[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

PROSPECTIVE GRANT OF EXCLUSIVE LICENSE: Development of autologous tumor infiltrating lymphocyte adoptive cells for the treatment of lung, breast, bladder, and HPV-positive cancers.

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to the current licensee, Lion Biotechnologies, Inc., which is located in Woodland Hills, California to practice the inventions embodied in the following patent applications and applications claiming priority to these applications:

1. U.S. Provisional Patent Application No. 61/237,889, filed August 26, 2009 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-01);
2. U.S. Patent No. 8,383,099 issued February 26, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-02);
3. U.S. Patent Application No. 13/742,541 filed January 16, 2013 entitled "Adoptive cell therapy with young T cells" (HHS Ref No. E-273-2009/0-US-03);
4. U.S. Provisional Patent Application No. 61/466,200 filed March 22, 2011entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);
5. PCT Application No. PCT/US2012/029744 filed March 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);
6. U.S. Patent Application No. 13/424,646 filed May 20, 2012 entitled "Methods of growing tumor infiltrating lymphocytes in gas-permeable containers" (HHS Ref No. E-114-2011/0-US-01);
7. U.S. Provisional Patent Application No. 61/846,161 filed July 15, 2013 entitled "Methods of Preparing Anti-human Papillomavirus Antigen T Cells" (HHS Ref No. E-494-2013/0-US-01);
8. PCT Application No. PCT/US2014/046478 filed July 14, 2014 entitled "Methods of Preparing Anti-human Papillomavirus Antigen T Cells" (HHS Ref No. E-494-2013/0-PCT-02);

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

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop, manufacture, distribute, sell and use unselected whole autologous tumor infiltrating lymphocyte (TIL) adoptive cell therapy products for the treatment of lung, breast, bladder, and HPV-positive cancers. Specifically excluded from this license are methods of generating or using selected subpopulations of TIL and the use of T cell receptors isolated from TIL.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Isolating cells from the tumor infiltrating lymphocytes (TIL) of a patient tumor sample provides a suitable initial lymphocyte

culture for further in vitro manipulations. NIH scientist have discovered that taking the isolated cells through one cycle of rapid expansion (including exposure to IL-2), rather than multiple cycles, yields lymphocyte cultures with higher affinity and longer persistence in patients. In addition, they have found that through the use of gas permeable (GP) flasks, they could obtain large quantities of highly reactive TIL from patient tumor samples for anti-cancer immunotherapy. If an adoptive T cell transfer immunotherapy is to gain regulatory approval and successfully treat a wide array of patients, it will need to be rapid, reliable, and technically simple. One of the most critical factors to this approach is the generation of effective lymphocyte cultures that will rapidly and repeatedly attack the target cells when infused into patients.

The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH 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.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 19, 2015

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Richard U. Rodriguez,
Acting Director

Office of Technology Transfer
National Institutes of Health

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