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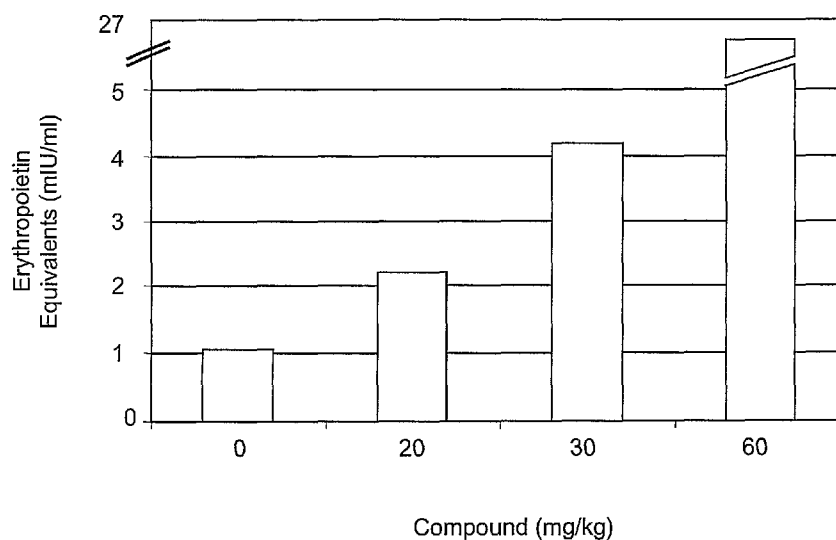
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[Continued on next page]

(54) Title: IMPROVED TREATMENT FOR ANEMIA USING A HIF-ALPHA STABILISING AGENT



(57) Abstract: The present invention relates to improved methods for treating anemia. Compounds which stabilise HIF-alpha useful for treating anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy, are provided.

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K31/00 A61K31/44 A61K31/47 A61K31/496 A61K31/17
A61K31/4725 A61K31/473 A61K31/4365 A61K33/26 A61K38/18
A61K45/06 A61P7/06

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

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 practical, search terms used)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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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

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"O" document referring to an oral disclosure, use, exhibition or other means

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"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

10 May 2007

Date of mailing of the International search report

12/06/2007

Name and mailing address of the ISA/

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	page 8, paragraph 18 - page 14, paragraph 20 pages 22-44, paragraphs 42,43 page 46, paragraph 52 - page 47, paragraph 53 page 48, paragraph 58 pages 64-65, paragraph 123 page 70, paragraph 134 page 72, paragraph 140 page 83, paragraphs 172,174 claims 1-5,34,35,37-41	
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Y	US 5 719 164 A (WEIDMANN KLAUS [DE] ET AL) 17 February 1998 (1998-02-17) cited in the application column 1, lines 6-11 column 1, line 65 - column 7, line 10 column 12, lines 10-12 examples claims 1,15	1-8, 14-19, 21,22, 24,26
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A	EP 0 606 046 A1 (CIBA GEIGY AG [CH]) 13 July 1994 (1994-07-13) page 2, lines 1-28 page 5, lines 12-50 page 8, lines 38-50 claims 1,7,21,22	10
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International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 2006/138511 A (FIBROGEN INC [US]; SEELEY TODD A [US]; LIU DAVID Y [US]; KLAUSS STEPHE) 28 December 2006 (2006-12-28) page 1, lines 6-9 page 3, lines 14-29 page 4, line 27 - page 5, line 4 page 9, line 25 - page 10, line 2 page 10, lines 24-30 page 12, line 23 - page 13, line 12 page 15, line 27 - page 26, line 12 page 31, lines 14-18 page 33, line 12 - page 35, line 6 page 41, line 11 - page 46, line 35 page 48, line 27 - page 54, line 7 page 63, lines 6-9 page 66, line 21 - page 67, line 2 page 70, line 23 - page 71, line 19 page 75, line 8 - page 77, line 2 table 5	1-14,21, 22,24, 26-28
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Box 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:

Although claims 1 and 3-28 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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 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 fee, this Authority did not invite payment of any additional fee.
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.
- ☐ 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, 14-28 (all partially)

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (I) wherein R1, R2 and R3 are identical or different and are hydrogen, hydroxyl, halogen, cyano, ... or (C7-C16)-aralkylsulfonyl (i.e. the pyridine or pyridazine of formula (I) forms a monocyclic system), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (I) wherein R1, R2 and R3 are identical or different and are hydrogen, hydroxyl, halogen, cyano, ... or (C7-C16)- aralkylsulfonyl (i.e. the pyridine or pyridazine of formula (I) forms a monocyclic system) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

2. claims: 1-8, 14-28 (all partially)

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a bicyclic system which is of formula (Ia), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a bicyclic system which is of formula (Ia) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

3. claims: 1-8 (partially), 11-12 (entirely), 13 (partially), 14-28 (partially)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a bicyclic system which is of formula (Ib) or formula (IV), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a bicyclic system which is of formula (Ib) or formula (IV) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

4. claims: 1-8, 14-28 (all partially)

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a bicyclic system which is of formula (Ic), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a bicyclic system which is of formula (Ic) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

5. claims: 1-8, 14-28 (all partially)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a tricyclic system which is of formula (Id), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (I) wherein R1 and R2, or R2 and R3, together with the pyridine or pyridazine carrying them, form a tricyclic system which is of formula (Id) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

6. claims: 1-7 (partially), 9 (entirely), 13-28 (partially)

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (II), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (II) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

7. claims: 1-7 (partially), 10 (entirely), 14-28 (partially)

A method for treating anemia or increasing hemoglobin levels in a subject, said method comprising administering to the subject an effective amount of an agent that stabilizes HIFalpha, wherein the agent is selected from a compound of formula (III), wherein the anemia treatment or the increased hemoglobin levels are associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

Use of an agent that stabilizes HIFalpha wherein the agent is selected from a compound of formula (III) in the manufacture of a medicament for the treatment of anemia, wherein the anemia treatment is associated with a lower risk of thrombosis or hypertension compared to that observed with rhEPO therapy.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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