[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Ocular Therapeutics Agent Delivery Devices and Methods for Making and Using Such Devices

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 patent license to practice the inventions embodied in Patent Applications USSN 09/808,149, filed Mar 15, 2001, issued Mar 30, 2004; PCT/US02/07836, filed Mar 14, 2002, designated EP, 02723446,7 and US 10/471,468, issued Feb 9, 2010; USSN 11/739,540, filed Apr 29, 2007; and USSN 12/647,980, filed Dec 28, 2009; entitled “Ocular Therapeutic Agent Delivery Devices and Methods For Making and Using Such Devices”, by Michael R. Robinson et al (NEI, CC, and NIBIB) (E-241-1999/0), to ODIN Biotech having a place of business in 4000 Hanover Street, Dallas, TX. The patent rights in this invention have been assigned to the United States of America. The exclusive patent license is one which qualifies under the Start-up Exclusive Patent License Agreement program, which is in place from October 1, 2011 through September 30, 2012.

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.

FOR FURTHER INFORMATION: Requests for a copy of the patent application, inquiries, and comments relating to the contemplated license should be directed to: Susan Ano, Ph.D., Branch Chief, IDME, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: anos@mail.nih.gov; Telephone: 301-435-5515; Facsimile: 301-402-0220.

SUPPLEMENTARY INFORMATION: The invention relates to a drug delivery system, compositions of, methods of making the drug delivery system, and methods of use as a drug delivery platform. Ocular therapeutics that require repeated intravitreal injections are associated with eye infections, retinal detachment, hemorrhaging, endophthalmitis, and/or cataracts, while topical solutions that require daily application are associated with patient non-compliance. This technology describes a drug delivery platform that can be designed to deliver therapeutics to the eye over months to years. Therefore, this technology can be used to design a therapeutic implant that reduces or eliminates patient non-compliance and/or improve patient safety. The therapeutic implant has the following advantages: a) it is bioerodible which makes it more noninvasive than repeated intravitreal injections and non-bioerodible implants; b) has a dual release system that allows the release of two distinct therapeutics or a single therapeutic at different rates; c) prolongs the therapeutic dose of an agent across the surface of the eye compared to topical solutions; d) reduces the risk of additional eye damage compared to repeated intravitreal injections; e) dispenses a therapeutic agent over a long period of time resulting in increase patient compliance and patient health; and f) is associated with reduced systemic drug side-effects compared to drugs applied systemically. Data are available for rodents, rabbits, dogs, and horses.

The field of use may be limited to “Episcleral Therapeutic Implant for Ophthalmic diseases”.

The prospective worldwide 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 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 404.7.

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.

May 1, 2012
Date

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

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