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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: GMCSF-BclxL-derived Chimeric Therapeutics for use in Treatment of Cancer, Neutropenia, CNS Injury and Parkinson's Disease

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 an exclusive patent license to practice the inventions embodied in technology family E-150-2005/0, including U.S. Patent application 11/991,692 [HHS Ref. E-150-2005/0-US-07], PCT Application PCT/US06/35070 [HHS Ref. E-150-2005/0-PCT-02] and foreign equivalents thereof, entitled "Methods and Compositions for Inhibiting Cell Death or Enhancing Cell Proliferation", to Medicenna Therapeutics, Inc., located in Vancouver, Canada. 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 exclusive patent license territory may be worldwide, and the field of use may be limited to:

> Development and commercialization of GMCSF-BclxL-derived chimeric therapeutics and immunotherapeutics, alone or in combination, for restoring, protecting, or stimulating cells in order to treat (i) cancer, (ii) neutropenia, (iii) CNS injury and (iv) Parkinson's disease.

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 patent license should be directed to: Surekha Vathyam, 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) 435-4076; Facsimile: (301) 402-0220; E-mail: vathyams@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The subject invention is to a chimeric protein comprising human granulocyte-macrophage colony stimulating factor (GMCSF) and B-cell lymphoma-extra large (BclxL). Chimeric proteins such as GMCSF-BclxL and its analogs have the potential to enhance cell survival, inhibit apoptosis and promote cell growth or proliferation (collectively referred to as "anti-apoptotic"). Such anti-apoptotic proteins could have utility for restoring, protecting and stimulating cells in patients to treat a variety of disorders.

This technology relates to compositions comprising an anti-apoptotic chimeric protein and its use to inhibit apoptosis *in vivo* and *ex vivo*. One domain of the chimeric protein is the ligand for GMCSF receptor. Receptors for GMCSF are found on a variety of normal tissues, including hematopoietic stem cells, neurons, and dendritic cells. The other domain is BclxL, which prevents targeted cell death. GMCSF-BclxL chimeric protein could potentially be used as an adjuvant to treat cancer and to treat acute neurological disorders (such as brain or spinal cord injury, stroke) or chronic CNS diseases (Alzheimers, Parkinson's, and ALS). It could be used to prevent hematopoietic cell loss during chemo or radiotherapy. It could also be used in patients receiving stem cell transplantation or in *ex vivo* expansion of hematopoietic stem and progenitor cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. 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 404.7.

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.

November 21, 2013
Date

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

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