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[Continued on next page]

- (54) Title: ANTI-TRANSFERRIN RECEPTOR ANTIBODIES AND METHODS OF USE

(57) Abstract: The present invention relates to anti-transferrin receptor antibodies and methods of their use.

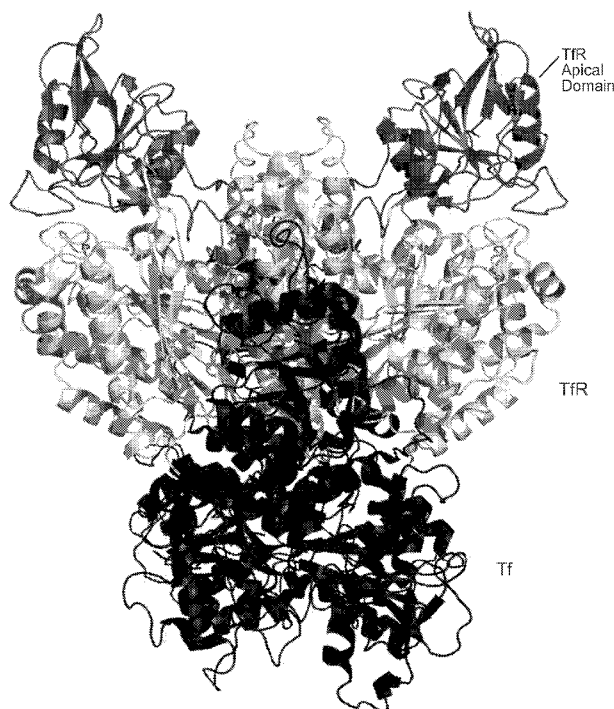


FIG. 1



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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, LT, 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.

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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).

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A. CLASSIFICATION OF SUBJECT MATTER

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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)

C07K 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 practicable, search terms used)

EP0-Internal, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	HOREJSI V ET AL: "MONOCLONAL ANTIBODIES AGAINST HUMAN LEUKOCYTE ANTIGENS II. ANTIBODIES AGAINST CD45 T200 CD3 T3 CD43 CD10 CALLA TRANSFERRIN RECEPTOR T9 A NOVEL BROADLY EXPRESSED 18-KDA ANTIGEN MEM-43 AND A NOVEL ANTIGEN OF RESTRICTED EXPRESSION MEM-74", FOLIA BIOLOGICA (PRAGUE), vol. 34, no. 1, 1 January 1988 (1988-01-01), pages 23-34, XP009179511, ISSN: 0015-5500 the whole document ----- -/--	1,3

☒ 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

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International application No

PCT/US2014/038847

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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T	----- Biocompare: "anti-Transferrin Receptor (p90, CD71) (TFRC) antibody (APC) ABIN238474 from antibodies-online", Biocompare.com, 1 August 2014 (2014-08-01), XP055133157, Retrieved from the Internet: URL:http://www.biocompare.com/9776-Antibodies/4144935-anti-Transferrin-Receptor-p90-CD71-TFRC-antibody-APC/ [retrieved on 2014-08-04] the whole document	1
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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/038847

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	TRACY R. DANIELS ET AL: "The transferrin receptor and the targeted delivery of therapeutic agents against cancer", BIOCHIMICA ET BIOPHYSICA ACTA (BBA) - GENERAL SUBJECTS, vol. 1820, no. 3, 1 March 2012 (2012-03-01), pages 291-317, XP055133141, ISSN: 0304-4165, DOI: 10.1016/j.bbagen.2011.07.016 The whole document, in particular section 3.2.3 -----	1
A	WHITE S ET AL: "COMBINATIONS OF ANTI-TRANSFERRIN RECEPTOR MONOCLONAL ANTIBODIES INHIBIT HUMAN TUMOR CELL GROWTH IN-VITRO AND IN-VIVO EVIDENCE FOR SYNERGISTIC ANTIPROLIFERATIVE EFFECTS", CANCER RESEARCH, AMERICAN ASSOCIATION FOR CANCER RESEARCH, US, vol. 50, no. 19, 1 January 1990 (1990-01-01), pages 6295-6301, XP008073808, ISSN: 0008-5472 The whole document, in particular, Table 1 -----	1
A	TAETLE R ET AL: "MECHANISMS OF GROWTH INHIBITION BY ANTI-TRANSFERRIN RECEPTOR MONOCLONAL ANTIBODIES", CANCER RESEARCH, AMERICAN ASSOCIATION FOR CANCER RESEARCH, US, vol. 46, no. 4, PART 01, 1 April 1986 (1986-04-01), pages 1758-1763, XP008061610, ISSN: 0008-5472 abstract -----	1
Y	WO 2012/075037 A1 (GENENTECH INC [US]; HOFFMANN LA ROCHE [CH]; DENNIS MARK [US]; WATTS RY) 7 June 2012 (2012-06-07) the whole document -----	45-74
Y	PAUL STEVEN M: "Therapeutic antibodies for brain disorders", SCIENCE / SCIENCE TRANSLATIONAL MEDICINE, WASHINGTON, DC : AAAS, US, vol. 3, no. 84, 25 May 2011 (2011-05-25), page 84ps20, XP009155720, ISSN: 1946-6242 the whole document ----- -/--	45-74

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/038847

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	COUCH JESSICA A ET AL: "Addressing safety liabilities of TfR bispecific antibodies that cross the blood-brain barrier", SCIENCE / SCIENCE TRANSLATIONAL MEDICINE, WASHINGTON, DC : AAAS, US, vol. 5, no. 183, 1 May 2013 (2013-05-01), XP008163922, ISSN: 1946-6242, DOI: 10.1126/SCITRANSLMED.3005338 The whole document, in particular, p.61, col.1, li.9-11. -----	45-74
T	BIEN-LY NGA ET AL: "Transferrin receptor (TfR) trafficking determines brain uptake of TfR antibody affinity variants", THE JOURNAL OF EXPERIMENTAL MEDICINE, ROCKEFELLER UNIVERSITY PRESS, US, vol. 211, no. 2, 10 February 2014 (2014-02-10), pages 233-244, XP009179491, ISSN: 0022-1007 the whole document -----	
T	WO 2013/177062 A2 (GENENTECH INC [US]; HOFFMANN LA ROCHE [CH]) 28 November 2013 (2013-11-28) the whole document -----	
A	RUDIKOFF S ET AL: "Single amino acid substitution altering antigen-binding specificity", PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF SCIENCES, vol. 79, 1 March 1982 (1982-03-01), pages 1979-1983, XP007901436, ISSN: 0027-8424, DOI: 10.1073/PNAS.79.6.1979 the whole document -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/038847

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.:

1, 3, 45-74(all partially)

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, 3, 45-74(all partially)

An isolated antibody, which is a monoclonal antibody, that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR.

2. claims: 1, 4, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, and which is a human, humanized, or chimeric antibody.

3. claims: 1, 5, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, and which is an antibody fragment that binds human TfR and primate TfR.

4-25. claims: 1, 6, 45-74(all partially)

21 different isolated antibodies that bind to human transferrin receptor (TfR) and primate TfR, wherein the antibody comprises HVR-L3, HVR-H2, and HVR-H3, respectively comprising the amino acid sequences of either: SEQ ID NOs: 31, 33 and 34; SEQ ID NOs: 36, 38 and 39; SEQ ID NOs: 36, 40 and 34; SEQ ID NOs: 42, 43 and 44; SEQ ID NOs: 31, 33 and 34; SEQ ID NOs: 46, 48 and 49; SEQ ID NOs: 52, 54 and 55; SEQ ID NOs: 52, 58 and 59; SEQ ID NOs: 62, 63 and 55; SEQ ID NOs: 52, 65 and 55; SEQ ID NOs: 68, 69 and 70; SEQ ID NOs: 73, 75 and 76; SEQ ID NOs: 79, 81 and 82; SEQ ID NOs: 79, 83 and 84; SEQ ID NOs: 87, 89 and 90; SEQ ID NOs: 93, 95 and 96; SEQ ID NOs: 99, 101 and 102; SEQ ID NOs: 127, 33 and 34; SEQ ID NOs: 52, 156 and 55; SEQ ID NOs: 52, 157 and 55, or SEQ ID NOs: 155, 54 and 55, and related subject-matter, wherein the antibody does not inhibit the binding of transferrin to TfR, and each antibody is a separate invention.

25-43. claims: 1, 7, 8, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody comprises HVR-H1, HVR-H2, and HVR-H3, respectively comprising the amino acid sequences of: SEQ ID NOs: 32, 33 and 34; SEQ ID NOs: 37, 38 and 39; SEQ ID NOs: 32, 40 and

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

34; SEQ ID NOs: 37, 43 and 44; SEQ ID NOs: 32, 33 and 34; SEQ ID NOs: 47, 48 and 49; SEQ ID NOs: 53, 54 and 55; SEQ ID NOs: 53, 58 and 59; SEQ ID NOs: 53, 63 and 55; SEQ ID NOs: 53, 65 and 55; SEQ ID NOs: 53, 69 and 70; SEQ ID NOs: 74, 75 and 76; SEQ ID NOs: 80, 81 and 82; SEQ ID NOs: 80, 83 and 84; SEQ ID NOs: 88, 89 and 90; SEQ ID NOs: 94, 95 and 96; SEQ ID NOs: 100, 101 and 102; SEQ ID NOs: 53, 156 and 55 or SEQ ID NOs: 53, 157 and 55; and related subject-matter, wherein the antibody does not inhibit the binding of transferrin to TfR, and each antibody is a separate invention.

44-50. claims: 1, 10, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, wherein the antibody comprises at least one HVR-H1, HVR-H2, HVR-H3, HVR-L1, HVR-L2, or HVR-L3 sequence selected from the group of sequences consisting of:

- (a) an HVR-H1 sequence of SEQ ID NO: 47, 53, 100 or ;
 - (b) an HVR-H2 sequence of SEQ ID NO: 48, 69, 101, 156 or 157;
 - (c) an HVR-H3 sequence of SEQ ID NO: 49, 76, or 102;
 - (d) an HVR-L1 sequence of SEQ ID NO: 45, 66 or 97;
 - (e) an HVR-L2 sequence of SEQ ID NOs: 30, 67 or 98; and
 - (f) an HVR-L3 sequence of SEQ ID NOs: 46, 68 or 102,
- and each antibody is a separate invention.

51-87. claims: 1, 11-13, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, wherein the antibody comprises

- (a) a VH sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 7, 8, 9, 10, 15, 16, 17, 18, 20, 25, 26, 27, 28, 108, 114, 120, 126, 153 or 154;
 - (b) a VL sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 4, 5, 6, 11, 12, 13, 14, 19, 21, 22, 23, 24, 105, 111, 117, 123, 151 or
 - (c) a VH sequence as in (a) and a VL sequence as in (b), and
- each antibody is a separate invention.

88-102. claims: 1, 15-18, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, and which is selected from the group consisting of antibodies 7A4, 8A2, 15D2, 10D11, 7B10, 15G11, 16G5, 13C3, 16G4, 16F6, 7G7, 4C2, 1B12, and 13D4, and relate subject-matter. Each antibody is

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

a separate invention.

103-172. claims: 1, 19, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, and which comprises a sequence or one or more HVR sequences corresponding to that of or one or more of those set forth for any one of the clones in Figures 3, 4 and 23., and relate subject-matter. Each antibody is a separate invention.

173-190. claims: 1, 9, 45-74(all partially)

An isolated antibody that binds to human transferrin receptor (TfR) and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, wherein the antibody comprising HVR-L1, HVR-L2, and HVR-L3, respectively comprising the amino acid sequences of: SEQ ID NOs: 29, 30 and 31; SEQ ID NOs: 35, 30 and 36; SEQ ID NOs: 41, 30 and 42; SEQ ID NOs: 29, 30 and 31; SEQ ID NOs: 45, 30 and 46; SEQ ID NOs: 50, 51 and 52; SEQ ID NOs: 56, 57 and 52; SEQ ID NOs: 60, 61 and 62; SEQ ID NOs: 60, 64 and 52; SEQ ID NOs: 66, 67 and 68; SEQ ID NOs: 71, 72 and 73; SEQ ID NOs: 77, 78 and 79; SEQ ID NOs: 85, 86 and 87; SEQ ID NOs: 91, 92 and 93; SEQ ID NOs: 97, 98 and 99, SEQ ID NOs: 29, 30 and 127, or SEQ ID NOs: 50, 51 and 155, wherein each antibody is a separate invention.

191-197. claims: 14, 53-57, 60(all partially)

An antibody comprising:

- (a) a VH sequence of SEQ ID NO: 108 and a VL sequence of SEQ ID NO: 105;
- (b) a VH sequence of SEQ ID NO: 114 and a VL sequence of SEQ ID NO: 111;
- (c) a VH sequence of SEQ ID NO: 120 and a VL sequence of SEQ ID NO: 117;
- (d) a VH sequence of SEQ ID NO: 126 and a VL sequence of SEQ ID NO: 123;
- (e) a VH sequence of SEQ ID NO: 153 and a VL sequence of SEQ ID NO: 105;
- (f) a VH sequence of SEQ ID NO: 154 and a VL sequence of SEQ ID NO: 105;
- (g) a VH sequence of SEQ ID NO: 108 and a VL sequence of SEQ ID NO: 155, and related subject-matter, wherein each antibody is a separate invention.

198-240. claims: 20, 53-57, 60(all partially)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

An isolated antibody that binds to the same epitope on TfR as an antibody selected from the group consisting of antibodies 7A4, 8A2, 15D2, 10D11, 7B10, 15G11, 16G5, 13C3, 16G4, 16F6, 7G7, 4C2, 1B12, 13D4, 15G11.v1, 15G11.v2, 15G11.v3, 15G11.v4, 15G11.v5, 7A4.v1; 7A4.v2, 7A4.v3, 7A4.v4, 7A4.v5, 7A4.v6, 7A4.v7, 7A4.v8, 7A4.v9, 7A4.v10, 7A4.v11, 7A4.v12, 7A4.v13, 7A4.v14, 7A4.v15, 7G7.v1, 16F6.v1, 16F6.v2, 16F6.v3, 16F6.v4, 15G11.N52A, 15G11.T53A or 15G11.W92A, and related subject-matter, wherein each antibody is a separate invention.

241. claims: 2, 21-44(completely); 3-8, 10-19, 45-57, 60, 64-74(partially)

An isolated antibody that binds to human TfR and primate TfR, wherein the antibody does not inhibit the binding of transferrin to TfR, and wherein one or more properties of the antibody have been modified to reduce or eliminate the impact of the antibody on reticulocytes and/or reduce the severity or presence of acute clinical symptoms in a subject or mammal treated with the antibody, and related subject-matter, wherein each antibody is a separate invention.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/038847

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