DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is by webcast only and is open to the public. Written comments will be accepted and registration is required to present oral comments. Information about the meeting and registration are available at https://ntp.niehs.nih.gov/go/165.

DATES:
Meeting: Scheduled for December 3, 2020, at 12:30 p.m. to adjournment on December 4, 2020, at approximately 5:00 p.m. Eastern Standard Time (EST).

Written Public Comment Submissions: Deadline is November 20, 2020.

Registration for Oral Comments: Deadline is November 20, 2020.

ADRESSES:
Meeting web page: The preliminary agenda, registration, and other meeting materials are available at https://ntp.niehs.nih.gov/go/165.

Webcast: The URL for viewing the meeting webcast will be provided on the meeting web page.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe. Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3209, Fax: 301–451–5759, Email: wolfe@niehs.nih.gov. Hand Deliver/ Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include an update on the status of the Division of the National Toxicology Program (DNTP)’s strategic realignment, an introduction to DNTP’s draft strategic plan, and presentations from two program areas. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (https://ntp.niehs.nih.gov/go/165) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page.

Meeting Attendance Registration: The meeting is open to the public with time scheduled for oral public comments. Registration is not required to view the webcast; the URL for the webcast is provided on the BSC meeting web page (https://ntp.niehs.nih.gov/go/165). TTYS users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: NTP invites written public comments. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf. The deadline for submission of written comments is November 20, 2020. Written public comments should be submitted through the meeting web page. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP web page, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The agenda allows for four formal public comment periods—two comment periods on Day 1 for DNTP’s strategic realignment and draft strategic plan, and two comment periods on Day 2 for the two program areas (up to 3 commenters, up to 5 minutes per speaker, per topic).

Persons wishing to make an oral comment are required to register online at https://ntp.niehs.nih.gov/go/165 by November 20, 2020. Oral comments will be received only during the formal comment periods indicated on the preliminary agenda. Oral comments will only be by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Registration is on a first-come, first-served basis. Each organization is allowed one time slot per topic. After the maximum number of speakers per comment period is exceeded, individuals registered to provide oral comment will be placed on a wait list and notified should an opening become available. Commenters will be notified approximately one week before the meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to NTP-Meetings@icf.com no later than November 20, 2020.

Meeting Materials: The preliminary meeting agenda is available on the meeting web page (https://ntp.niehs.nih.gov/go/165) and will be updated one week before the meeting.

Background Information on the BSC: The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, epidemiology, risk assessment, carcinogenesis, mutagenesis, cellular biology, computational toxicology, neurotoxicology, genetic toxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets periodically. The authority for the BSC is provided by 42 U.S.C. 217a, section 222 of the Public Health Service Act (PHS), as amended.

The BSC is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development of a Direct Ocular Administered Formulation of Metformin for Use in Therapeutic Treatment of Retinal Degenerative Diseases in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye 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 certain of the inventions embodied in the Patents and Patent Applications listed in the SUPPLEMENTARY INFORMATION section of this notice to Connectyx Technologies Holdings Group located in Boca Raton, Florida.

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 November 6, 2020 will be considered.

ADRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Tedd Fenn, Senior Technology Transfer Manager, NCI Technology Transfer Center at Telephone: (240) 276-5530 or Email: Tedd.Fenn@nih.gov.

SUPPLEMENTARY INFORMATION: Intellectual Property


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 rights to develop, make use and sell, a direct ocular-administered formulation of metformin for use as therapeutics to treat retinal degenerative diseases in human.

Metformin administration to Retinal Pigment Epithelium (“RPE”) cells derived from age-related macular degeneration patients and to RPE cells derived from Stargart’s-patients shows reduced accumulations of disease associated retinal deposits, suggesting clinical treatment value for metformin in retinal degenerative diseases.

Metformin is FDA approved for the treatment of diabetes. No formulation of metformin is available for direct ocular use. Development of a direct ocular delivery metformin formulation could provide improved treatment effects for retinal degenerative diseases, without major systemic side effects.

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 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.


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

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