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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive License: Topical Antibiotic with Immune Stimulating Oligodeoxynucleotide Molecules to Speed Wound Healing; and Use of CpG Oligodeoxynucleotides to Induce Epithelial Cell Growth

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 (NIH), Department of Health and Human Services, is contemplating the grant of a start-up exclusive license to practice the inventions embodied in: US provisional Applications 61/639,688 (E-294-2011/0-US-01) filed April 27, 2012 and PCT application PCT/US2013034639 (E-294-2011/0-PCT-02) filed March 29, 2013, each entitled “Topical Antibiotic with Immune Stimulating oligodeoxynucleotide Molecules to Speed Wound Healing” and US application 12/205,756 (E-328-2001/1-US-01) filed September 2008 and issued as US patent 8,466,116, each entitled “Use of CpG Oligodeoxynucleotides to Induce Epithelial Cell Growth” to Tollgene having a place of business at 2429 Ginny Way, Lafayette, CO 80026. The patent rights in these inventions have been assigned to the United States of America.

DATE: Only written comments and/or application for a license that 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.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: Tedd.Fenn@mail.nih.gov; Telephone: 424-500-2005; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION:

The prospective start-up exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within fifteen (15) 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.

These technologies relate to use of CpG oligodeoxynucleotides (ODNs) to accelerate wound healing. The E-294-2011/0, technology relates to an antibiotic composition containing the toll-like receptor-7 (TLR7) ligand (imidazoquinoline) and an immunostimulatory K ODN. There is evidence that this formulation may produce more rapid wound healing versus standard antibiotic formulations. Because standard antibiotics eliminate bacteria at a wound site, they also eliminate the molecular signals

present in bacterial DNA that stimulate the immune system's wound healing processes. The ODN and imidazoquinoline act as artificial immune stimulants that mimic the bacterial signals to improve healing rates. The E-328-2001/1 technology relates to a method of inducing epithelial cell growth by administration of immunostimulatory ODNs. The stimulation of epithelial cell growth also promotes wound healing.

The proposed field of exclusivity may be limited to human and veterinary therapeutics for treatment of wounds.

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.

July 26, 2013
Date

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