[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Evaluation Option Patent License: "The development and use of diazeniumdiolated and hybrid diazeniumdiolated compounds for the treatment of ovarian cancer in humans."

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 a Start-up Exclusive Evaluation Option License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Tar Meta Biosciences, Inc.("TarMeta") located in King of Prussia, PA, USA**.**

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 FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Start-up Exclusive Evaluation Option License should be directed to: Kathleen Higinbotham, Senior Technology Transfer Manager, NCI Technology Transfer Center, Riverside 5, Suite 400, 8490 Progress Dr., Frederick, MD 21701, Telephone: (301)-624-8775; Facsimile: (301)-631-3027 E-mail: higinbok@mail.nih.gov

SUPPLEMENTARY INFORMATION:

Intellectual Property

1) E-025-2010/0 entitled "Nitric Oxide-based Cancer Therapeutic Agents For Lung Cancers With Elevated Levels Of Reactive Oxygen Species (ROS) And/or Low Levels Of Antioxidant Defense/DNA Repair Mechanisms."

a) United States Provisional Patent Application No. 61/261,175 filed November 13, 2009;
b) PCT Application No. PCT/US2010/056446 filed November 12, 2010;
c) United States Patent Application No. 13/509,431 filed June 01, 2012, US Patent 9,205,091 issued December 08, 2015;
d) Australian Patent Application No. 2010319398 filed May 09, 2012;
e) Canadian Patent Application No. 2,780,633 filed May 10, 2012;
f) European Patent Application No. 10778814.3 filed May 14, 2012;

2) E-220-2011/0 entitled "Hybrid Diazeniumdiolated Compounds, Pharmaceutical Compositions, And Method Of Treating Cancer."
   a) United States Provisional Patent Application No. 61/549,862, filed October 21, 2011;
   b) PCT Application No. PCT/US2012/060785 filed October 18, 2012;
   c) United States Patent Application No. 14/352,096 filed April 16, 2014, US Patent 9,168,266 issued October 27, 2015;
   d) Australian Patent Application No. 2012326105 filed April 14, 2014;
   e) Canadian Patent Application No. 2,852,682 filed April 14, 2014;
   f) European Patent Application No. 12841601.3 filed April 14, 2014, European Patent 2768824 issued December 07, 2016;
      i) German Patent 602012026435.7 issued December 07, 2016;
      ii) French Patent 2768824 issued December 07, 2016; and
      iii) UK Patent 2768824 issued December 07, 2016.

The patent rights in these inventions have been assigned 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 development and use of diazeniumdiolated and hybrid diazeniumdiolated compounds for the treatment of ovarian cancer in humans."

The present inventions describe the use of diazeniumdiolate-based nitric oxide (NO)-releasing compounds wherein the cancer cell has an elevated level of reactive oxygen species (ROS), as well as the use of hybrid prodrug molecules that combine a diazeniumdiolated compound and a poly(ADP-ribose) polymerase (PARP) inhibitor in cancer cells to produce synergistic effects, whether alone or as an adjuvant for other therapies. The hybrid prodrug is expected to enhance cytotoxicity by creating DNA damage with NO and preventing its repair with the PARP inhibitor. The prodrug and the hybrid are activated by glutathione S-transferase and are predicted to be effective in cancers with reactive oxygen species (ROS), both of which are elevated in many cancers. In addition, the prodrug and hybrid may have synergy with therapeutics (such as proteasome inhibitor bortezomib and doxorubicin) which act through

generation of ROS. Taken together, these features suggest that the prodrug and hybrid may have therapeutic applications in cancer patients whose tumors include high levels of ROS.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Start-up Exclusive Evaluation Option 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.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-up Exclusive Evaluation Option License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: March 21, 2017.

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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