

Dated: April 8, 2016.

**Elizabeth A. Fowler,**  
Deputy Director for Management Operations  
Indian Health Service.

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BILLING CODE 4165-16-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Development of the CB1/iNOS Series of Compounds as a Therapeutic To Treat System Sclerosis, Scleroderma, and Other Skin Fibrotic Diseases in Humans

**AGENCY:** National Institutes of Diabetes and Digestive and Kidney Diseases, Public Health Service, PHS, National Institutes of Health.

**ACTION:** Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the following inventions embodied in the following patent applications, entitled "CB1 receptor mediating compounds":

1. U.S. Provisional Patent Application No.: 61/991,333, HHS Ref. No.: E-140-2014/0-US-01, Filed: May 09, 2014
2. PCT Application No.: PCT/US2015/029946, HHS Ref. No.: E-140-2014/0-PCT-02, Filed: May 08, 2015
3. U.S. Provisional Patent Application No.: 61/725,949, HHS Ref. No.: E-282-2012/0-US-01, Filed: November 13, 2012
4. PCT Application No.: PCT/US2013/069686, HHS Ref. No.: E-282-2012/0-PCT-02, Filed: November 12, 2013
5. U.S. Patent Application No.: 14/442,383, HHS Ref. No.: E-282-2012/0-US-03, Filed: May 12, 2015
6. Canadian Patent Application No.: 2889697, HHS Ref. No.: E-282-2012/0-CA-04, Filed: April 27, 2015
7. European Patent Application No.: 13802153.0, HHS Ref. No.: E-282-2012/0-EP-05, Filed: June 01, 2015
8. Indian Patent Application No.: 3733/DELNP/2015, HHS Ref. No.: E-282-2012/0-IN-06, Filed: May 01, 2015
9. Japanese Patent Application No.: 2015-542015, HHS Ref. No.: E-282-2012/0-JP-07, Filed: May 11, 2015
10. Chinese Patent Application No.: 201380069389.9, HHS Ref. No.: E-282-2012/0-CN-08, Filed: July 3, 2015
11. US Provisional Application No.: 62/171,179, HHS Ref. No.: E-282-2012/1-US-01, Filed: June 04, 2015

to Vital Spark Inc., ("Vital Spark"), a company incorporated under the laws of Delaware and having an office in

Jerusalem, Israel. The patent rights in these inventions have been assigned to the United States of America. This license may be worldwide. The field of use may be limited to the use of the Licensed Patent Rights to "develop the CB1/iNOS series of compounds as a therapeutic to treat systemic sclerosis, scleroderma, and other skin fibrotic diseases."

**DATES:** Only written comments and/or applications for a license which are received by the Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases on or before May 4, 2016 will be considered.

**ADDRESSES:** Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty Tong, Ph.D., Sr. Licensing and Patenting Manager, Technology Advancement Office, The National Institute of Diabetes and Digestive and Kidney Diseases, 12A South Drive, Bethesda, MD 20892, Email: [betty.tong@nih.gov](mailto:betty.tong@nih.gov). A signed confidentiality non-disclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** This technology, and its corresponding patent applications, is directed to methods of treating fibrosis, obesity and associated diseases such as type 2 diabetes by administering an agent that reduces appetite, body weight, hepatic steatosis, and insulin resistance. This technology may be useful as a means for treating various fibrotic diseases and metabolic syndromes without serious adverse neuropsychiatric side effects.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the Technology Advancement Office 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 404.7.

Properly filed competing applications for a license in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: April 13, 2016.

**Anna Amar,**  
Acting Deputy Director, Technology Advancement Office, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-13-228: Biomarkers for Diabetes and Kidney Diseases using Biosamples from the NIDDK Repository (R01).

**Date:** June 1, 2016.

**Time:** 11:00 a.m. to 1:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, ROOM 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, [begumn@niddk.nih.gov](mailto:begumn@niddk.nih.gov).

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK-KUH Fellowship Review.

**Date:** June 3, 2016.

**Time:** 8:00 a.m. to 9:00 a.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Melrose Hotel, 2430 Pennsylvania Ave. NW., Washington, DC 20037.

**Contact Person:** Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard,