[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Evaluation License: Live Attenuated Codon-deoptimized Respiratory Syncytial Virus Vaccines

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 (HHS), is contemplating the grant of a worldwide exclusive evaluation option license to practice the inventions embodied in: HHS Ref. No E-080-2013/0 and /1, "Attenuation Of Human Respiratory Syncytial Virus By Genome Scale Codon-Pair Deoptimization," US Provisional Patent Applications 61/762,768 filed February 8, 2013 and 61/794,155 filed March 15, 2013, and PCT/US2014/015274 filed February 7, 2014, to Codagenix, Inc., having its principle place of business in Stony Brook, New York.

The United States of America is an assignee to the patent rights of these inventions.

The contemplated exclusive license may be limited to a live attenuated codon-deoptimized respiratory syncytial virus vaccine. Upon the expiration or termination of

the start-up exclusive evaluation license, Codagenix will have the right to execute a start-up exclusive patent commercialization license with no greater field of use and territory than granted in the evaluation license.

DATE: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION 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: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; E-mail: shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The invention pertains to live attenuated respiratory syncytial viruses that can be used in prophylactic vaccines. The viruses are generated using codon-pair deoptimization techniques, resulting in attenuation based on hundreds or thousands of nucleotide substitutions with no differences at the amino acid level. The most notable strain has mutations in the NS1, NS2, N, P, M, SH, G, F, or L genes and referenced by the designation RSV MinFLC (SEQ ID No: 5 in the patent application). Experimental

growth data for representative viruses in mice and in African Green Monkeys demonstrated in vivo growth attenuation.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) 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.

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: March 3, 2014.

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

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