

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Human-Bovine Reassortant Rotavirus Vaccine

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

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 in the U.S., Europe, and Canada only to practice the invention embodied in U.S. Serial Number 60/094,425, filed July 28, 1998, PCT filed (PCT/US99/17036) on July 27, 1999, and National Stage filed in China, India, Korea, Australia, Canada, Europe, Japan, Brazil and the U.S., entitled "Multivalent Human-Bovine Rotavirus Vaccine" (DHHS ref. E-015-1998/0) to Aridis, LLC, having a place of business in Portola Valley, California. The patent rights in these inventions 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 7, 2004 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Susan Ano, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: anos@od.nih.gov; Telephone: (301) 435-5515; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: 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, 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.

This technology describes multivalent immunogenic compositions comprising at least four human-bovine reassortant rotaviruses, where the gene encoding VP7 protein from G1, G2, G3, or G4 human rotavirus strain is inserted into a bovine rotavirus backbone. These VP7 serotypes represent the clinically most

important human rotavirus serotypes, which depends on VP4 and VP7 proteins, both found in the viral capsid and both of which independently induce neutralizing antibodies. Additionally, human-bovine reassortants for VP7 serotypes G5 and G9 and a bovine-bovine reassortant for VP7 G10 serotype are mentioned. Each of these reassortants is monovalent, and administered as a multivalent mixture. Compared to other human-bovine rotavirus reassortants, the compositions described in this technology induce an immunological response at significantly lower dosage than other human-bovine rotavirus reassortants (which required 10-100 times the dose of human-rhesus reassortants) and does not result in a low-grade, transient fever.

The field of use may be limited to development of human-bovine reassortant rotavirus vaccines.

The licensed territory will be exclusive in the U.S., Canada, and Europe.

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.

Dated: May 28, 2004.

Steven M. Ferguson,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); Notice of a Meeting of the NTP Board of Scientific Counselors

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors on June 29, 2004, at the Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC 27703.

The NTP Board of Scientific Counselors ("the Board") is composed of scientists from the public and private sector and provides primary scientific oversight to the NTP.

Agenda and Registration

The meeting on June 29, 2004 begins at 8:30 a.m. and is open to the public from 8:30 a.m. to approximately 3:30 p.m., when it will be closed to the public until adjournment. The closure is in accordance with the provisions set forth in section 552b(c)(4) "disclosure of commercial or financial information," (c)(6) "disclosure of information of personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy" and (c)(9) "disclosure of information of a premature nature which would significantly frustrate implementation of a proposed agency action" of Title 5 U.S.C. for the review and evaluation of the Carcinogenic Potency Database.

Attendance at the public meeting will be limited only by the space available. Persons needing special assistance should contact the Executive Secretary (contact information below) at least 7 business days in advance of the meeting.

A draft agenda with a tentative schedule is provided below. Primary agenda topics include: (1) NTP activities for development of a roadmap (or framework) for implementation of the NTP Vision for the 21st Century (<http://ntp-server.niehs.nih.gov>), (2) report from the Board's Working Group on the review of statistical methods to analyze photocarcinogenicity studies, (3) planned NTP Studies on trimethylolpropane triacrylate (TMPTA), (4) activities of the NTP Board's Technical Reports Review Subcommittee, and (5) an update on the Report on Carcinogens, including the status of the Eleventh Edition, and on the public meeting held January 27, 2004, to receive comment on the review process and criteria used to evaluate nominations to the Report on Carcinogens.

The agenda and background materials on agenda topics, as available, will be posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>, see What's New) or available upon request to the Executive Secretary (contact information below). Following the meeting, minutes will be prepared and available through the NTP Web site and upon request to Central Data Management, NIEHS, P.O. Box 12233, MD E1-02, Research Triangle Park, NC 27709; telephone: 919-541-3419, fax: 919-541-3687, and e-mail: CDM@niehs.nih.gov.

Public Comments Welcome

Time is allotted during the meeting for the public to present comments to the Board and NTP staff on any agenda topic. This meeting provides another