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This document is scheduled to be published in the Federal Register on 02/25/2021 and available online at [federalregister.gov/d/2021-03872](https://www.federalregister.gov/d/2021-03872), and on [govinfo.gov](https://www.govinfo.gov)

## 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., 301-594-8730; [peter.soukas@nih.gov](mailto: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, 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

**Improved live-attenuated vaccine for respiratory syncytial virus (RSV) bearing codon-pair deoptimized NS1, NS2, N, P, M and SH genes and additional point mutations in the P gene**

**Description of Technology:**

RSV is the most important viral agent of severe respiratory disease in infants and young children worldwide and also causes substantial morbidity and mortality in older adults. RSV is estimated to cause more than 33 million lower respiratory tract illnesses, three million hospitalizations, and nearly 200,000 childhood deaths worldwide annually, with many deaths occurring in developing countries. However, despite the prevalence of RSV and the dangers associated with infection, no RSV vaccine has been successfully developed to date. Accordingly, there is a public health need for RSV vaccines.

This vaccine candidate comprises live RSV that was attenuated by subjecting the protein-coding sequences of the viral NS1, NS2, N, P, M, and SH genes to codon-pair deoptimization, which resulted in many nucleotide substitutions that were silent at the amino acid level but conferred attenuation. In addition, specific amino acid substitutions were identified and introduced into the P protein that improved attenuation and genetic stability. Genetic stability was confirmed *in vitro*, and attenuation was confirmed in experimental animals.

This live-attenuated RSV vaccine is designed to be administered intranasally by drops or spray to infants and young children. Based on experience with other live-attenuated RSV vaccine candidates, the present candidates are anticipated to be well tolerated in humans and are available for clinical evaluation. The National Institute of Allergy and Infectious Diseases has

extensive experience and capability in evaluating live-attenuated RSV vaccine candidates in pediatric clinical studies, and opportunity for collaboration exists.

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 diagnostics
- Vaccine research

**Competitive Advantages:**

- Ease of manufacture
- B cell and T cell activation
- Low-cost vaccines
- Intranasal administration/needle-free delivery

**Development Stage:**

- In vivo data assessment (animal)

**Inventors:** Cyril Le Nouen (NIAID), Ursula Buchholz (NIAID), Peter Collins (NIAID).

**Intellectual Property:** HHS Reference No. E-104-2020-0 - U.S. Provisional Application No. 63/023,949, filed May 13, 2020

**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: February 18, 2021.

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Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-03872 Filed: 2/24/2021 8:45 am; Publication Date: 2/25/2021]