DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-BCMA Immunotoxin for the Treatment of Human Cancer

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to BEORO Therapeutics, GmbH. (“Beoro”) located in Seefeld, Germany.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A Lambertson, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

The following represents the intellectual property to be licensed under the prospective agreement:


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 USC 552.

Dated: June 1, 2018.

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.

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