



(51) International Patent Classification:

A61K 38/26 (2006.01) A61P 9/10 (2006.01)
A61P 3/10 (2006.01) A61P 13/12 (2006.01)
A61P 5/50 (2006.01)

(21) International Application Number:

PCT/EP2016/055954

(22) International Filing Date:

18 March 2016 (18.03.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

15159733.3 18 March 2015 (18.03.2015) EP
15191585.7 27 October 2015 (27.10.2015) EP

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
— with sequence listing part of description (Rule 5.2(a))

(88) Date of publication of the international search report:

3 November 2016

(54) Title: TREATMENT OF TYPE 2 DIABETES MELLITUS PATIENTS

(57) Abstract: The present invention refers to lixisenatide for use in the reduction of progression of urinary albumin excretion in a type 2 diabetes mellitus patient.



WO 2016/146812 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/055954

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K38/26 A61P3/10 A61P5/50 A61P9/10 A61P13/12
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, EMBASE, BIOSIS, CHEM ABS Data, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/156296 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; SILVESTRE LOUISE [FR]; BOKA GABOR [FR]) 22 November 2012 (2012-11-22) page 1, line 23 - page 2, line 28 tables 4,34	1-32
X	WO 2012/156299 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; NIEMOELLER ELISABETH [DE]; SILVESTRE) 22 November 2012 (2012-11-22) page 2, line 5 - line 16 tables 4,17,18,23,24,25,28,34,35	1-32
X	WO 2013/060850 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]) 2 May 2013 (2013-05-02) page 1, line 27 - page 2, line 8; tables 24,25	1-32
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

22 August 2016

Date of mailing of the international search report

09/09/2016

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/055954

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/028172 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; BOKA GABOR [FR]; MIOSSEC PATRICK [FR]) 8 March 2012 (2012-03-08) page 1, line 23 - page 2, line 9; tables 4,18,25	1-32
X	----- GAME F: "Novel hypoglycaemic agents: Considerations in patients with chronic kidney disease", NEPHRON - CLINICAL PRACTICE 2014 S. KARGER AG CHE, vol. 126, no. 1, 2014, pages 14-18, XP002757892, ISSN: 1660-2110 abstract "lixisenatide" on page 17	1-8, 16-32
X	----- GIORDA CARLO B ET AL: "Pharmacokinetics, safety, and efficacy of DPP-4 inhibitors and GLP-1 receptor agonists in patients with type 2 diabetes mellitus and renal or hepatic impairment. A systematic review of the literature.", ENDOCRINE AUG 2014, vol. 46, no. 3, August 2014 (2014-08), pages 406-419, XP002757893, ISSN: 1559-0100 abstract page 407, column 1, line 52 - column 2, line 5 page 415, column 1, line 20 - line 25 "Conclusions"	1-8, 16-32
A	----- HASSLACHER C ET AL: "Diabetic kidney disease", EXPERIMENTAL AND CLINICAL ENDOCRINOLOGY AND DIABETES JULY 2014 GEORG THIEME VERLAG DEU, vol. 122, no. 7, July 2014 (2014-07), pages 391-394, XP9190099, ISSN: 0947-7349 "Therapy objectives and Therapy" on page 392 "Important" on page 392	1-8, 16-32
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/055954

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>Pamela Katz ET AL: "The clinical burden of type 2 diabetes in patients with acute coronary syndromes: Prognosis and implications for short- and long-term management", Diabetes & Vascular Disease Research, November 2014 (2014-11), pages 395-409, XP055295749, Sage UK: London, England Retrieved from the Internet: URL:http://dvr.sagepub.com/content/11/6/395.full.pdf [retrieved on 2016-08-16] abstract "Introduction"; table 2 page 404, column 1, paragraph 2 -----</p>	9-32
X	<p>BENTLEY-LEWIS RHONDA ET AL: "Rationale, design, and baseline characteristics in Evaluation of LIXisenatide in Acute Coronary Syndrome, a long-term cardiovascular end point trial of lixisenatide versus placebo", AMERICAN HEART JOURNAL, MOSBY- YEAR BOOK INC, US, vol. 169, no. 5, 12 February 2015 (2015-02-12), pages 631-638, XP029574006, ISSN: 0002-8703, DOI: 10.1016/J.AHJ.2015.02.002 abstract page 632, paragraph 4 page 636, column 1, paragraph 2 -----</p>	9-32
X	<p>DAVID AGUILAR: "Heart failure and diabetes: Time to pay attention", AMERICAN HEART JOURNAL, vol. 162, no. 5, November 2011 (2011-11), pages 795-797, XP55127419, ISSN: 0002-8703, DOI: 10.1016/j.ahj.2011.08.016 page 795, column 1, paragraph 2; table I page 796, column 1, paragraph 1 -----</p>	9-32
X	<p>PETERSEN ANDREAS B ET AL: "Clinical potential of lixisenatide once daily treatment for type 2 diabetes mellitus.", DIABETES, METABOLIC SYNDROME AND OBESITY : TARGETS AND THERAPY 2013, vol. 6, 2013, pages 217-231, XP002760843, ISSN: 1178-7007 abstract Conclusion -----</p>	9-32
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/055954

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>PAULUS WOHLFART ET AL: "Cardioprotective effects of lixisenatide in rat myocardial ischemia-reperfusion injury studies", JOURNAL OF TRANSLATIONAL MEDICINE, BIOMED CENTRAL, LONDON, GB, vol. 11, no. 1, 28 March 2013 (2013-03-28), page 84, XP021145575, ISSN: 1479-5876, DOI: 10.1186/1479-5876-11-84 abstract</p> <p style="text-align: center;">-----</p>	9-32
X	<p>JOHN R PETRIE: "The cardiovascular safety of incretin-based therapies: a review of the evidence", CARDIOVASCULAR DIABETOLOGY, BIOMED CENTRAL, LONDON, GB, vol. 12, no. 1, 6 September 2013 (2013-09-06), page 130, XP021159743, ISSN: 1475-2840, DOI: 10.1186/1475-2840-12-130 abstract Introduction; table 1 "Weight" "Blood pressure" "Conclusions"</p> <p style="text-align: center;">-----</p>	9-32
X	<p>RUETTEN H ET AL: "Protective effects of the GLP-1 receptor agonist lixisenatide on ischaemia-reperfusion-induced myocardial infarction in an isolated rat heart model", DIABETOLOGIA, SPRINGER, BERLIN, DE, vol. 54, no. Suppl.1, September 2011 (2011-09), page S329, XP009163469, ISSN: 0012-186X abstract</p> <p style="text-align: center;">-----</p>	9-32
X	<p>HUEBSCHLE T ET AL: "Anti-atherosclerotic activity of lixisenatide in ApoE knockout mice", DIABETOLOGIA, vol. 55, no. Suppl. 1, October 2012 (2012-10), page S334, XP9191395, & 48TH ANNUAL MEETING OF THE EUROPEAN-ASSOCIATION-FOR-THE-STUDY-OF-DIABETES; BERLIN, GERMANY; OCTOBER 01 -05, 2012 abstract</p> <p style="text-align: center;">-----</p>	9-32

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2016/055954

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-8(completely); 16-32(partially)

Lixisenatide or/and a pharmaceutically acceptable salt thereof, for use in the reduction of progression of urinary albumin excretion in a type 2 diabetes mellitus patient.

2. claims: 9-15(completely); 16-32(partially)

Lixisenatide or/and a pharmaceutically acceptable salt thereof, for use in the reduction of cardiovascular morbidity or/and cardiovascular mortality in a type 2 diabetes mellitus patient who experienced at least one acute coronary syndrome event.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/055954

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
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