[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 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 A signed Confidential Disclosure Agreement may be required to receive any unpublished information.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.

Antibody Targeting Cell Surface Deposited Complement Protein C3d

Available for licensing and commercial development is a patent estate covering anti-C3d antibodies, antibody fragments, and their methods of use for killing cancer cells expressing C3d complement protein on their surface, and more particularly for the treatment of patients with Chronic Lymphocytic Leukemia (CLL); a malignancy of mature B-cells and the most common leukemia in the US. The most commonly used monoclonal antibodies (mAbs) are of mouse origin that have been chimerized or humanized to carry human constant regions (typically the human lgG1 isotype), required for the recruitment of human effector mechanisms. The complement system consists of soluble plasma proteins and is activated upon binding of a mAb to target cells resulting in the deposition of complement components on the cell surface and formation of the membrane attack complex (MAC), which can kill cells inducing lysis. The invention originated from an observation during CLL patient treatment with chemotherapy in combination with an anti CD20 mAb (e.g., rituximab or ofatumumab). Upon infusion complement is deposited on the cell surface of CLL cells, a subset of cells is killed, and other cells escape having lost CD20 expression due to a process called trogocytosis by which antibody-CD20 complexes are pulled of the CLL cell surface by immune cells that bind the Fc-portion of the mAb. It has been noted that C3d is stably attached to the CLL cells that escape from further rituximab or ofatumumab targeting and remains detectable for weeks on these cells. C3d, thus, could serve as a neoantigen that could be targeted with anti C3d specific mAbs to kill off escaped tumor cells.

Potential Commercial Applications:

Development Stage:

• mouse data available

Inventors: Adrian Wiestner, Martin Skarzynski, Christoph Rader (all of NHLBI), and

Margaret A. Lindorfer, Ronald P. Taylor, and Berengere Vire (all of the University of Virginia School of Medicine)

Relevant Publications:

- Robinson, et al. Blood. 2018 Aug 2;132(5):521-532. doi: 10.1182/blood-2018-02-830992.

Intellectual Property: HHS Reference No. E-758-2013-0 and -1; U.S. Provisional Patent Application 61/924,967 filed January 8, 2014 (converted), International Patent Application PCT/US2015/010620 filed January 8, 2015 (nationalized), U.S. Patent Application 15/110, 557 filed January 8, 2015, Canadian Patent Application 2936346 filed January 8, 2015, European Patent Application 15701442.4 filed January 8, 2015, and U.S. Divisional Patent Application 16/047,929 filed January 8, 2015.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301-435-5019; shmilovm@mail.nih.gov.

Dated: October 4, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager,

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development.

[FR Doc. 2018-22359 Filed: 10/12/2018 8:45 am; Publication Date: 10/15/2018]