Title: RECOMBINANT ANTI-CD30 ANTIBODIES AND USES THEREOF

Abstract: The present invention relates to methods and compositions for the treatment of Hodgkin’s Disease, comprising administering proteins characterized by their ability to bind to CD30, or compete with monoclonal antibodies AC10 or HeFi-1 for binding to CD30, and exert a cytostatic or cytotoxic effect on Hodgkin’s Disease cells. Such proteins include derivatives of monoclonal antibodies AC10 and HeFi-1. The proteins of the invention can be humanized, or chimeric antibodies; further, they can be conjugated to cytotoxic agents such as chemotherapeutic drugs. The invention further relates to nucleic acids encoding the proteins of the invention. The invention yet further relates to a method for identifying an anti-CD30 antibody useful for the treatment or prevention of Hodgkin’s Disease.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61K 39/395, 39/40, 39/42
US CL. : 435/325, 424/133.1
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)
U.S. : 435/325, 424/133.1

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>DA COSTA. et al. Immune Recruitment by Bispecific Antibodies for the Treatment of</td>
<td>1, 2, 5, 7</td>
</tr>
<tr>
<td></td>
<td>Hodgkin disease, Cancer Chemotherapy and Pharmacology, 2000, Volume 46(Suppl),</td>
<td></td>
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<tr>
<td></td>
<td>pages 833-836, see entire document.</td>
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<tr>
<td>Y</td>
<td>ENGERT et al. Evaluation of Ricin A Chain-containing Immunotoxins Directed against</td>
<td>1-7</td>
</tr>
<tr>
<td></td>
<td>the CD30 Antigen as Potential Reagents for the Treatment of Hodgkin’s Disease,</td>
<td></td>
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<td></td>
<td>Cancer Research, 1 January 1990, Volume 50, pages 84-88, see entire document.</td>
<td></td>
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</tbody>
</table>

☐ 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 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

"Y" 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
10 September 2002 (10.09.2002)

Date of mailing of the international search report
30 SEP 2002

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks
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Authorized officer
Nathalie Davis, PhD
Telephone No. 703-308-0196

Form PCT/ISA/210 (second sheet) (July 1998)
BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-7, drawn to a method of treatment or prevention of Hodgkin’s disease by administering an antibody that binds CD30.

Group II, claim(s) 8-19, drawn to a method of treatment or prevention of Hodgkin’s disease by administering a protein that competes for CD30 binding with an antibody.

Group III, claim(s) 20-24 and 34-38, drawn to an antibody composition that binds CD30 and pharmaceutical.

Group IV, claim(s) 25-35 and 39-47, drawn to a protein that competes for CD30 binding with an antibody and pharmaceutical.

Group V, claim(s) 48-66, drawn to a nucleic acid encoding a protein that competes for CD30 binding with an antibody.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I-V is the administration of a molecule that binds CD30 in the treatment of Hodgkin’s Disease.


The special technical feature of Group I is treatment using an antibody that immunospecifically binds CD30; Group II is treatment using a protein that competes for CD30 binding with an antibody; Group III is an antibody that binds CD30; Group IV is a protein that competes for CD30 binding with an antibody; Group V is a nucleic acid that encodes a protein that competes for CD30 binding with an antibody.

A. In the event applicant pays for additional species to be examined with the main invention of Group II, claims 8-19 or in the event applicant pays for the examination of Group V, claims 48-66, applicant is required to elect a single species of SEQ ID NO: comprising SEQ ID NO: 1-32. SEQ ID NO: 1-32 are patentably distinct based on structural and functional differences.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

2. In the absence of any response from the applicant, this Authority will establish the International Preliminary Examination Report based on the main invention. The claims drawn to the main invention are as follows:

Claims 1-7, as it reads on SEQ ID NO: 4.