DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be held as a virtual meeting and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The intramural programs and projects as well as the grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with intramural programs and projects as well as the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: May 10, 2022.

Closed: 11:00 a.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Closed: 12:15 p.m. to 12:45 p.m.

Agenda: Report to Council from the Board of Scientific Counselors (BSC).

Open: 1:15 p.m. to 4:45 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–6480, *sweiss@nida.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 12, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301–496–2644; *peter.soukas@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases (NIAID), 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Expression of Prefusion-Stabilized Spike S Glycoprotein of SARS CoV–2 From Avian Paramyxovirus Type 3 (APMV3)

Description of Technology: Severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) emerged in 2019 as the causative agent of coronavirus disease 2019 (COVID–19) and has created a pandemic and global crisis in public health. Vaccines for SARS–CoV–2 are increasingly available under emergency use authorizations; however, authorizations for use are currently limited to individuals five (5) years or older. They also involve intramuscular immunization, which does not directly stimulate local immunity in the respiratory tract, the primary site of SARS–CoV–2 infection, shedding and spread. Ideally, a vaccine should be effective as a single dose and should induce systemic and mucosal immunity with the ability to restrict SARS–CoV–2 infection and respiratory shedding.

The application relates to a live virus-vectored intranasal vaccine candidate to prevent infection and transmission of SARS–CoV–2. Avian paramyxovirus type 3 (APMV3) was used as a vaccine vector to express the spike (S) protein stabilized in prefusion conformation by six proline substitutions (APMV3/S–6P). The S protein was from the first available SARS–CoV–2 sequence. A lack of pre-existing immunity in humans and attenuation by host range restriction make APMV3 a vector of interest. Unlike avian paramyxovirus 1 (Newcastle Disease Virus), APMV3 is not a significant pathogen in poultry. The APMV3/S–6P vaccine is expected to induce durable and broad systemic and respiratory mucosal immunity against SARS–CoV–2. In the hamster model, a single intranasal dose of APMV3/S–6P induced a strong serum neutralizing antibody response to the vaccine-matched SARS–CoV–2 isolate WA1, and a strong serum IgG and IgA response to S protein and its receptor-binding domain. Serum antibodies of APMV3/S–6P-immunized hamsters effectively neutralized SARS–CoV–2 of lineages B.1.1.7 (Alpha) and B.1.351(Beta). Immunized hamsters challenged with SARS–CoV–2, strain WA1, did not exhibit weight loss and lung inflammation, and SARS–CoV–2 replication in the upper and lower respiratory tract was low or undetectable. Thus, a single intranasal dose of APMV3/S–6P fully protected hamsters from SARS–CoV–2 challenge, suggesting that APMV3/S–6P is suitable for clinical development.

Based on experience with this and other live-attenuated virus-vectored vaccine candidates in previous clinical studies, the present candidate is anticipated to be well-tolerated in humans. The National Institute of Allergy and Infectious Diseases has extensive experience and capability in evaluating live-attenuated respiratory