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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: James M. Robinson, 301–761–7542; James.Robinson4@nih.gov. Licensing information and copies of the 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Methods for diagnosing and treating *Mycobacterium tuberculosis* (Mtb) infection through detection of CD153 expression level.

Description of Technology:

Mycobacterium tuberculosis (Mtb) infection continues to be the leading cause of death due to a single infectious agent and poses significant global health challenges. Past research has shown that CD4 T cells are essential for resistance to Mtb infection, and for decades it has been thought that IFN(γ) production is the primary mechanism of CD4 T cell-mediated protection.

NIAID researchers have discovered that the expression of TNF superfamily molecule CD153 (TNSF8) is required for control of the pulmonary Mtb infection by CD4 T cells. The results have shown that, in Mtb infected mice, CD153 expression is highest on Ag-specific Th1 cells in the lung tissue parenchyma. On the contrary, CD153 deficient mice have developed high pulmonary bacterial loads and succumb early to Mtb infection. In Mtb infected non-human primates, CD153 expression is much higher on Ag-specific CD4 T cells in the airways compared to the blood, and the frequency of Mtb-specific CD153-expressing CD4 T cells inversely correlates with bacterial loads in granulomas. Further, in Mtb infected humans, CD153 defines a subset of highly polyfunctional Mtb-specific CD4 T cells that are much more abundant in individuals with controlled latent Mtb infection compared to those with active TB. Since the expression of CD153 by CD4 T cells is a major immune mechanism of host protection against Mtb infection, the discovery can be used to effectively diagnose and treat Mtb infections in the future.

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:

- *Mycobacterium tuberculosis* diagnostic that measures the production of CD153 as an indicator of the disease and its severity
- A companion diagnostic can be used to determine the effectiveness of a vaccine against a *Mycobacterium tuberculosis* infection in a subject
- Therapeutic use to treat *Mycobacterium tuberculosis* in a subject

Competitive Advantages:

- Ability to be used as a target for Mtb diagnostics and therapeutics

Development Stage:

- Proof of concept in animal models and human subject.

Inventors: Daniel L. Barber (NIAID), Michelle A. Sallin (NIAID), Keith D. Kauffman (NIAID)

Publications: Sallin, Michelle A., et al. "Host resistance to pulmonary Mycobacterium tuberculosis infection requires CD153 expression." Nature microbiology (2018): 1.

Intellectual Property: HHS Reference No. E-085-2018 US Patent Application No. 62/633,816 filed February 2, 2018

Licensing Contact: James M. Robinson, 301–761–7542; James.Robinson4@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 the methods of

treating human tuberculosis**.** For collaboration opportunities, please contact James M. Robison at 301–761–7542 or James.Robinson4@nih.gov.

Dated: October 31, 2018.

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Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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