[Billing Code 4140-01-P]

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:

US Patent Application 62/255,255 (HHS reference E-010-2016-0-US-01), US Patent Application 62/257,493 (HHS reference E-010-2016-1-US-01), and PCT Patent Application PCT/US2016/061320 (HHS reference E-010-2016-2-PCT-01);

US Patent Application 61/887,418 (HHS reference E-771-2013-0-US-01), US Patent Application 61/908,464 (HHS reference E-771-2013-1-US-01), US Patent Application 61/982,051 (HHS reference E-771-2013-2-US-01), US Patent Application 61/052,665 (HHS reference E-771-2013-3-US-01), PCT Application PCT/US2014/058941 (HHS reference E-771-2013-4-PCT-01), US Patent 9,388,222 (HHS reference E-771-2013-4-US-02), Australian Patent Application 2014329437 (HHS reference E-771-2013-4-AU-08), Canadian Patent Application 2926215 (HHS reference E-771-2013-4-CA-09), Chinese Patent Application 201480062185.7 (HHS Reference E-771-2013-4-CN-10), European Patent Application 14789449.7 (HHS reference E-771-2013-4-EP-11), Indian Patent Application 201647015226 (HHS reference E-771-2013-4-IN-12), Russian Patent Application 2016114406 (HHS reference E-771-2013-4-RU-13), Japanese Patent Application (HHS reference E-771-2013-4-JP-14), and US Patent Application 15/191,392 (HHS reference E-771-2013-4-US-15);

US Patent Application 61/535,668 (HHS reference E-263-2011-0-US-01), PCT Application PCT/US2012/055034 (HHS reference E-263-2011-0-PCT-02), Australian Patent 2012308591 (HHS reference E-263-2011-0-AU-03), Canadian Patent Application 2846608 (HHS reference E-263-2011-0-CA-04), European Patent 2755993 (HHS reference E-263-2011-0-EP-05), US Patent 9,206,240 (HHS reference E-263-2011-0-US-06), Hong Kong Patent Application 14111650.2 (HHS reference E-263-2011-0-HK-07), US Patent 9,657,066 (HHS reference E-263-2011-0-US-08), US Patent Application 15/488,898 (HHS reference E-263-2011-0-US-09) and European Patent Application 14/927,645 (HHS reference E-263-2011-0-EP-18);

US Patent Application 61/495,085 (HHS reference E-174-2011-0-US-01), PCT Application PCT/US2012/041234 (HHS reference E-174-2011-0-PCT-02), Australian Patent 2012268013 (HHS reference E-174-2011-0-AU-03), Brazilian Patent Application 112013031262-9 (HHS reference E-174-2011-0-BR-04), Canadian Patent Application 2838013 (HHS reference E-174-2011-0-CA-05), Chinese Patent Application 201280039071.1 (HHS reference E-174-2011-0-CN-06), European Patent 2718308 (HHS reference E-174-2011-0-EP-07) as validated in Germany, Spain, France, the United Kingdom, and Italy, Hong Kong Patent Application 14105911.9 (HHS reference E-174-2011-0-HK-08), Japanese Patent 6100764 (HHS reference E-174-2011-0-JP-09), South Korean Patent Application 2013-7032402 (HHS reference E-174-2011-0-KR-10), Mexican Patent Application MX/a/2013/014388 (HHS reference E-174-2011-0-MX-11), Russian Patent 2627216 (HHS reference E-174-2011-0-RU-12), US Patent 9,346,859 (HHS reference E-174-2011-0-US-13), Hong Kong Patent Application 14106689.7 (HHS reference E-174-2011-0-HK-14), US Patent 9,765,123 (HHS reference E-174-2011-0-US-15), Australian Patent Application 2017200541 (HHS reference E-174-2011-0-AU-16), European Patent Application 17163568.3 (HHS reference E-174-2011-0-EP-17), Japanese Patent Application 2017-031283 (HHS reference E-174-2011-0-JP-18), and US Patent Application 15/693,705 (HHS reference E-174-2011/0-US-24);

U.S. Patent Application 61/241,620 (HHS reference E-269-2009-0-US-01), PCT Application PCT/US2010/048504 (HHS reference E-269-2009-0-PCT-02), Australian Patent 2010292069 (HHS reference E-269-2009-0-AU-03), Canadian Patent 2773665 (HHS reference E-269-2009-0-CA-04), Chinese Patent 201080049559.3 (HHS reference E-269-2009-0-CN-05), European Patent 2475398 (HHS reference E-269-2009-0-EP-06), as validated in France, Germany, Italy, Spain and the United Kingdom, Indian Patent Application 3197/CHENP/2012 (HHS reference E-269-2009-0-IN-07), Japanese Patent 5795765 (HHS reference E-269-2009-0-JP-08), Russian

Patent Application 2012114005 (HHS reference E-269-2009-0-RU-09), and US Patent 8,936,792 (HHS reference E-269-2009-0-US-10);

U.S. Patent Application 60/969,929 (HHS reference E-292-2007-0-US-01), PCT Application PCT/US2008/075296 (HHS reference E-292-2007-0-PCT-02), Australian Patent 2008296194 (HHS reference E-292-2007-0-AU-03), Canadian Patent 2698357 (HHS reference E-292-2007-0-CA-04), European Patent 2197903 (HHS reference E-292-2007-0-EP-05) as validated in Austria, Belgium, Bulgaria,, Switzerland, Cyprus, Germany, Denmark, Estonia, Spain, Finland, France, the United Kingdom, Greece, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, and Turkey, US Patent 8,871,906 (HHS reference E-292-2007-0-US-06), European Patent 2570425 (HHS reference E-292-2007-0-EP-07) as validated in France, Germany, the United Kingdom, Italy and Spain, and Hong Kong Patent Application 13106628.2 (HHS reference E-292-2007-0-HK-08);

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, US 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:
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> 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.

[FR Doc. 2018-12179 Filed: 6/6/2018 8:45 am; Publication Date: 6/7/2018]