DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Method for the Diagnosis and Treatment of Vascular Disease

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to Endothelix, Inc., having a place of business in Houston, TX, to practice the invention embodied in U.S. Patent Application No. 60/426,545 filed November 15, 2002, U.S. Patent Application No. 60/445,417 filed February 5, 2003, PCT Patent Application PCT/US03/36317 filed November 12, 2003, and U.S. Patent Application No. 10/534,626 filed May 11, 2005. The contemplated exclusive license may be limited to the following field of use: an FDA-approvable vascular endothelial function diagnostic test. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before September 4, 2007 will be considered.

ADDRESSES: Requests for a copy of the patent, inquiries, comments, and other materials relating to the contemplated license should be directed to: Tara L. Kirby, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: 301–435–4426; Facsimile: 301–402–0220; E-mail: kirbyt@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Cardiovascular disease is a major health risk throughout the industrialized world. Atherosclerosis, the most prevalent of cardiovascular diseases, is the primary cause of heart attack, stroke, and gangrene of the extremities. It is also the principal cause of death in the United States.

The inventors have developed a technique for evaluating vascular function by counting endothelial progenitor cells (EPCs) in a blood sample. They found that decreased numbers of EPCs correlate significantly with decreased vascular function. A diagnostic test developed utilizing this discovery would have the advantages of being minimally invasive and low cost compared to other currently available diagnostics.

The invention describes methods for diagnosing decreased vascular function, detecting increased cardiovascular risk, and diagnosing atherosclerosis. Also included are methods for assaying the number of endothelial progenitor cells and methods for treating a subject with decreased vascular function by administering a therapeutically effective amount of endothelial 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 404.7. The prospective exclusive license may be granted unless, within 60 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 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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.


Steven M. Ferguson,
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