Methods of Using and Compositions Containing Dulaglutide

The present invention relates to the field of medicine. More particularly, the present invention relates to methods of using new doses of dulaglutide and compositions containing such higher doses of dulaglutide.

Dulaglutide, the active ingredient in Trulicity®, is a glucagon-like peptide-1 (GLP-1) receptor agonist (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). Two once weekly dulaglutide doses, 0.75 mg and 1.5 mg, were studied in the Phase 3 development program and received regulatory approval in the United States (US), European Union and other jurisdictions in 2014. Since their approval in 2014, these two doses of dulaglutide have been used to treat many patients with T2D, resulting in significant reductions in HbA1c with low risk of hypoglycemia, and reductions in body weight.

While therapy with currently approved doses of dulaglutide enabled the majority of patients included in the Phase 3 program to attain their glycemic targets (with or without use of other concomitant medications for T2D), significant numbers of patients receiving approved therapies today, including dulaglutide, are not reaching glycemic control goals (*see, e.g.*, Stark Casagrande et al. The prevalence of meeting A1c, blood pressure, and LDL goals among people with diabetes, 1988-2010. *Diabetes Care*. 2013;36(8):2271-2279). Therefore, there remains an important medical need to provide enhanced efficacy of pharmaceutical agents while also preserving an overall acceptable benefit/risk profile.

The doses, methods and compositions of the present invention seek to meet that need. The benefits of the present invention include providing additional glycemic control, as evidenced for example by further reductions in HbA1c, and/or weight loss as compared to the currently approved doses of dulaglutide. Moreover, the present invention provides such benefits while maintaining an acceptable profile of safety risks and adverse events.

Summary

In one aspect of the present disclosure, there is provided a use of dulaglutide in the manufacture of a medicament for improving glycemic control in a subject in need thereof with type 2 diabetes, wherein:

a) an initial dose of 0.75 mg of dulaglutide is to be administered once weekly;

b) increasing the dose to 1.5 g of dulaglutide which is to be administered once weekly;

c) increasing the dose to 3.0 g of dulaglutide which is to be administered once weekly after at least 4 weeks on the 1.5 mg dose; and

d) increasing the dose to 4.5 g of dulaglutide which is to be administered once weekly after at least 4 weeks on the 3.0 mg dose.

Description

The present invention provides a method of improving glycemic control in a subject having type 2 diabetes (T2D) and in need of additional glycemic control, comprising:

a) identifying a subject having T2D and in need of further glycemic control;

WE CLAIM:

1. Use of dulaglutide in the manufacture of a medicament for improving glycemic control in a subject in need thereof with type 2 diabetes, wherein:

a) an initial dose of 0.75 mg of dulaglutide is to be administered once weekly;

b) increasing the dose to 1.5 g of dulaglutide which is to be administered once weekly;

c) increasing the dose to 3.0 g of dulaglutide which is to be administered once weekly after at least 4 weeks on the 1.5 mg dose; and

d) increasing the dose to 4.5 g of dulaglutide which is to be administered once weekly after at least 4 weeks on the 3.0 mg dose.

2. The use of claim 1, wherein the dose increases of each of steps b) through d) are performed when there is a need to reduce the subject's HbA1c level.

3. The use of claim 2, wherein said 4.5 mg of dulaglutide that is to be administered does not result in unacceptable gastrointestinal tolerability in the subject as compared to administration of 1.5 mg of dulaglutide once weekly.

4. The use of claim 3, wherein said 4.5 mg of dulaglutide that is to be administered once weekly results in a greater body weight reduction in the subject as compared to administration of 1.5 mg of dulaglutide once weekly.