

Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012-0-SG-06], United States Patent 9,409,994 entitled "High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof" [HHS Ref. E-136-2012-0-US-07], and all continuing U.S. and foreign patents/patent applications for the technology family; and (B) U.S. Provisional Patent Application 62/584,421 entitled "Chimeric Antigen Receptors Targeting Tumor Antigens" [HHS Reference E-016-2018-0-US-01], PCT Patent Application PCT/US2018/059645 entitled "Chimeric Antigen Receptors Targeting Tumor Antigens" [HHS Reference E-016-2018-0-PCT-02], Chinese Patent Application 201880073043.9 entitled "Chimeric Antigen Receptors Targeting Tumor Antigens" [HHS Reference E-016-2018-0-CN-03], European Patent Application 18822526.2 entitled "Chimeric Antigen Receptors Targeting Tumor Antigens" [HHS Reference E-016-2018-0-EP-04], South Korean Patent Application 10-2020-7014565 entitled "Chimeric Antigen Receptors Targeting Tumor Antigens" [HHS Reference E-016-2018-0-KR-05] and U.S. Patent Application 16/762,459 entitled "Chimeric Antigen Receptors Targeting Tumor Antigens" [HHS Reference E-016-2018-0-US-06], and all continuing U.S. and foreign patents/patent applications for the technology family.

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 field of use may be limited to the following:

"The development, production and commercialization of a monospecific chimeric antigen receptor (CAR)-based immunotherapy for the prophylaxis and treatment of GPC3-expressing human cancers using unmodified, allogeneic NK cells transduced with a viral vector that expresses a CAR and a gene circuit regulating the expression of one or more armoring payloads, wherein:

(1) The CAR includes:

a. A single antigen specificity comprising at least the complementary determining region (CDR) sequences of the anti-GPC3 antibody known as YP7, and

b. an intracellular signaling domain;

(2) the gene circuit includes either (a) a synthetic transcription factor that is stabilized or activated by a small molecule drug or environmental signal, or (b) a synthetic promoter element that is responsive to a small molecule drug or environmental signal; and

(3) the armored payload is selected from:

- a. An immune-stimulating cytokine,
- b. a chemokine,
- c. a growth factor,
- d. a co-activation molecule, and
- e. a tumor microenvironment modulator.

The Licensed Field of Use specifically excludes the use of autologous T cells or T cells that have been genetically modified to become allogeneic. For clarity "allogeneic" means the cells are from a donor that is not the recipient and the term "unmodified" means that no genetic engineering with genome editing tools is performed."

This technology discloses the development of chimeric antigen receptors that recognize the glypican3 (GPC3) cell surface protein. GPC3 is expressed on the cell surface of several solid tumors, including liver cancers (such as hepatocellular cancer (HCC)), certain ovarian cancers, and neuroblastomas. Although the FDA has approved certain therapies for the treatment of liver cancer, those therapies only provide a minimal increase in the life expectancy of patients. The development of a new therapeutic targeting GPC3 will benefit public health by providing an improved and more effective treatment for patients.

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 fifteen (15) 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 completed 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 in 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: September 23, 2020.

Richard U. Rodriguez,
Associate Director, Technology Transfer
Center, National Cancer Institute.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Neurosciences Special Review Panel.

Date: November 4, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neurosciences Center Building, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review, Branch Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20817, (301) 443-0800, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: September 25, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

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