

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; New Approaches to Synthetic Lethality for Mutant KRas-Dependent Cancers (U01).

Date: April 13, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove; 9609 Medical Center Drive; Room 7W032; Rockville, MD 20850; (Telephone Conference Call).

Contact Person: Clifford W. Schweinfest, Ph.D.; Scientific Review Officer; Special Review Branch; Division of Extramural Activities; National Cancer Institute, NIH; 9609 Medical Center Drive, Room 7W108; Bethesda, MD 20892-9750; 240-276-6343; schweinfestcw@mail.nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee A—Cancer Centers.

Date: May 7, 2015.

Time: 8:00 a.m. to 4:45 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda; (Formerly Holiday Inn Select); 8120 Wisconsin Avenue; Bethesda, MD 20814.

Contact Person: Shamala K. Srinivas, Ph.D.; Associate Director; Office of Referral, Review, and Program Coordination; Division of Extramural Activities; National Cancer Institute, NIH; 9609 Medical Center Drive, 7W530; Bethesda, MD 20892-9750; 240-276-6442; ss537t@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: March 17, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Evaluation Option License Agreement: Pre-Clinical Evaluation and Commercial Development of Anti-Tyrosine Kinase-Like Orphan Receptor 1 Antibody-Drug Conjugates for the Treatment of Human Cancers

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 a start-up exclusive evaluation option license agreement to practice the inventions embodied in U.S. Patent Application No. 61/172,099 entitled "Anti-human ROR1 Antibodies" filed April 23, 2009 [HHS Ref. E-097-2009/0-US-01], PCT Application No. PCT/US2010/032208 entitled "Anti-human ROR1 Antibodies" filed April 23, 2010 [HHS Ref. E-097-2009/0-PCT-02], European Patent Application No. 10715077.3 entitled, "Anti-human ROR1 Antibodies" filed October 24, 2011 [HHS Ref. No. E-097-2009/0-EP-03], U.S. Patent Application No. 13/265,582 entitled, "Anti-human ROR1 Antibodies" filed October 21, 2011 [HHS Ref. No. E-097-2009/0-US-04], Australian Patent Application No. 2010238723 entitled, "Anti-human ROR1 Antibodies" filed October 21, 2011 [HHS Ref. No. E-097-2009/0-AU-04], Canadian Patent Application No. 2,759,733 entitled, "Anti-human ROR1 Antibodies" filed October 21, 2011 [HHS Ref. No. E-097-2009/0-CA-05], US Provisional Application No. 61/418,550 entitled, "Chimeric rabbit/human ROR1 antibodies" filed December 1, 2010 [HHS Ref. E-039-2011/0-US-01], PCT Application No. PCT/US2011/062670 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-PCT-02];

Australian Patent Application No. 2011336650 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-AU-03], Canadian Patent Application No. 2818992 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-CA-04], European Patent Application No. 11791733.6 entitled, "Chimeric rabbit/human ROR1 antibodies" filed November 30, 2011 [HHS Ref. E-039-2011/0-EP-05] and U.S. Patent Application No. 13/990,977 entitled, "Chimeric rabbit/human ROR1 antibodies" filed May 31, 2013 [HHS Ref. E-039-2011/0-US-06] and all related continuing and foreign patents/patent applications for the technology family to NBE Therapeutics, Ltd. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective start-up exclusive evaluation option license territory may be worldwide and the field of use may be limited to pre-clinical evaluation and commercial development of an antibody-drug conjugate comprising an anti-tyrosine protein kinase transmembrane receptor (ROR1) antibody for the treatment of human ROR1 expressing cancers utilizing enzymatic conjugation methods linking a small molecule to a full-length antibody, wherein the full-length antibody moiety comprises the anti-ROR1 antibodies or CDR3s within the scope of the Licensed Patent Rights. For avoidance of doubt, this Agreement explicitly excludes the following: (a) Antibody-drug conjugates utilizing non-enzymatic conjugation linking small molecules to said antibodies, (b) immunotoxins comprising anti-ROR1 antibodies and *Pseudomonas* exotoxins, and (c) non-full-length bispecific antibodies. Upon expiration or termination of the start-up exclusive evaluation option license, NBE Therapeutics, Ltd. will have the right to execute a start-up exclusive patent commercialization license which will supersede and replace the start-up exclusive evaluation option license with no broader territory than granted in the start-up exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATED: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 6, 2015 will be considered.