

U.S. Patent Application 60/703,798 (HHS reference E-262-2005-0-US-01), PCT Application PCT/US2006/028986 (HHS reference E-262-2005-0-PCT-02), Australian Patent 2006275865 (HHS reference E-262-2005-0-AU-03), Canadian Patent 2616987 (HHS reference E-262-2005-0-CA-04), European Patent 1910407 (HHS reference E-262-2005-0-EP-05) as validated in Switzerland, Germany, Spain, France, the United Kingdom, and Italy, U.S. Patent 8,907,060 (HHS reference E-262-2005-0-US-06), European Patent 2311854 (HHS reference E-262-2005-0-EP-07) as validated in Switzerland, Germany, Spain, France, the United Kingdom, and Italy, European Patent 2332970 (HHS reference E-262-2005-0-EP-08) as validated in Germany, Spain, France, the United Kingdom, and Italy, Australian Patent 2012216642 (HHS reference E-262-2005-0-AU-15), Australian Patent 2014208269 (HHS reference E-262-2005-0-AU-22), European Patent Application 15191388.6 (HHS reference E-262-2005-0-EP-28), European Patent 3006457 (HHS reference E-262-2005/0-EP-29) as validated in Austria, Belgium, Germany, Spain, France, the United Kingdom, Ireland, Italy, the Netherlands, and Poland, European Patent 3006458 (HHS reference E-262-2005-0-EP-30) as validated in Austria, Belgium, Germany, Spain, France, the United Kingdom, Ireland, Italy, the Netherlands, and Poland, Australian Patent 2016202754 (HHS reference E-262-2005-0-AU-31), and Canadian Patent Application 2941466 (HHS reference E-262-2005/0-CA-32);

and all continuing applications and foreign counterparts to the patents and applications listed above for each technology.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, 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 the following:

“The development and commercialization of a monospecific BCMA-targeted immunotoxin, whereby the immunotoxin is comprised of:

- (1) the complementary determining region (CDR) sequences of either
 - i. the anti-BCMA antibody known as BM24; or
 - ii. the anti-BCMA antibody known as BM306; and

(2) a *Pseudomonas* Exotoxin A-based payload consisting of a PE25 variant with or without alterations of one or more amino acids in one or more B cell and/or T cell epitopes. for the treatment of hematological malignancies.”

The E-010-2016 technology discloses antibodies that recognize the BCMA (B Cell Maturation Antigen) protein. BCMA is expressed on the cell surface of several forms of cancer, most notably multiple myeloma. Although these BCMA antibodies can potentially be used in many therapeutic formats (e.g., unconjugated antibodies, bispecific antibodies (and variants thereof), antibody-drug conjugates (ADCs), chimeric antigen receptors (CARs), etc., to target cancer cells for destruction, the contemplated field of use only concerns the development of one specific format (recombinant immunotoxins) using one type of toxin variant (*Pseudomonas* Exotoxin A variants). Many other formats, and therefore fields of use, remain available for licensing and development.

The E-263-2011-0, E-174-2011-0, E-269-2009-0, E-292-2007, E-262-2005-0 and E-771-2013-0-5 technologies (i.e., “non-E-010-2016-0 technologies”) all concern distinct variants of *Pseudomonas* Exotoxin A which can be used in the BCMA-targeted immunotoxin. The *Pseudomonas* Exotoxin A variants represent the “payload” portion of the immunotoxin, which is the portion that instigates the destruction of the cancer cells that are targeted by the aforementioned BCMA antibodies.

The development of a new therapeutic targeting BCMA will benefit public health by offering up a treatment for these cancers in instances when conventional first line therapies are ineffective.

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

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed 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: June 1, 2018.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2018-12179 Filed 6-6-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice to Close Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Nursing Research Special Emphasis Panel; Multicenter Clinical Grants.

Date: June 6, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Tamizchelvi Thyagarajan, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892, (301) 594-0343, Tamizchelvi.thagarajan@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 Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: June 1, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-12178 Filed 6-6-18; 8:45 am]

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