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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement:

Development and Commercialization of Aza-Epoxy Guaiane Derivatives for Treatment of Renal Cancer

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to ElexiMed LLC, a company having a place of business at 5003 Green Mountain Circle, Suite 4, Columbia MD 21044, USA, to practice the inventions embodied in the following patent applications.

Intellectual Property - PCT Patent Application No. PCT/US2015/014601, entitled “Aza-Englerin Analogues - Novel Natural Product-Based Nitrogen-Containing Anti-Cancer Agents” filed February 5, 2015 (HHS Ref. No.: E-090-2014/2-PCT-01); US Provisional Patent Application No. 62/018,381, entitled “Aza-epoxy-guaiane derivatives and treatment of cancer” filed June 27, 2014 (HHS Ref. No. E-090-2014/1-US-01); and US

Provisional Patent Application No. 61/936,285, entitled “Aza-englerin analogues and use in cancer therapy” filed February 5, 2014 (HHS Ref. No. E-090-2014/0-US-01).

The patent rights in these inventions have been assigned to the Government of the United States of America and the University of Hawaii.

The territory of the prospective Start-Up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to “Development and commercialization of aza-epoxy guaiane derivatives for treatment of renal cancer.”

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, ElexiMed LLC will have the exclusive right to execute a Start-Up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NCI 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 application(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Rose Freel, Ph.D., Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, Riverside 5, Suite 400, 8490 Progress Drive. Frederick, MD 21702; telephone: 301-624-1257; Facsimile: 301-631-3027; E-mail: rose.freel@nih.gov. A signed confidentiality nondisclosure

agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This technology describes aza-englerins, synthetic analogues of the natural product Englerin A which displays potent and selective anti-cancer properties in several cancer cell lines. The aza-englerins were developed as novel cancer therapeutics and show significant bioavailability after oral administration in mice.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement may be granted unless the NCI receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

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: December 2, 2015.

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

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