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(54) Benævnelse: The invention relates to the treatment or prevention of autoimmune diseases and latent autoimmune diabetes in the adults

(57) Sammendrag:

The invention provides the use of antagonists of IL-21 in the treatment of late autoimmune diabetes of the adults and for prolonging the remission phase in patients with newly diagnosed type 1 diabetes as well as for reducing the secondary failure rate of treatment with orally active hypoglycaemic agents and/or postponing the need for insulin therapy in islet cell antibody (ICA), insulin antibody, heat shock protein (hsp) antibody and/or GAD antibody positive patients with type 2 diabetes;

CLAIMS

1. Use of an IL-21 antagonist for the manufacture of a medicament for the treatment of latent autoimmune diabetes in adults.

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2. Use of an IL-21 antagonist for the manufacture of a medicament for prolonging the remission phase in patients with newly diagnosed type 1 diabetes.

3. Use of an IL-21 antagonist for the manufacture of a medicament for reducing the secondary failure rate of treatment with orally active hypoglycaemic agents and/or postponing the need for insulin therapy in islet cell antibody (ICA), insulin antibody-, heat shock protein (hsp) 60 antibody- and/or GAD antibody-positive patients with type 2 diabetes;

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4. A pharmaceutical composition comprising an IL-21 antagonist in combination with another agent that suppress immune responses and/or promotes the generation of regulatory immune responses.

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5. The use of an IL-21 antagonist for the manufacture of a medicament for the treatment of autoimmune diseases administered in combination with another agent that suppress immune responses and/or promotes the generation of regulatory immune responses

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6. The use according to claim 5 wherein the autoimmune diseases are Type 1 Diabetes and LADA.

7. The use according to claim 5 wherein the compounds that suppress immune responses and/or promote regulatory immune responses are CD3 antagonists, hereunder OKT3, CD25 antagonists, CTLA-4 agonists, IL-2 antagonists, IL-2R antagonists, thiazolidinediones (TZDs).

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8. The use of an IL-21 antagonist for the manufacture of a medicament for the treatment of autoimmune diseases including T1D and LADA administered in combination with one or more agents that stimulates the regeneration or neoformation of β -cells.

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9. The use according to claim 8 wherein the compounds that promote regeneration and/or neoformation of β -cells are selected from gastrin, gastrin analogues, epidermal growth

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factor (EGF), EGF-R agonists, fibroblast growth factor (FGF), FGF-R agonists, Keratinocyte growth factor, growth hormone (GH), Ghrelin, glucagon-like peptide (GLP)-1, GLP-1 analogues, hereunder Liraglutide;

5 10. The use of an? One or more? antagonist of IL-21 for the manufacture of a medicament for the treatment of complications and disorders resulting from or associated with obesity administered together with one or more antidiabetics, antiobesity agents, antihypertensive agents, and/or agents for the treatment of complications resulting from or associated with diabetes.

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 11. A pharmaceutical composition comprising an antagonist of IL-21 together with one or more compounds that suppress immune responses and/or promote regulatory immune responses.

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 12. A pharmaceutical composition comprising an antagonist of IL-21 together with one or more agents that stimulate the regeneration or neoformation of β -cells.

 13. A pharmaceutical composition comprising an antagonist of IL-21 together with antidiabetics, antiobesity agents, antihypertensive agents, and/or agents for the treatment of complications resulting from or associated with diabetes.

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 14. A method for the treatment of latent autoimmune diabetes in the adults by administering an effective amount of an antagonist of IL-21;

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 15. A method for prolonging the remission phase in patients with newly diagnosed type 1 diabetes by administering an effective amount of an antagonist of IL-21;

 16. A method for reducing the secondary failure rate of treatment with orally active hypoglycaemic agents and/or postponing the need for insulin therapy in islet cell antibody (ICA), insulin antibody, heat shock protein (hsp) 60 antibody and/or GAD antibody positive patients with type 2 diabetes by administering an effective amount of an antagonist of IL-21.

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