

Terry Clark,

Office of the Secretary, Paperwork Reduction  
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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:** Chris Kornak at 240-627-3705 or [Chris.Kornak@nih.gov](mailto: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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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](mailto: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.

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## 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](mailto: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-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