**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of an Exclusive Start-Up Patent License for Evaluation: Immunotherapy for relapsed/refractory diffuse large B cell lymphoma

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

**ACTION**: Notice.

**SUMMARY**: The National Heart, Lung, and Blood Institute, of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive start-up patent license for evaluation to ONK Therapeutics, a start-up company spun-off from the National University of Ireland Galway, and incorporated under the laws of the Republic of Ireland, to practice, for a limited time, the inventions covered by the patent estate listed in the Supplementary Information section of this notice. Upon expiration of the evaluation period the granted licenses may be converted into a fully exclusive patent commercialization license for the term of the last to expire of the patent estate upon the company providing NHLBI with a commercial development plan supporting such a conversion. This notice is intended to apprise the public of a aforementioned license and provide a fifteen (15) day notice period for the objection.

**DATES**: Only written comments and/or applications for a license which are received by the National Heart, Lung, and Blood Institute on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES**: Requests for copies of patent applications (electronic only), inquiries, and comments relating to the contemplated an exclusive patent license should be emailed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019 shmilovm@nih.gov.

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property (Patent Estate)**

HHS Ref. No. E-036-2015-0 and -1, U.S. Provisional Patent Application 62/079,975 filed November 14, 2014 (expired), International Patent Application PCT/US2015/060646 filed November 13, 2015 (nationalized), U.S. Patent Application 15/525,921 having an effective filing date of November 13, 2015, and U.S. Divisional Patent Application 16/985,797 filed August 5, 2020, any and all continuation or divisional applications claiming priority to any of the above.

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in field of use that may be limited to *Immunotherapy against relapsed or refractory diffuse large B cell lymphoma*, and where the "Licensed Products" may be defined to be limited to transgenically modified allogeneic natural killer cells within the scope of the Licensed Patent Rights that transiently express one or more of a (1) CCR7 receptor, (2) CD16a (HA-CD16), (3) a DR5 specific TRAIL, or (4) CD19 chimeric antigen receptor.

The aforementioned patent estates cover methods of treating a subject with a tumor by administering transgenically modified adoptive NK (natural killer cells), methods of generating transgenic NK cells, and transgenic NK cells per se. In particular, the claims cover include transgenic NKs expressing CCR7 and CD16a (HA-CD16). The treatment methods also include dependent claims where the transgenic NK cells are co-administered with a monoclonal antibody therapeutic (e.g., rituximab). CCR7 is a chemokine receptor (chemokine (C—C motif) receptor 7) known to direct cellular migration to secondary lymphoid tissues, including lymph nodes where hematological malignancies such as diffuse large B cell lymphoma (DLBCL) reside. Normally, CCR7 is expressed by only a small subset of resting primary NK cells.

CD16 includes Fc receptors FcγRIIIa (CD16a) and FcγRIIIb (CD16b) found on the surface of natural killer (NK) cells and other leukocytes. CD16a binds to the Fc tail of IgG antibodies which then activates the NK cell for antibody-dependent cellular toxicity (ADCC). Human wild type CD16 has a relatively low affinity for IgG1 antibodies. However, a single nucleotide polymorphism (SNP rs396991) in the CD16a gene (F to V at position 158; referred to hereafter as HA-CD16) results in substantially higher IgG1 affinity and superior NK mediated ADCC.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive licenses, both the one granted for the evaluation period and if converted into a full exclusive patent commercialization license, will be royalty bearing. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Heart, Lung, and Blood 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 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 August 5, 2020.

**Michael Shmilovich,**

*Senior Licensing and Patenting Manager,*

*National Heart, Lung, and Blood Institute.*

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