TABLE 1—APPROVED ANDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED—Continued

Application No.	Drug	Applicant
ANDA 086511	Ona-Mast (phentermine HCl) Capsules, 30 mg	MM Mast and Co.
ANDA 086516	Ona-Mast (phentermine HCl) Capsules, 30 mg	Do.
ANDA 086550	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Shire Richwood, Inc., 7900 Tanners Gate Dr., Suite 200, Florence, KY 41042.
ANDA 086551	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086552	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086553	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086554	X-Trozine (phendimetrazine tartrate) Tablets, 35 mg	Do.
ANDA 086735	Phentermine HCl Capsules, 15 mg	Camall Co., Inc.
ANDA 086748	Theophylline Elixir, 80 mg/15 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 086766	Nitrofurazone Ointment, 0.2%	Wendt Laboratories, Inc.
ANDA 087081	Nitrofurazone Topical Solution, 0.2%	Do.
ANDA 087226	Phentermine HCl Capsules, 30 mg	Camall Co., Inc.
ANDA 087371	X-Trozine L.A. (phendimetrazine tartrate) Extended-Release Capsules, 105 mg.	Shire Richwood, Inc.
ANDA 087392	Aminophylline Injection, 25 mg/mL	Pharma Serve, Inc., Subsidiary of Torigian Laboratories, 218–20 98th Ave., Queens Village, NY 11429.
ANDA 087394	X-Trozine (phendimetrazine tartrate) Capsules, 35 mg	Shire Richwood, Inc.
ANDA 087442	Neosar (cyclophosphamide) for Injection, 100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial, and 2 g/vial.	Bedford Laboratories, Division of Ben Venue Laboratories, Inc., 300 Northfield Rd., Bedford, OH 44146.
ANDA 087487	Melfiat-105 (phendimetrazine tartrate) Extended-Release Capsules, 105 mg.	Numark Laboratories, Inc., 75 Mayfield Ave., Edison, NJ 08837.
ANDA 087636	Tropicamide Ophthalmic Solution, 0.5%	Miza Pharmaceuticals USA, Inc., c/o Optopics Laboratories.
ANDA 087637	Tropicamide Ophthalmic Solution, 1%	Do.
ANDA 087681	Paracaine (proparacaine HCl) Ophthalmic Solution, 0.5%	Optopics Laboratories Corp.
ANDA 087764	Oby-Trim (phentermine HCl) Capsules, 30 mg	Shire Richwood, Inc.
ANDA 087932	Triamcinolone Acetonide Cream, 0.025%	Ambix Laboratories, Division of Organics Corp. of America.
ANDA 088786	Sodium Polystyrene Sulfonate USP Powder, 453.6 g/bottle	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.
ANDA 088897	Promethazine VC Plain (phenylephrine HCl and promethazine HCl) Syrup, 5 mg/5 mL and 6.25 mg/5 mL.	Do.
ANDA 089141	Aerolate (theophylline) Oral Solution, 150 mg/15 mL	Fleming and Co. Pharmaceuticals, Inc.
ANDA 089417	Methocarbamol Tablets USP, 500 mg	American Therapeutics, Inc.
ANDA 089418	Methocarbamol Tablets USP, 750 mg	Do.
ANDA 089478	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Do.
ANDA 089479	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Do.
ANDA 089480	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 089514	Trihexyphenidyl HCl Elixir, 2 mg/5 mL	Pharmaceutical Ventures, Ltd., P.O. Box D3700, Pomona, NY 10970.
ANDA 089726	Prednisone Oral Solution, 5 mg/5 mL	Wockhardt EU Operations (Swiss) AG, c/o Morton Grove Pharmaceuticals, Inc.

FDA finds that the holders of the ANDAs listed in table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the ANDAs listed in table 1 and all amendments and supplements thereto, is hereby withdrawn, effective October 22, 2021.

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23075 Filed 10–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent Commercialization License: CD28H Domain-Containing Chimeric Antigen Receptors and Methods of Use

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Ankarys Therapeutics Inc., located at 110 Cumberland Street, Suite 520, M5R 3V5, Toronto, Ontario, Canada, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before November 8, 2021 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Dawn Taylor-Mulneix, Technology Transfer and Patent Specialist, Technology Transfer and

Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health; phone number 301–767–5189, or *dawn.taylor-mulneix@nih.gov.*

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement: PCT Patent Application Number PCT/US2020/024985, filed March 26, 2020, entitled ''CD28H Domain-Containing Chimeric Antigen Receptors and Methods of Use'' (HHS Reference No. E–097–2020–00–PCT), and U.S. and foreign patent applications claiming priority to the aforementioned application.

All rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent commercialization license territory may be worldwide, and the field of use may be limited to: ''Use of natural killer cell immunotherapies for the treatment of multiple myeloma, non-Hodgkin lymphoma, and pancreatic cancer''.

Engineered chimeric antigen receptors (CARs) that are expressed in cytotoxic T cells and natural killer (NK) cells have been used to specifically target tumor cells. However, CAR–T and CAR–NK cells are still subject to down regulation by their inhibitory receptors after injection into patients.

Scientists at NIAID have developed CAR constructs that overcome inhibition of NK cells by receptors for human major histocompatibility complex molecules HLA–E and HLA–C, based on in vitro studies. The CAR contains an antigen binding domain of receptor CD28 homolog (CD28H), a CD28H transmembrane domain (TM), a CD28H signaling domain, and other intracellular signaling domains, such as 2B4 (CD244) and CD3 zeta chain (CD3zeta). A variant of this CAR, in which the antigen binding domain of CD28H is replaced by a single-chain antibody variable region (scFv) that binds to CD19, rendered NK cells resistant to inhibition by HLA–E and HLA–C on CD19+ tumor cells. An abstract for this invention was published in the **Federal Register** on April 22, 2020.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent commercialization license will be royalty bearing, and may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: October 19, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021–23092 Filed 10–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular and Molecular Biology of Neurodegeneration Study Section, October 28, 2021, 10:00 a.m. to October 29, 2021, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 24, 2021, FR Doc 2021–20784 86 FR 53084.

This meeting is being amended to change the Contact Person from Christine Jean DiDonato to Laurent Taupenot, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (301) 435–1203. The meeting is closed to the public.

Dated: October 19, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–23082 Filed 10–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

Date: November 16–17, 2021.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Population Sciences and Epidemiology.

Date: November 17–18, 2021.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ananya Paria, DHSC, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007H, Bethesda, MD 20892, (301) 827–6513, *pariaa@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Disease and Reproductive Health.

Date: November 17–18, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139,