(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: September 23, 2019.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2019–20965 Filed 9–26–19; 8:45 am]

**BILLING CODE 4140–01–P**

## 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:** Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.* Licensing information may be obtained by communicating with 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

**Improvement of Broadly HIV-Neutralizing Antibodies; Anti-HIV–1 Antibody VRC01.23 for Prevention or Treatment of HIV Infection**

*Description of Technology:*

Scientists at NIAID have developed broadly neutralizing antibodies (bNAbs) with enhanced neutralizing activity against HIV–1. Specifically, previously unknown gp120 interactions with a newly elucidated quaternary receptor (CD4)-binding site in the HIV–1 envelope have been discovered by engrafting the extended heavy-chain framework region 3 (FR3) loop of VRC03 onto several potent bNAbs (including VRC01, VRC07 and N6). The new antibodies show improved binding with CD4 by interacting with both binding sites and as a result show improved neutralization of various HIV–1 strains. Furthermore, they show reduced autoreactivity and, as a result, have prolonged *in vivo* half-life.

One of several antibodies that were developed using this technology is VRC01.23. It combines the VRC03 framework 3 alteration, with a G54W mutation in the heavy chain, and a 3 amino acid deletion in the light chain. The modifications improved the potency while reducing the autoreactivity. In particular, VRC01.23 is capable of neutralizing 96% of HIV–1 viruses tested at geometric mean IC50 =0.042 ug/ml, which is ~10-fold more potent than VRC01.

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:*

- Improving human monoclonal antibodies for HIV treatment or prevention
- New candidates for use as a therapeutic or as a prophylactic

*Competitive Advantages:*

- Interaction with multiple HIV binding sites
- Reduced autoreactivity when using the VRC03 framework 3 region mutation
- Improved neutralization breadth and potency over existing antibodies
- Extended in vivo half-life

*Development Stage:*

- Pre-clinical

*Inventors:* Paolo Lusso, Qingbo Liu, Peter Kwong, Young Do Kwon, and John Mascola, all of NIAID.

*Publications:* Liu, Qingbo, et al. ''Improvement of antibody functionality by structure-guided paratope engraftment.'' Nature communications 10.1 (2019): 721.

*Intellectual Property:* HHS Reference No. E–034–2018–0–PCT–01—PCT Application No. PCT/US2019/019021 filed on 21 February 2019.

*Licensing Contact:* To license this technology, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov,* and reference E–034–2018.

*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 this technology. For collaboration opportunities, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.*

Dated: September 18, 2019.

**Wade W. Green,**

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

[FR Doc. 2019–20994 Filed 9–26–19; 8:45 am]

**BILLING CODE 4140–01–P**

## 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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

**FOR FURTHER INFORMATION CONTACT:** Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

Antagonists of Hyaluronan Signaling for Treatment of Airway Diseases, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD), constitute a major health burden in the development word. It is estimated that nearly15.0% of the adult population in the US are affected with such diseases, and the economic cost burden is over $23 billion annually. Unfortunately, the current options for treatment of such diseases are quite limited, consisting only of bronchodilators and inhaled steroids. The need for a novel and more effective class of therapeutics agents is imperative. The subject invention provides for a potentially more specific and effective treatment of airway diseases as compared with existing treatments. It is based on the inhibition of Hyaluronan (HA), a structural polysaccharide that plays a role in the signaling pathway that leads to the

onset of airway diseases. Such inhibition blocks the development of airway inflammation and airway hyperresponsiveness (AHR), two of the components associated with airway diseases, and thus may be useful in the treatment of such diseases. The invention discloses two antagonists of HA, *i.e.* heparosan, and Hyaluronan oligosaccharides (oHAs). Their administration to a human subject in need can be accomplished *via* the use of an inhaler or nebulizer.

*Potential Commercial Applications:*

- Treatment of Airway Diseases

*Development Stage:*

- *In Vitro* data available

*Inventors:* Stavros Garantziotis (NIEHS), John Hollingsworth (Duke), Brian P. Toole (UMSC), Jian Liu (UNC)

*Intellectual Property:* HHS Reference E–080–2012: Issued Patents: US Patent No. 9,717,752 issued 08/01/2017; European Patent No. 2827877 issued 05/08/2019 and validated in Germany, France, and the United Kingdom. Pending application: Canadian Patent Application No. 2872569 filed 03/08/2013.

*Licensing Contact:* Uri Reichman, Ph.D., MBA, 301–435–4616; *uri.reichman@nih.gov.*

Dated: September 17, 2019.

**Uri Reichman Sr.,**

*Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.*

[FR Doc. 2019–20993 Filed 9–26–19; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Prospective Grant of Exclusive Patent License: Capsid-Free AAV Vectors, Compositions, and Methods for Vector Production and Gene Delivery

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Generation Bio Co. (''Generation Bio''), a company based in Cambridge, Massachusetts (in the exclusive field specified below), and a co-exclusive license to Generation Bio and Spark Therapeutics, a company based in Philadelphia, Pennsylvania (in the co-exclusive field specified below), to practice the inventions embodied in the patent application listed in the Supplementary Information section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development within 15 days from the date of publication of this notice in the **Federal Register** will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Uri Reichman, Ph.D., MBA, Senior Licensing and Patenting Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–435–4616, or *uri.reichman@nih.gov*.

**SUPPLEMENTARY INFORMATION:** The following and all continuing U.S. and foreign patents/patent applications thereof are included in the intellectual property to be licensed under the prospective agreements to Generation Bio and Spark Therapeutics: NIH reference #E–241–2010.

U.S. patent 9,598,703 issued March 03, 2017; Israeli patent 228328 issued December 01, 2018; Australian patent 2012228376 issued October 05, 2017, and pending applications in Brazil (BR 11 2013 023185 8 A2), Canada (application 2829518), China (application 201280022523.5), Europe (application 12 708035.6), India (application 8000/DELNP/2013), Japan (application 2013–557138), and S. Korea (application10–2013–7026982).

The invention is jointly owned by the Government of the United States and by the following French institutions: Association Institut De Myologie, Sorbonne University, INSERM, and CNRS. The patent rights in these inventions have been assigned to the Government of the United States of America, and to the French institutions by their respective employees who are the inventors of the subject matter claimed in the patent rights. The prospective patent license will be granted worldwide and in fields of use not broader than the following:

*Exclusive field:* Electroporation-mediated delivery of DNA-based vectors to express therapeutic molecules for the treatment or prevention of human diseases.

*Co-exclusive field:* The treatment or prevention of cancer by administration of DNA-based vectors (with the exception of electroporation mediation) to express therapeutic molecules.

All Fields of Use with the exception of the aforementioned fields are available for licensing by other parties on nonexclusive terms.

The subject technology provides DNA-based constructs for human therapeutics or preventative therapies. Such DNA-based constructs may be useful in gene therapy for treating genetic disorders, or other diseases by expressing therapeutic molecules. These constructs are AAV genome-based, where the gene of interest (therapeutic payload) is inserted between two ITRs (Inverted Terminal Repeats). The resulting constructs are devoid of the AAV capsid, and thus nonviral. They are advantageous over conventionally used AAV vectors, as they are non-immunogenic. They are also advantageous over plasmid-based expression constructs since they are of eukaryotic origin and thus devoid of the bacterial-type DNA methylation as typically present in plasmids.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI 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. Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. Comments and objections submitted 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: September 17, 2019.

**Uri Reichman Sr.,**

*Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.*

[FR Doc. 2019–20992 Filed 9–26–19; 8:45 am]

**BILLING CODE 4140–01–P**