Claims

1. Use of a pharmaceutical combination in the manufacture of a medicament for the treatment of a type 2 diabetes mellitus patient, said combination comprising
   (a) lixisenatide or/and a pharmaceutically acceptable salt thereof,
   (b) insulin glargine or/and a pharmaceutically acceptable salt thereof, and
   (c) optionally metformin or/and a pharmaceutically acceptable salt thereof,

   wherein the patient does not receive concomitant treatment with at least one of a sulfonylurea, a DPP-4 inhibitor and a glinide and wherein the type 2 diabetes mellitus is not adequately controlled with a basal insulin and one to three oral anti-diabetics alone, the one to three oral anti-diabetics being selected from the group consisting of a sulfonylurea, a DPP-4 inhibitor and a glinide.

2. The use according to claim 1, wherein the type 2 diabetes mellitus to be treated is further not adequately controlled with compound (b) and optionally compound (c) alone.

3. The use according to claim 1 or 2, wherein the patient to be treated is obese.

4. The use according to any of the preceding claims, wherein the patient to be treated has an age of at least 65 years.

5. The use according to any of the preceding claims, wherein prior to the onset of therapy with the combination according to claim 1, the patient has a fasting plasma glucose of at least 9 mmol/L when treated with a basal insulin and one to three oral anti-diabetics alone, the one to three oral anti-diabetics being selected from the group consisting of a sulfonylurea, a DPP-4 inhibitor and a glinide.

6. The use according to any of the preceding claims, wherein prior to the

onset of therapy with the combination according to claim 1, the patient has a fasting plasma glucose concentration in the range of 5.6 to 6.9 mmol/L or a fasting plasma glucose concentration of at least 6.6 mmol/L when treated with compound (b) and optionally compound (c) alone.

7. The use according to any of the preceding claims, wherein prior to the onset of therapy with the combination according to claim 1, the patient has a HbA1c of at least 8.5% when treated with a basal insulin and one to three oral anti-diabetics alone, the one to three oral anti-diabetics being selected from the group consisting of a sulfonylurea, a DPP-4 inhibitor and a glinide.

8. The use according to any of the preceding claims, wherein prior to the onset of therapy with the combination according to claim 1, the patient has a HbA1c of at least 7.5 % when treated with compound (b) and optionally compound (c) alone.

9. The use according to any of the claims 5 to 8, wherein the basal insulin is selected from insulin glargine, insulin detemir and isophane insulin (NPH insulin).

10. The use of any of the preceding claims, wherein in the patient to be treated, type 2 diabetes mellitus has been diagnosed for at least 1 year or at least 2 years prior to the onset of a therapy with compounds (a), (b) and optionally (c).

11. The use of any of the preceding claims, wherein the administration of the combination comprises the steps:
(i) administration of compounds (b) and (c) for at least 4 weeks, and
(ii) continuing treatment by administration of compounds (a), (b) and (c),
wherein the amount of compound (b) to be administered in step (i) is adjusted so that a predetermined fasting plasma glucose level or/and a predetermined self-monitored plasma glucose level is reached or at least approximated.

12. The use according to claim 11, wherein the amount of compound (b) to be

administered in step (i) is adjusted so that

(I) a fasting plasma glucose level or/and a fasting self-monitored plasma glucose level of 4.4 mmol/l to 5.6 mmol/l, or/and

(II) a self-monitored plasma glucose level (SMPG) of 7.8 mmol/l (or 140 mg/dl) or less

is reached or at least approximated.

13. The use according to claim 12, wherein the self-monitored plasma glucose level in (II) is a 4-point self-monitored plasma glucose level or a 7-point self-monitored plasma glucose level.

14. The use of any of the preceding claims, wherein

(a) lixisenatide or/and the pharmaceutically acceptable salt thereof is prepared for parenteral administration,

(b) insulin glargine or/and or/and the pharmaceutically acceptable salt thereof is prepared for parenteral administration, or/and

(c) metformin or/and the pharmaceutically acceptable salt thereof is prepared for oral administration.