A61K 1/00 (2006.01) C07K 16/28 (2006.01)


(72) Inventors; and


(54) Title: FORMULATION FOR ANTI-α4β7 ANTIBODY

(57) Abstract: Antibody formulations are described comprising a mixture of a non-reducing sugar, an anti-α4β7 antibody and at least one amino acid. The disclosed formulations have improved stability, reduced aggregate formation, and may retard degradation of the anti-α4β7 antibody therein or exhibit any combinations thereof. The present invention further provides a safe dosing regimen of these antibody formulations that is easy to follow, and which results in a therapeutically effective amount of the anti-α4β7 antibody in vivo.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61P1/00 A61K39/395 C07K16/28

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
C07K 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, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<td>Y</td>
<td>CLELAND J L ET AL: &quot;A SPECIFIC MOLAR RATIO OF STABILIZER TO PROTEIN IS REQUIRED FOR STORAGE STABILITY OF A LYOPHILIZED MONOCLONAL ANTIBODY&quot;, JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN PHARMACEUTICAL ASSOCIATION, WASHINGTON, US, Vol. 90, No. 3, 1 March 2001 (2001-03-01), Pages 310-321, XP001179875, ISSN: 0022-3549, DOI: 10.1002/1520-6017 (200103)90:3&lt;310: :AID-JPS 6x3.0. C0;2-R abstract page 313, column 1, paragraph 1; figures 1-4; tables 1,2</td>
<td>1-34,67, 68</td>
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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

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*A" document member of the same patent family

Date of the actual completion of the international search

26 September 2012

Date of mailing of the international search report

29/10/2012

Name and mailing address of the ISA:

European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Kl ee, Barbara

Form PCT/ISA/210 (second sheet) (April 2005)
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<td>WO 01/78779 A2 (MILLENNIUM PHARM INC [US]; GENENTECH INC [US]; BRETTMAN LEE R [US]; F0) 25 October 2001 (2001-10-25) claims 1-69</td>
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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).

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.:

   1-34, 67, 68

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

1. Claims: 1-34, 67, 68
   Stable formulation of the anti-alpha4beta7 antibody

2. Claims: 35, 36
   Determination of the quality of a lyophilized product

3. Claims: 37-66
   Treatment of inflammatory disease with antibodies directed against alpha4beta7 integrin