Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–17886 Filed 8–19–19; 8:45 am]

BILLING CODE 4150–29–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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

Floxed Targeted Mouse Strain for Use in Conditional Deletion of the Irf8 Gene

Description of Technology

IRF8, a member of interferon regulatory factor (IRF) family of transcription factors is a novel intrinsic transcriptional inhibitor of TH17-cell differentiation. TH17-cells are believed to be involved in the pathogenesis of various autoimmune/inflammatory diseases. The Irf8f floxed targeted mutated mouse strain can be used to selectively ablate expression of IRF8 in any cell type in which a Cre recombinase gene is activated. This will permit the identification of IRF8-regulated genes and their effects in specific types of developing and mature cells. These materials could be used to help define patterns of gene expression important for the development and function of cells including possible contributions to understanding: Normal immune responses, inflammatory conditions, autoimmunity and anti-viral responses.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

- Target identification in B and T cell deficiency, macrophage defects and hematopoiesis.
- A tool for investigating IRF8 mediated issues associated with inflammation and autoimmunity.
- Investigative tool for development of potential therapeutics for lymphoma and Human Chronic Myeloid Leukemia.

Competitive Advantages

- Mice with established germ line transmission for use in conditional deletion of the IRF8 gene in any cell type.

Development Stage

- Research Use.

Inventors: Herbert Carpenter Morse III (NIAID).

Publications: Ouyang, Xinshou, et al. ''Transcription factor IRF8 directs a silencing programme for TH17 cell differentiation.'' *Nature Communications* 2, Article number: 314 (2011).

Licensing Contact: To license this technology, please contact Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov,* and reference E–062–2012–0.

Dated: August 6, 2019.

Suzanne M. Frisbie,

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

[FR Doc. 2019–17868 Filed 8–19–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Lyell Immunopharma, Inc. (''Lyell''), located in South San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before September 19, 2019 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: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240)–276–7856; Facsimile: (240)–276–5504; Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–016–2015: Chimeric Antigen Receptor Targeting both CD19 and CD22

1. U.S. Provisional Patent Application 62/135,442, filed March 19, 2015 (E–106–2015–0–US–01);
2. International Patent Application PCT/US2016/023055, filed March 18, 2016 (E–106–2015/0–PCT–02)
3. U.S. Patent Application No.: 15/559,485, filed September 19, 2017 (E–E–106–2015/0–US–03)

E–017–2017: CD19/CD22 Bicistronic CAR Targeting Human B-Cell Malignancies

1. U.S. Provisional Patent Application 62/506,268, filed May 15, 2017 (E–017–2017–0–US–01);
2. International Patent Application PCT/US2018/032,809, filed May 15, 2018 (E–017–2017/0–PCT–02)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to: ''Treatment of B cell malignancies using autologously-derived T cell expressing chimeric antigen receptor(s) (CAR) specific for both CD19 and CD22 utilizing the anti-CD19 antigen binding domain of the FM63 antibody and the anti-CD22 antigen binding domain of the M971 antibody.'' The proposed territory is worldwide.

This technology discloses CAR therapies that target both CD19 and CD22 by utilizing the anti-CD19 binder

known as FM63 and the anti-CD22 binder known as M971. CD19 and CD22 are each expressed on the surface of B cells in B cell malignancies and are hallmark examples of antigen targeting in CAR–T therapies, with CD19-targeting CAR–T therapies being the first FDA approved CAR–T, and CD22-targeting CAR–T showing early promise in clinical trials for ALL and NHL.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within thirty (30) days from the date of this published Notice, the National Cancer Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 6, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–17866 Filed 8–19–19; 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: Vince Contreras, Ph.D., 240–669–2823; *vince.contreras@nih.gov.* Licensing information and copies of the U.S. patent application 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.

Recombinant Nipah F Proteins and Their Use

Description of Technology

Nipah virus is an emerging pathogenic paramyxovirus responsible for sporadic and isolated outbreaks of severe respiratory and neurologic disease in Southern Asia. As a zoonotic virus, disease can manifest in both animals and human with indigenous fruit bats acting as natural reservoirs of the virus. The effects of viral infection vary from acute respiratory distress to fatal encephalitis. There are currently no approved therapeutics or vaccines against the virus, and growing concerns that this highly pathogenic infection has the potential to cause larger epidemics capable of inflicting significant mortality burden.

Like the RSV fusion (F) glycoprotein, the Nipah fusion glycoprotein is a target of neutralizing antibodies that mediate protection against infection. Previous studies of prefusion-stabilized F glycoproteins from pneumoviruses and other paramyxoviruses (*e.g.* RSV and PIVs) have shown they elicit higher titers of neutralizing antibodies in both animals and humans than post-fusion F proteins.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) designed disulfide, cavity-filling and other mutations that stabilize the Nipah F glycoprotein in the prefusion conformation and bind prefusion-specific antibodies. These mutations also increase protein expression yields up to 50-fold making the recombinant proteins easy to manufacture and amenable to the use of genetic immunization using nucleic acid or vector-based applications.

The stabilized prefusion state of the Nipah F glycoprotein may be an ideal vaccine immunogen to elicit broad potent Nipah neutralizing antibodies. First and second generation prefusion molecules have been designed and tested in small animals and results (immunogenicity and stability) appear promising.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

- Vaccine—to elicit potent neutralizing antibodies against the Nipah Env glycoprotein.

Competitive Advantages

Nipah prefusion F design has the following features compared to wild-type fusion glycoprotein:

- Robust stabilization.
- Up to 50-fold increase in expression yields, making the recombinant proteins easy to manufacture.
- Potential to link the recombinant glycoprotein to nanoparticles or oligomerization peptides.

Development Stage: In vivo testing (rodents).

Inventors: Barney S. Graham (NIAID), Rebecca J. Loomis (NIAID), Guillaume Stewart-Jones (NIAID), John R. Mascola (NIAID), and Jason McLellan (NIAID).

Intellectual Property: HHS Reference Number E–050–2018 includes U.S. Provisional Patent Application Number 62/714,230 filed 08/03/2018.

Related Intellectual Property: PCT Application No. PCT/US2008/087719 filed 19/12/2008.

Licensing Contact: Vince Contreras, Ph.D., 240–669–2823; *vince.contreras@nih.gov.*

Dated: August 7, 2019.

Suzanne M. Frisbie,

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

[FR Doc. 2019–17867 Filed 8–19–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a time and room change in the meeting of the HEAL (Helping to End Addiction Long-term) Multi-Disciplinary Working Group, August 21, 2019, 08:30 a.m., to August 22, 2019, 03:45 p.m., Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 23, 2019, 84FR35402.