



DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Production of Attenuated Respiratory Syncytial Virus Vaccines

AGENCY: National Institutes of Health.

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 Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a an exclusive license to practice the following invention as embodied in the following patent applications: (1) E-194-1999/0, Collins et al., “Production of Attenuated Respiratory Syncytial Virus Vaccines Involving Modification of M2 ORF2”, U.S. Provisional Patent Application Number 60/143,097, filed July 9, 1999, PCT Patent Application Number PCT/US2000/18534, filed July 7, 2000, U.S. Patent Application Number 09/611,829 (now U.S. Patent Number 6,713,066), and U.S. Patent Application Number 11/011,502 (now U.S. Patent Number 7,485,440), (2) E-135-2010/0, Collins et al., “Genetically Stable Live Attenuated Vaccine for Respiratory Syncytial Virus (RSV) with an Attenuation and Temperature Sensitive Phenotype Conferred by an Amino Acid Deletion”, U.S. Provisional Patent Application Number 61/624,010, filed April 13, 2012, PCT Patent Application Number PCT/US2013/030836, filed March 13, 2013, United States Patent Application Number 14/394,226, filed October 13, 2014, European Patent Application Number 13712641.3, filed March 13,

2013, (3) E-216-2014/0, Collins et al., “Versions of Respiratory Syncytial Virus (RSV) Vaccine Candidate LID Delta M2-2 with Increased Attenuation”, U.S. Provisional Patent Application Number 62/266,199, filed December 11, 2015, (4) E-241-2014/0, Collins et al., “Improved RSV F Protein for Expression from a Heterologous Vector”, U.S. Provisional Patent Application Number 62/105,667, filed January 20, 2015, PCT Patent Application Number PCT/US2016/014154, filed January 20, 2016, and (5) E-037-2016/0, Collins et al., “Attenuated RSV Vaccine Strains in which the NS1 and/or NS2 Genes have been Shifted to Promoter-Distal Positions”, U.S. Provisional Patent Application Number 62/266,206, filed December 11, 2015, to Sanofi Pasteur, Inc., having a place of business in Swiftwater, Pennsylvania, U.S.A. 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 National Institute of Allergy and Infectious Diseases, Technology Transfer and Intellectual Property Office on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** 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: Peter Soukas, Senior Technology Licensing Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, Rockville, MD 20852-9804, Tel: (301) 594-8730 or email: ps193c@nih.gov.

SUPPLEMENTARY INFORMATION: Respiratory syncytial virus (RSV) is the most important cause of viral acute lower respiratory infection (ALRI) in infants and children worldwide and is responsible for over 30 million new ALRI episodes worldwide and up

to 199,000 deaths in children under five (5) years old. In the United States, the virus infects nearly all children at least once by the age of two (2) and is the most common cause of bronchiolitis and infant pneumonia, causing up to 125,000 hospitalizations of children each year. RSV disease burden is less understood in the developing world, but available data indicates that the virus causes a significant proportion of childhood ALRI in these parts of the world, particularly in the first months of life. The drug palivizumab (Synagis) can help prevent RSV disease in high risk infants, but it cannot treat or cure already-serious RSV infection. No vaccine exists today to prevent RSV due to an incomplete understanding of the body's immune response to the virus, which has challenged and delayed RSV vaccine development efforts.

The methods and compositions of this invention provide a means for prevention of RSV and/or parainfluenza virus (PIV) infection by immunization with live attenuated, immunogenic viral vaccines against RSV and/or PIV.

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 part 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 part 404.

The field of use may be limited to live attenuated vaccines against respiratory syncytial virus (RSV) and/or parainfluenza virus (PIV) infections in humans.

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: 2/16/16.

Suzanne Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office ,

NIAID.

BILLING CODE 4140-01-P

[FR Doc. 2016-03486 Filed: 2/19/2016 8:45 am; Publication Date: 2/22/2016]