РОССИЙСКАЯ ФЕДЕРАЦИЯ

ФЕДЕРАЛЬНАЯ СЛУЖБА
ПО ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ

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(54) КОМПОЗИЦИИ И СПОСОБЫ ДЛЯ ЛЕЧЕНИЯ БОЛЕЗНИ ГОШЕ

(57) Реферат:

Группа изобретений относится к области медицины и касается фармацевтической композиции для лечения болезни Гоше и способа лечения. Композиция содержит велаглюцеразу в эффективном количестве, лимонную кислоту, полисорбат 20, цитрат натрия, сахарозу. Группа изобретений обеспечивает уменьшение иммунного ответа и уменьшение реакций на участке инъекций у пациентов, проходящих лечение болезни Гоше. 3 н. и 34 з.п. ф-лы, 9 пр., 40 табл., 26 фиг.

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RUSSIAN FEDERATION

FEDERAL SERVICE
FOR INTELLECTUAL PROPERTY

(19) **RU** (11) **2 568 831** (13) **C2**

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(12) ABSTRACT OF INVENTION

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RU 2568831 C2

(54) COMPOSITIONS AND METHODS FOR TREATING GAUCHER DISEASE

(57) Abstract:

FIELD: medicine, pharmaceutics.

SUBSTANCE: group of inventions relates to field of medicine and deals with pharmaceutical composition for treating Gaucher disease and method of treatment. Composition contains velaglucerase in effective quantity, citric acid, polysorbate 20, sodium citrate, and sucrose.

EFFECT: group of inventions provides reduction of immune response and reduction of reactions on region of injections in patients subjected to treatment of Gaucher disease.

37 cl, 9 ex, 40 tbl, 26 dwg

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TRANSLATION

FEDERAL SERVICE FOR INTELLECTUAL PROPERTY, PATENTS AND TRADEMARKS (ROSPATENT)

DECISION

on grant of patent for invention

(21) Application № 2012107103/15(010779) (22) Date of filing the application July 28, 2010

Basing on the results of substantive examination of the patent application conducted in respect to

☐claimed invention

☒ claimed group of inventions

the concordance thereof to the subject of patent rights and the requirements of patentability set forth by the Civil Code of the Russian Federation has been revealed and in this connection decision to grant the Patent of the Russian Federation on the invention is made.

The Conclusion on the results of the examination is enclosed.

Enclosure: 4 sheets

Acting Director General

L.L. Kiriy

DECISION ON GRANT

PATENT FOR INVENTION

(21) Application № **2012107103/15(010779)**. (22) Date of filing the application **July 28, 2010**
(24) Date from which industrial property rights may have effect **July 28, 2010**
(85) Date of commencement of the national phase **February 28, 2012**

PRIORITY IS FIXED ON DATE

☐ (22) Date of filing the application
☐ (23) Date of filing of additional materials of to the earlier application №
☐ (62) ☐ priority date of the application № of from which the present application has been divided up
☐ filing date of the application № of from which the present application has been divided up
☐ (66) Filing date of the earlier application №
☒ (30) Data relating to priority under the Paris Convention

(31) Number assigned to priority application	(32) Date of filing priority application	(33) Country code	Claim
61/229,195	**July 28, 2009**	**US**	
61/303,044	**February 10, 2010**	**US**	
61/317,513	**March 25, 2010**	**US**	
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61/359,338	**June 28, 2010**	**US**	

(86) PCT Application number and date **US2010/043586** of **July 28, 2010**.
(87) PCT Publication number and date WO2011/017177 of **February 10, 2011**

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(73) Assignee(s) **SHIRE HUMAN GENETIC THERAPIES, US**

(54) Title **COMPOSITIONS AND METHODS FOR TREATING GAUCHER DISEASE**

The Examination department basing on the results of substantive examination of the patent application conducted in respect to

☐ originally filed claims ☒ claims amended by the applicant

has revealed their concordance to the requirements of patentability set forth by the Articles 1349 and 1350 of the Civil Code of the Russian Federation and decided to grant the Patent of the Russian Federation for the following claims:

(21) 2012107103/15

(51) IPC

A61K 38/46 (2006.01)

A61K 38/47 (2006.01)

A61P 43/00 (2006.01)

(57)

1. A pharmaceutical composition for the treatment of Gaucher disease, comprising velaglucerase in an effective amount, a lyoprotectant, a buffer salt, and a stabilizing agent.

2. The pharmaceutical composition of claim 1, wherein the lyoprotectant comprises a carbohydrate.

3. The pharmaceutical composition of claim 2, wherein the carbohydrate is sucrose.

4. The pharmaceutical composition of claim 1, wherein the buffer salt comprises citrate, citrate acid, or both.

5. The pharmaceutical composition of claim 4, wherein the citrate is sodium citrate.

6. The pharmaceutical composition of claim 1, wherein the stabilizing agent comprises polysorbate.

7. The pharmaceutical composition of claim 6, wherein the polysorbate is polysorbate 20.

8. The pharmaceutical composition of claim 1, comprising velaglucerase, citric acid, polysorbate 20, sodium citrate, and sucrose.

9. The pharmaceutical composition of claim 8, comprising about 2.5 mg/mL velaglucerase, about 50 mg/mL sucrose, about 12.9 mg/mL sodium citrate dihydrate, about 1.3 mg/mL citric acid monohydrate, and about 0.11 mg/mL polysorbate 20.

10. The pharmaceutical composition of any one of claims 1, 8 or 9, wherein the composition is a lyophilized composition.

11. The pharmaceutical composition of claim 10, wherein the moisture content of the lyophilized composition is 1% to 6%.

12. The pharmaceutical composition of claim 10, wherein the moisture content of the lyophilized composition is 3% to 5%.

13. The pharmaceutical composition of claim 1, wherein the composition is a liquid composition.

14. The pharmaceutical composition of claim 1 or 13, wherein the composition is a reconstituted solution.

15. The pharmaceutical composition of claim 14, wherein the composition is reconstituted with Sterile Water for Injection, physiological saline, bacteriostatic water, CREMOPHOR EL™, or phosphate buffered saline (PBS).

16. The pharmaceutical composition of claim 15, further comprising sodium chloride.

17. The pharmaceutical composition of any one of claims 1, 8 or 9, wherein the composition is compatible with parenteral administration.

18. The pharmaceutical composition of claim 17, wherein the parenteral administration is intravenous, intradermal, or subcutaneous administration.

19. The pharmaceutical composition of any one of claims 1-9, 16 or 18, comprising one or more of a sterile diluent, an antibacterial or antifungal agent, an antioxidant agent, a chelating agent, a buffer, or an agent for the adjustment of tonicity.

20. The pharmaceutical composition of claim 19, wherein the sterile diluent is selected from the group consisting of Sterile Water for Injection, a saline solution, a fixed oil, polyethylene glycol, glycerine, and propylene glycol.

21. The pharmaceutical composition of claim 19, wherein the antibacterial or antifungal agent is selected from the group consisting of benzyl alcohol, methyl paraben, chlorobutanol, phenol, ascorbic acid, and thimerosal.

22. The pharmaceutical composition of claim 19, wherein the antioxidant agent comprises ascorbic acid or sodium bisulfite.

23. The pharmaceutical composition of claim 19, wherein the chelating agent comprises ethylenediaminetetraacetic acid.

24. The pharmaceutical composition of claim 19, wherein the buffer comprises acetate, citrate, or phosphate.

25. The pharmaceutical composition of claim 19, wherein the agent for the adjustment of tonicity comprises sodium chloride or dextrose.

26. The pharmaceutical composition of any one of claims 1-9, 11-16, 18, 20 to 25, comprising a solvent or dispersion medium.

27. The pharmaceutical composition of any one of claims 1-9, 11-16, 18, 20 to 25, wherein the solvent or dispersion medium comprises water, ethanol, polyol, or a suitable mixture thereof.

28. The pharmaceutical composition of any one of claims 1-9, 11-16, 18, 20 to 25, comprising lecithin or a surfactant.

29. The pharmaceutical composition of any one of claims 1-9, 11-16, 18, 20 to 25, comprising a pharmaceutically acceptable carrier selected from the group consisting of Sterile Water for Injection, physiological saline, bacteriostatic water, CREMOPHOR EL™, and phosphate buffered saline (PBS).

30. The pharmaceutical composition of any one of claims 1-9, 16, 18, 20 to 25, comprising an isotonic agent.

31. The pharmaceutical composition of claim 30, wherein the isotonic agent is a sugar, a polyalcohol, or sodium chloride.

32. The pharmaceutical composition of claim 31, wherein the sugar is sucrose.

33. The pharmaceutical composition of claim 31, wherein the polyalcohol is mannitol or sorbitol.

34. The pharmaceutical composition of any one of claims 1 to 9, 16, 18, 20-25, 31-33, comprising an agent that delays absorption.

35. The pharmaceutical composition of claim 34, wherein the agent that delays absorption is aluminum monostearate or gelatin.

36. A pharmaceutical composition for the treatment of Gaucher disease, comprising velaglucerase in an effective amount and citric acid, polysorbate 20, sodium citrate, and sucrose.

37. A method for treatment of Gaucher disease, comprising administration of the pharmaceutical composition according to any one of claims 1-36 in a therapeutically effective amount.

(56) US5620884 A, 15.04.1997
US7348000 B2, 25.03.2008
US5549892A1, 27.08.1996

Note: The original description and the abstract corrected by the Examiner will be used at publication.

Encl.: Abstract corrected by the Examiner, 1 sheet.

Patent Examiner

Enclosure No. 1

To application No. 2012107103/15

Abstract

(54) COMPOSITIONS AND METHODS FOR TREATING GAUCHER DISEASE

(57) A group of inventions relates to medicine and concerns a pharmaceutical composition for treating Gaucher disease and a method for treatment. The composition comprises velaglucerase in an effective amount, citric acid, polysorbate 20, sodium citrate, sucrose. A group of inventions provides decreasing an immune response and reducing injection site reaction in subjects undergoing treatment for Gaucher disease. 3 independent claims and 34 dependent claims, 9 examples, 40 tables, 26 figures.

Reviewer