

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

#### FOR FURTHER INFORMATION CONTACT:

Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479; Michael Shmilovich; [shmilovm@nih.gov](mailto:shmilovm@nih.gov); telephone: 301-435-5019. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

#### SUPPLEMENTARY INFORMATION:

Technology description follows.

#### Cannabinoid Receptor Modulating Compounds

Available for licensing and commercial development are potentially therapeutic compounds for metabolic, inflammatory and fibrotic disorders. The filed patent applications includes extensive descriptions of the exemplary molecules and their various constituents. The cannabinoid receptor mediating compounds can be neutral antagonists. A CB<sub>1</sub> inverse agonist is a drug that on its own produces an effect opposite to that of a CB<sub>1</sub> agonist, and is also able to block the effect of a CB<sub>1</sub> agonist. In contrast, a CB<sub>1</sub> neutral antagonist can only do the latter (*i.e.*, blocking the effect of a CB<sub>1</sub> agonist), but has no effect on its own. CB<sub>1</sub> inverse agonism is usually documented by the ability of a drug to decrease GTPγS binding and/or to increase adenylate cyclase activity. The compounds may show functional bias for GTPγS or β-Arrestin or activity for both GTPγS and β-Arrestin. Secondary targets could include, but not limited to, the enzyme inducible nitric oxide synthase (iNOS) or adenosine monophosphate kinase (AMPK), as suggested by findings that inhibition of iNOS or activation of AMPK improves insulin resistance, and reduces fibrosis and inflammation. The rights pursued claim compounds,

pharmaceutical compositions, and methods of use.

#### Potential Commercial Applications

- Pharmaceuticals
- Cancer therapy
- Anti-fibrotic therapy
- Inflammatory and autoimmune disease

#### Development Stage

- Early stage

**Inventors:** Malliga R. Iyer, Ph.D.; Pinaki Bhattacharjee, Ph.D.; Resat Cinar, PharmD, MBA; George Kunos, M.D., Ph.D.; Szabolcs Dvoracko Ph.D., (all of NIAAA).

**Intellectual Property:** HHS Reference No. E-189-2021-0; U.S. Provisional Patent Application No. 63/319,642 filed March 14, 2022; International Patent Application PCT/U2023/014846 filed March 8, 2023.

**Licensing Contact:** Michael Shmilovich; 301-435-5019; [michael.shmilovich@nih.gov](mailto:michael.shmilovich@nih.gov).

This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

Dated: June 23, 2023.

**Michael A. Shmilovich,**

*Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Trials SEP (UG3, U24).

**Date:** July 27, 2023.

**Time:** 2:00 p.m. to 6:00 p.m.

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

**Place:** National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

**Contact Person:** Zhihong Shan, Ph.D., MD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205-J, Bethesda, MD 20892, (301) 827-7085, [zhihong.shan@nih.gov](mailto:zhihong.shan@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 26, 2023.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

#### Project: SAMHSA Generic Clearance for Grant Program Monitoring Activities

To carry out OMB Circular A-102<sup>1</sup> and 2 CFR part 215.51,<sup>2</sup> SAMHSA must collect grant program information necessary to ensure compliance with Federal and programmatic requirements. The Generic Clearance for Grant Program Monitoring Activities allows SAMHSA to collect standardized information from its grant recipients necessary to perform agency program oversight activities such as monitoring progress on recipient activities and determining and responding to

<sup>1</sup> Circular A-102: [https://www.whitehouse.gov/wp-content/uploads/legacy\\_drupal\\_files/omb/circulars/A102/a102.pdf](https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A102/a102.pdf).

<sup>2</sup> 2 CFR part 215.51: <https://www.govinfo.gov/content/pkg/CFR-2012-title2-vol1/pdf/CFR-2012-title2-vol1-subtitleA.pdf>.