Most mortality occurs in the developing world where clinical care is less accessible. Mortality is low in the developed countries, but the morbidity is substantial: In the United States alone, RSV is associated with an estimated 132,000–172,000 hospitalizations annually in children less than 5 years old. There is not yet available a vaccine or an effective antiviral drug suitable for routine use.

This invention relates to a broadly antiviral small chemical molecule, Rostafuroxin, expected to be well tolerated in humans and available for clinical evaluation. In particular, this patent application relates to the novel and unexpected finding that Rostafuroxin substantially inhibits RSV infection.

ATP1A1 is a host protein involved with cellular entry of RSV. RSV entry was found to require activation of a signaling cascade mediated by ATP1A1 which resembles the signaling pathway (also mediated by ATP1A1) triggered by cardiotonic steroids.

Though not evaluated for RSV, ATPA1A was previously implicated as a pro-viral factor in the infection cycles of a number of viruses, but the nature of its involvement and mechanism of action were unknown.

Rostafuroxin, a synthetic digitoxigenin derivative, is a small-molecule that is known to specifically bind ATP1A1. It has not been previously known to have any antiviral activity.

The inventors have evidence that Rostafuroxin inhibits RSV infection in respiratory epithelial cells. Rostafuroxin inhibits RSV induced ATP1A1-mediated signaling pathway required for RSV entry. This was demonstrated in A549 cells, a widely used human respiratory epithelial cell line, and in primary human airway epithelial cells derived from a healthy human.

Rostafuroxin has been previously tested in clinical studies as an anti-hypertensive agent. It has no adverse effects in healthy humans and, importantly, does not lower the normal systolic blood pressure of healthy individuals.

Rostafuroxin is a promising anti-viral drug candidate for RSV and possibly other viruses that use the same pathway for host cell entry.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Viral therapeutics
- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- Broad antiviral activity
- Favorable safety profile in clinical trials

Development Stage:

- In vivo data assessment (animal)

Inventors: Shirin Munir (NIAID), Matthias Lingemann (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E–202–2018–0—U.S. Provisional Application No. 62/737,899, filed September 27, 2018 (pending).

Licensing Contact: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Dated: October 15, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–23312 Filed 10–24–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chronic Disease and Epidemiology.

Date: October 24, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301–435–0684, *olufokunbisamd@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 18, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23266 Filed 10–24–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1855]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents