

TABLE 1—ANDAS FOR WHICH FDA IS WITHDRAWING APPROVAL

| Application No. | Drug product(s) | Applicant or holder |
|-------------------|--|--|
| ANDA 40117 | Vicodin HP (Acetaminophen and Hydrocodone Bitartrate Tablets), 660 mg/10 mg. | AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064. |
| ANDA 88058 | Vicodin (Acetaminophen and Hydrocodone Bitartrate Tablets), 500 mg/5 mg. | AbbVie Inc. |
| ANDA 89736 | Vicodin ES (Acetaminophen and Hydrocodone Bitartrate Tablets), 750 mg/7.5 mg. | AbbVie Inc. |
| ANDA 89166 | SYNALGOS-DC-A (Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Capsules), 356.4 mg/30 mg/16 mg. | Leitner Pharmaceuticals LLC, 340 Edgemont Ave., Bristol, TN 37620. |
| ANDA 40366 | Acetaminophen and Hydrocodone Bitartrate Oral Solution, 500 mg/15 milliliters (mL); 7.5 mg/15 mL. | Nesher Pharmaceuticals USA LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044. |
| ANDA 040148 | Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg. | Watson Laboratories, 311 Bonnie Circle, Corona, CA 92880. |
| ANDA 040637 | Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablets, 712.8 mg/60 mg/32 mg. | West-Ward Pharmaceutical Corp., 435 Industrial Way West, Eatontown, NJ 07724. |

With respect to the ANDAs listed in table 1 (with the exception of ANDA 040148), for the reasons discussed in the January 14, 2011, and March 27, 2014, notices, the Director of CDER, under section 505(e)(2) of the FD&C Act and under authority delegated to her by the Commissioner of Food and Drugs (the Commissioner), finds that new evidence of clinical experience, not contained in the applications listed in table 1 and not available at the time the applications were approved, shows that prescription drugs containing more than 325 mg of acetaminophen per dosage unit are not safe for use under the conditions of use that formed the basis upon which the applications were approved (21 U.S.C. 355(e)(2)). Therefore, approval of the applications for the drug products listed in table 1 of this document (with the exception of ANDA 040148), and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

With respect to ANDA 040148 listed in table 1, under § 314.150(d), and under authority delegated to the Director of CDER by the Commissioner, approval of ANDA 040148 and all amendments and supplements thereto, is withdrawn (see **DATES**).

The safety issue discussed in this document and the March 27, 2014, and January 14, 2011, **Federal Register** notices is limited to products containing more than 325 mg of acetaminophen per dosage unit. Thus, the withdrawal of approval of products containing more than 325 mg of acetaminophen per dosage unit listed in table 1 does not change the approval status of any products with 325 mg or less of acetaminophen per dosage unit that were approved under the same

application. In addition, the withdrawal of approval of products containing more than 325 mg of acetaminophen per dosage unit does not change the approval status of products with 325 mg or less of acetaminophen per dosage unit that refer to or rely on the withdrawn products. For example, this withdrawal action will not affect the approval status of an ANDA for a product that contains 325 mg or less per dosage unit that references a product listed in table 1, but for which FDA approved a suitability petition for a lower strength under section 505(j)(2)(C) of the FD&C Act and § 314.93 (21 CFR 314.93)).

Dated: July 14, 2014.

Peter Lurie,
Associate Commissioner for Policy and Planning.

[FR Doc. 2014-16820 Filed 7-16-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Chimeric Antigen Receptors Targeting B-Cell Maturation Antigen To Treat or Prevent Cancer and Autoimmune Disease

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Bluebird Bio to practice the inventions embodied in US Provisional Patent Application Serial No. 61/622,600, entitled

“Chimeric Antigen Receptors Targeting B-cell Maturation Antigen” [HHS Ref. E-040-2012/0-US-01], and International (PCT) Application No. PCT/US13/32029, entitled “Chimeric Antigen Receptors Targeting B-cell Maturation Antigen” [HHS Ref. E-040-2012/0-PCT-02], and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

Use of the Patent Rights to make and have made, to sell, to offer for sale, to import, and to use in humans, human autologous peripheral blood T-cells modified by recombinant human immunodeficiency virus (“HIV”)–based lentiviral vectors or murine leukemia virus (“MLV”)–based gamma-retroviral vectors to express chimeric antigen receptors that recognize B-cell Maturation Antigen (“BCMA”) for the treatment or prevention of cancer and autoimmune diseases.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before August 18, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; Email: mccuepat@od.nih.gov.

SUPPLEMENTARY INFORMATION: These inventions concern a series of chimeric antigen receptors (CARs) that specifically target BCMA, a protein that is highly expressed on the surface of

multiple myeloma cells. The pending patent application includes claims to compositions and vectors incorporating the CARs, as well as methods of destroying multiple myeloma cells using T-cells engineered to express a CAR.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 14, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014-16764 Filed 7-16-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; North American Prodrome Longitudinal Study-3 [NAPLS].

Date: July 25, 2014.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861, dsommers@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: July 11, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-16746 Filed 7-16-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Small Grants Program for Epidemiology.

Date: July 23, 2014.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2E032, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Gerald G. Lovinger, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W266, Bethesda, MD 20892-8329, 240-276-6385, lovingeg@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI U01 Review.

Date: August 26, 2014.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 3W032/034, Rockville, MD 20850.

Contact Person: Ben Prickril, Ph.D., Scientific Review Officer, Research Program and Review Branch, DEA, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W634, Rockville, MD 20850, 240-276-5794, prickril@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project Meeting II (P01).

Date: September 30–October 1, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Majed M. Hamavy, Ph.D., MBA, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W120, Rockville, MD 20850, 240-276-6457, mh101v@nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee J—Career Development.

Date: October 29, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Ilda F. S. Melo, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Rockville, MD 20850, 240-276-6468, ilda.melo@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/sep/sep.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 11, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-16744 Filed 7-16-14; 8:45 am]

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