



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Antibody-Drug Conjugates (ADCs) for Targeting CD56-positive Tumors

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 McSAF Inside Oncology SAS (“McSAF Inside Oncology”) located in Tours, France.

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 **[INSERT**

DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] 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: Rose Freel, Ph.D., Unit Supervisor, NCI Technology Transfer Center, Telephone: (301) 624-1257; E-mail: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/199,707 filed July 31, 2015, entitled “Antibody-drug conjugates for targeting CD56-positive tumors” [HHS Reference No. E-221-2015-0-US-01];
2. International Patent Application No. PCT/US2016/044777 filed July 29, 2016, entitled “Antibody-drug conjugates for targeting CD56-positive tumors” [HHS Reference No. E-221-2015-0-PCT-02]; and
3. United States Patent No. 10,548,987 issued February 02, 2020 (corresponding to United States Patent Application No. 15/747,620 filed January 25, 2018), entitled “Antibody-drug conjugates for targeting CD56-positive tumors” [HHS Reference No. E-221-2015-0-US-03].

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 use, development, and commercialization of an antibody-drug conjugate (ADC) for the treatment of Merkel cell carcinoma, wherein the ADC utilizes any technology for attachment of the cytotoxic payload and has:

- (1) The CDR sequences of the m906 antibody; and
- (2) a cytotoxic payload.”

and

“The use, development, and commercialization of an antibody-drug conjugate (ADC) for the treatment of CD56-positive cancers except glioblastoma, wherein the ADC:

(1) has the CDR sequences of the m906 antibody;

(2) has a cytotoxic payload; and

(3) utilizes solely McSAF Inside Oncology’s proprietary or exclusively licensed bioconjugation technologies for attachment of the linker-payload(s) to the m906 antibody.

The E-221-2015 patent family is directed to ADCs utilizing the CD56-specific monoclonal antibody known as m906 and conjugated to a drug. The technology is intended to be used as a therapeutic for CD56-positive cancers such as neuroblastoma, multiple myeloma, ovarian cancer, acute myeloid leukemia, and small cell lung cancer. The exclusive field of use which may be granted to McSAF Inside Oncology applies to only ADCs which either 1) treat Merkel Cell Carcinoma; or 2) use McSAF Inside Oncology’s proprietary bioconjugation platform for attachment of the antibody to the linker-payload. Accordingly, the proposed scope of rights which may be conveyed under the license covers only a portion of the total scope of the E-221-2015 patent family and only a subset of the possible ADCs that incorporate the m906 antibody as well as the possible therapeutic applications of the ADCs.

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 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 from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: May 6, 2024.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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