[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Evaluation Option Exclusive License: Development of Granulysin Immunotherapy

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 evaluation option license to practice the inventions embodied in U.S. Provisional Patent Application. No. 61/250,601, filed October 12, 2009, HHS Ref. No.: E-158-2009/0-US-01, Titled: "Granulysin Immunotherapy"; International Application No. PCT/US2010/052036, filed October 8, 2010, HHS Ref. No.: E-158-2009/0-PCT-02, Titled: "Granulysin Immunotherapy"; U.S. Patent Application No. 13/501,726, filed April 12, 2012, HHS Ref. No.: E-158-2009/0-US-06, Titled: "Granulysin Immunotherapy", and foreign equivalents thereof to Orpheden Therapeutics, Inc. ("Orpheden"), a Delaware corporation doing business principally in the state of Illinois. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the development of 15kD granulysin as set forth in the Licensed Patent Rights for the treatment of human cancers.

Upon the expiration or termination of the exclusive evaluation option license, Orpheden will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer 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 the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., 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: Granulysin is a cytolytic and proinflammatory molecule expressed by activated human cytotoxic T lymphocytes (CTLs) and natural killer (NK) cells when they are attached to disease cells including

infection, cancer, transplantation, autoimmunity, skin and reproductive maladies. Granulysin is made in a 15-kDa form that is cleaved into a 9-kDa form at both the amino and the carboxy termini. Granulysin is broadly cytolytic against tumors and microbes. It has been implicated in many of diseases and studies suggest that granulysin may be a useful therapeutic directly contributing to immunity against foreign molecules for a wide variety of diseases.

This technology describes the use of 15 kD granulysin for enhancing immune responses.

Investigators at the NIH have discovered that 15 kD granulysin activates monocytes and induces them to differentiate into mature dendritic cells and activates allospecific T cells.

The proof of this principle was demonstrated by mice expressing granulysin *in vivo* showing markedly improved anti-tumor responses, with increased numbers of activated dendritic cells and cytokine-producing T cells. Furthermore, current data suggest that dendritic cells matured with 15 kD granulysin are superior to the well-established GM-CSF induction. There appears to be a significant market opportunity for use of the 15 kD granulysin for the *ex vivo* dendritic cell maturation and adoptive immunotherapy.

The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless 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 within fifteen (15) days from the date of this published notice.

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 evaluation option 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: July 9, 2014.

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Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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