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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

Humanized Murine Monoclonal Antibodies That Neutralize Type-1 Interferon (IFN) Activity

Description of Technology

Interferons (IFNs) are a family of cytokines that function in response to an immune challenge such as a viral or bacterial infection. Type I IFNs are produced by immune cells (predominantly monocytes and dendritic cells) as well as fibroblasts and signal through a specific cell surface receptor complex (IFNAR) that consist of IFNAR1 and IFNAR2 chains. Type-I IFNs exert several common effects including antiviral, antiproliferative, and immunomodulatory activities. However, Type I IFNs also have pro-inflammatory effects, especially in the presence of TNF-α. Therefore, neutralizing the pro-inflammatory effect of Type I interferon could have wide clinical applications in autoimmune diseases like SLE, or in acute and chronic viral diseases like SARS–CoV–2, HIV or HCV infection, respectively, in which IFN-induced inflammation may be detrimental.

Scientists at the National Institute of Allergy and Infectious Diseases (NIAID) have developed two anti-IFN receptor 2 (IFNAR2) antibodies, B7 and A10, that are effective *in vitro* at neutralizing Type I IFN activities. The antibodies are comprised of two heavy chains and two light chains of amino acids. Both antibodies are able to bind to the extracellular domain of IFNAR2, Type I IFN receptor subunit 2, thus suppressing IFN signaling.

Because there are no potent IFNAR2 antibodies for therapies commercially available at this time, these antibodies are a novel therapeutic tool that could be used exclusively or in combination to treat chronic inflammatory diseases (like autoimmune disorders such as SLE) in which sustained IFN production may lead to both systemic and specific organ dysfunctions or chronic viral diseases (such as HIV, HCV) in which sustained IFN production has deleterious effects on immunologic function.

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

Therapeutics for the treatment of chronic inflammatory conditions:

- In chronic inflammatory diseases (*e.g.,* autoimmune disorders such as SLE).
- In chronic viral diseases (such as HIV, HCV infection).
- In acute viral or inflammatory diseases (*e.g.,* SARS–CoV–2).

Development Stage

- Pre-clinical.

Inventors: Paolo Lusso, M.D. Ph.D., Hana Schmeisser, Ph.D., Kathryn C. Zoon, Ph.D., Qingbo, Liu, Ph.D., all of NIAID.

Publications:

A.N. Morrow, H. Schmeisser, T. Tsuno, K.C. Zoon. A novel role for IFN-stimulated gene factor 3II in IFN-γ induction of antiviral activity in human cells. *J Immunol* 186: 1685–93, 2011.

C.A. Balinsky, H. Schmeisser, S. Ganesan, K. Singh, T.C. Pierson, K.C. Zoon. Nucleolin interacts with the dengue virus capsid protein and plays a role in formation of infectious virus particles. *J Virol* 87: 13094–106, 2013.

H. Schmeisser, S.B. Fey, J. Horowitz, E.R. Fischer, C.A. Balinsky, K. Miyake, J. Bekisz, A.L. Snow, K.C. Zoon. Type I interferons induce autophagy in certain human cancer cell lines. *Autophagy* 9: 683–96, 2013.

L.A. Zaritsky, J.R. Bedsaul, K.C. Zoon. Virus multiplicity of infection affects type I interferon subtype induction profiles and interferon-stimulated genes. *J Virol* 89 (22): 11534–48, 2015.

C.A. Balinsky, H. Schmeisser, A.I. Wells, S. Ganesan, T. Jin, K. Singh, K.C. Zoon. IRAV (FLJ112886), an interferon stimulated gene with antiviral activity against Dengue Virus, interacts with MOV 10. *J Virol* 14: 91(5), e01606–16, 2017.

A.W.T. Chiang, S. Li, B.P. Kellman, G. Chattopadhyay, Y. Zhang, Ch. Ch. Kuo, J.M. Gutierrez, F, Ghazi, H. Schmeisser, P. Ménard, S.P. Bjørn, B.G. Voldborg, A.S. Rosenberg, M. Puig, Nathan E. Lewis. Combating viral contaminants in CHO cells by engineering innate immunity. *Sci Rep 9* (1), 8827, 2019.

Intellectual Property: HHS Reference No. E–220–2020–0; U.S. provisional application No. 63/094,572 filed on 10/21/2020 and PCT application PCT/US2021/056067.

Licensing Contact: To license this technology, please contact Chris Kornak 240–627–3705 or *chris.kornak@nih.gov,* and reference E–220–2020.

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: April 8, 2022.

Surekha Vathyam,

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 of Diagnostic for Imaging and Early Detection of Pancreatic Cancer and Pre-Cancerous Lesions by Targeting the Cholecystokinin-B Receptor

AGENCY: National Institutes of Health.

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, sublicensable, patent license to Georgetown University ''Georgetown'', a private university located in Washington DC, to its rights to the invention embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice.