

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Commercialization License: The Development of a Circularly Permuted IL4-Targeted *Pseudomonas* Exotoxin A (cpIL4-PE38KDEL) for the Treatment of Cancers and Urological Disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, indicates that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive commercialization license to practice the inventions embodied in:

(a) Technology families E-047-1994/0 and E-047-1994/1, including U.S. Patent 5,635,599 entitled "Proteins Comprising Circularly Permuted Ligands" [HHS Ref. E-047-1994/0-US-01], PCT Application PCT/US95/04468 entitled "Circularly Permuted Ligands and Circularly Permuted Chimeric Molecules" [HHS Ref. E-047-1994/0-PCT-02], European Patent 0754192 entitled "Proteins Comprising Circularly Permuted Ligand" [HHS Ref. E-047-1994/0-EP-15, validated in Austria, Belgium, France, Italy, Liechtenstein, The Netherlands, Spain, Switzerland and the United Kingdom], Canadian Patent 2187283 entitled "Proteins Comprising Circularly Permuted Ligands" [HHS Ref. E-047-1994/0-CA-14], Australian Patent 694211 entitled "Proteins Comprising Circularly Permuted Ligands" [HHS Ref. E-047-1994/0-CA-14], and U.S. Patent 6,011,002 entitled "Circularly Permuted Ligands and Circularly Permuted Chimeric Molecules" [HHS Ref. E-047-1994/1-US-01];

(b) Technology family E-021-2010/0, including U.S. Patent Application 61/105,408 entitled "Targeted Cargo Protein Combination Therapy" [HHS Ref. E-021-2010/0-US-01] and U.S. Patent Application 12/579,281 entitled "Targeted Cargo Protein Combination Therapy" [HHS Ref. E-021-2010/0-US-02];

and all related continuing and foreign patents/patent applications for these technology families, to Medicenna Therapeutics, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective start-up exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

The treatment of cancers and urological disorders that express the IL4 receptor on their cell surface by using cpIL4-PE38KDEL.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 23, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive commercialization license should be directed to: David A. Lambertson, 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) 435-4632; Facsimile: (301) 402-0220; Email: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Targeted toxins are fusion proteins which have been designed to direct therapeutic agents to specific diseased cells. Targeted toxins comprise two primary domains: a targeting domain and a toxin domain (the therapeutic agent). Diseased cells are targeted through the interaction of the targeting domain with a protein that is preferentially expressed on the cells. Once targeted to the cells, the toxin domain is able to exert its cytotoxic activity and kill the specific cell without affecting cells which do not express the target. Since there are a number of cell surface proteins that are preferentially expressed on diseased cells, targeted toxins are potential therapeutic candidates in the treatment of several diseases such as cancer and urological disorders.

The specific targeted toxins for which this start-up exclusive license may be granted comprise a targeting domain which contains a circularly permuted interleukin 4 (cpIL4) ligand, which binds to the IL4 receptor. The IL4 receptor is a cell surface protein that is preferentially expressed on several types of cancer cells and cells associated with urological disorders. By linking cpIL4 to the *Pseudomonas* exotoxin A variant PE38KDEL, it is possible to selectively kill the IL4 receptor-expressing cells, leaving non-diseased cells alone. This can result in an effective therapeutic strategy with fewer side effects than a non-targeted therapy.

The prospective start-up exclusive commercialization license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and

conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective start-up exclusive 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 start-up 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.

Dates: July 1, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2013-0574]

Merchant Marine Personnel Advisory Committee: Intercessional Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of Federal Advisory Committee Working Group Meeting.

SUMMARY: A working group of the Merchant Marine Personnel Advisory Committee (MERPAC) will meet to work on Task Statement 82, entitled "The review and submittal of recommendations for proposed revisions to forms CG-719K, Merchant Mariner Credential Medical Evaluation Report and CG-719K/E, Merchant Mariner Evaluation of Fitness for Entry Level Ratings." This meeting will be open to the public.

DATES: A MERPAC working group will meet on July 24, 2013, and July 25, 2013, from 8 a.m. until 4 p.m. Please note that the meeting may adjourn early if all business is finished. Written comments to be distributed to working group members and placed on MERPAC's Web site are due by July 10, 2013.

ADDRESSES: The working group will meet at the Jemal Building of U.S. Coast Guard Headquarters, Room 10-0718, 1900 Half St. SW., Washington, DC