for at least 20 weeks. In an other embodiment, is a method for improving chronic weight management in a patient in need thereof, wherein said patient is unable to achieve their weight loss goal using a GLP-1 RA treatment, comprising administering tirzepatide, or a pharmaceutically acceptable salt thereof to a patient in need thereof. In certain embodiments, the GLP-1 RA is once weekly 0.75 mg dulaglutide. In certain
10 embodiments, the GLP-1 RA is once weekly 1.5 mg dulaglutide. In certain embodiments, the GLP-1 RA is once weekly 3.0 mg dulaglutide. In certain embodiments, the GLP-1 RA is once weekly 4.5 mg dulaglutide. In certain embodiments, the GLP-1 RA is 0.75 mg dulaglutide. In certain embodiments, the GLP-1 RA is semaglutide. In an embodiment, a

WE CLAIM:

1. Use of a tirzepatide, or pharmaceutically acceptable salt thereof in the manufacture of a medicament for improving glycemic control in a patient in need thereof, wherein the patient is receiving GLP-1 RA treatment and wherein the tirzepatide, or
5 pharmaceutically acceptable salt thereof is to be administered once weekly.
2. The use as claimed by Claim 1 wherein the patient receiving GLP-1 RA treatment is unable to achieve their HbA1c treatment goal.
3. The use as claimed by Claim 1 or 2 wherein the tirzepatide once weekly dose is selected from the group consisting of 2.5 mg, 5.0 mg, 7.5mg, 10mg, 12.5mg, 15mg,
10 20mg, and 25 mg tirzepatide, or a pharmaceutically acceptable salt thereof.
4. The use as claimed by any one of Claims 1 to 3 wherein an initial tirzepatide dose is 5.0 mg tirzepatide or a pharmaceutically acceptable salt thereof.
5. The use as claimed by any one of Claims 1 to 4, wherein the GLP-1 RA is dulaglutide.
- 15 6. The use as claimed by any one of Claims 1 to 4 wherein the GLP-1 RA is semaglutide.
7. The use as claimed by any one of Claims 1 to 4 wherein the GLP-1 RA is liraglutide.
8. The use as claimed by Claim 6, wherein the patient was treated with semaglutide
20 for a treatment period of at least 6 months prior to administration of the tirzepatide, or a pharmaceutically acceptable salt thereof.
9. The use as claimed by any one of Claims 1 to 4 wherein the GLP-1 RA is a nonpeptide GLP-1 RA.
10. The use as claimed by any one of Claims 1 to 9 wherein the patient has a BMI
25 greater than or equal to 25 kilograms/square meter (kg/m^2).
11. Use of a tirzepatide, or pharmaceutically acceptable salt thereof in the manufacture of a medicament for improving chronic weight management in a patient in need thereof, wherein said patient is unable to achieve their weight management treatment goal with GLP-1 RA treatment and wherein the tirzepatide, or pharmaceutically
30 acceptable salt thereof is to be administered once weekly.
12. The use as claimed by Claim 11 wherein the initial once weekly tirzepatide dose is 5.0 mg tirzepatide or a pharmaceutically acceptable salt thereof.