

Dated: November 6, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024-26682 Filed 11-14-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Novel Kinase Inhibitory Aplithianines

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing and/or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S.

Government and are available for licensing and/or collaboration to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT:

Inquiries related to these licensing or collaboration opportunities should be directed to: Taryn Dick, Ph.D., M.B.A., Technology Transfer Manager, NCI, Technology Transfer Center, Email: taryn.dick@nih.gov or Phone: 301-631-3007.

SUPPLEMENTARY INFORMATION:

Researchers at the NCI seek licensing and/or co-development research collaborations for a class of novel aplithianine-derived small molecule analogs that compete with ATP for binding on a range of clinically relevant kinases. In 2022, the NCI Molecular Targets Program (MTP) completed a screen of approximately 150,000 pre-fractionated natural products from the NCI Program for Natural Product Discovery (NPNPD). From this screen, a class of active compounds, named Aplithianines A & B (isolated from the marine organism *Aplidium* sp.), showed

broad potential applicability to numerous kinases of importance, including but not limited to:

- Oncogenic gene fusion DNAJB1-PRKACA (PKADJ):
 - Implicated in an ultra-rare adolescent liver cancer.
- Wild type protein kinase A (PKA):
 - Implicated in Cushing's Disease.
- Protein kinase G (PKG):
 - Potential treatment of malaria.
- Ccdc2-like kinases (CLK) 1 and 2:
 - Implicated in gastric cancer.
- DYRK family of kinases:
 - Implicated in gastric or colon cancer as well as infections caused by a protozoa or parasites.

This technology describes the Original Family of compounds filed. Subsequent to this filing, two additional cohorts of related, but patentably distinct cohorts of compounds, have been filed. Both the Second and the Third Cohorts comprise the same chemical scaffold of the broadest generic formula of this Original Family but represent patentably distinct subgenus formulas.

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Structural Representatives:		
	Aplithianines A	Aplithianines B
Parent natural products isolated from the marine organism <i>Aplidium</i> sp.		
NIH Reference Number: E-044-2022 patent family (“Original Family”): The claims are directed to compositions of matter encompassing this broad Markush structure.	<p style="text-align: center;">(I)</p>	
NIH Reference Number: E-202-2023 patent family (“Second Cohort”) The claims are directed to compositions of matter encompassing these broad Markush structures.	<p style="text-align: center;">(I)</p>	<p style="text-align: center;">(II)</p>
NIH Reference Number: E-162-2024 Patent family (“Third Cohort”) The claims are directed to compositions of matter encompassing this broad Markush structures.	<p style="text-align: center;">(Ia)</p>	

not promiscuous kinase inhibitors. The subject kinase inhibitors have broad potential commercial applicability's for cancer, immune suppression, preventing organ rejection, treating diabetic neuropathic pain, malaria, or protozoa infection. To date, there are no approved therapeutics targeting DNAJB1-PRKCA, an oncogenic gene fusion, which is ubiquitously and exclusively detected in the tumors of patients with ultra-rare fibrolamellar hepatocellular carcinoma FLHCC.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E-044-2022.

Related Technologies: E-202-2023 and E-162-2024.

Product Type: Therapeutic.

Therapeutic Area(s): Oncology, Infectious Disease, Rare/Neglected Diseases.

Potential Commercial Applications:

- Gastric cancer.
- Ultra-rare adolescent liver cancer.
- Solid cancers susceptible to kinase inhibitors.

- Cushing's Disease.
- Transplantation.
- Diabetic neuropathic pain.
- Malaria.
- Protozoa infection.

Competitive Advantages:

- Applicability to numerous clinically relevant kinases, including:
 - Oncogenic gene fusion DNAJB1-PRKACA (PKADJ).
 - Wild type protein kinase A (PKA).
 - Protein kinase G (PKG).
 - Cdc2-like kinases (CLK) 1 and 2.
 - DYRK family of kinases.
- Applicable to a range of kinases, but are not promiscuous kinase inhibitors.
- Broad potential commercial applicability for several blockbuster indications including:
 - cancer, immune suppression, transplantation, diabetic neuropathic pain, malaria, and protozoa infection.

• No approved therapeutics targeting DNAJB1-PRKCA.

Publications:

• O'Keefe BR, et al. Biochemical Discovery, Intracellular Evaluation, and Crystallographic Characterization of Synthetic and Natural Product Adenosine 3',5'-Cyclic Monophosphate-Dependent Protein Kinase A (PKA) Inhibitors. PMID: 37082750, <https://pubmed.ncbi.nlm.nih.gov/37082750/>.

• O'Keefe BR, et al. Discovery and Synthesis of a Naturally Derived Protein Kinase Inhibitor that Selectively Inhibits Distinct Classes of Serine/Threonine Kinases. PMID: 37843072, <https://pubmed.ncbi.nlm.nih.gov/37843072/>.

Patent Status:

- E-044-2022: PCT/US2023/070304.
- E-202-2023: PCT/US2024/038376.

- E-162-2024: 63/672,577.

Development Stage: Pre-clinical (*in vivo* validation).

Dated: November 12, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024-26663 Filed 11-14-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; 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 Center for Complementary and Integrative Health Special Emphasis Panel; NCCIH Conference Grant (R13 Clinical Trial Not Allowed).

Date: December 10, 2024

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Michael E. Authement, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, 6707 Democracy Boulevard, Bethesda, MD 20817, michael.authement@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: November 8, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-26562 Filed 11-14-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Improved Methods for Cryopreservation of Cells, Tissues, and Organs

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Eye Institute (NEI), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of licensing and/or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing and/or collaboration to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT:

Inquiries related to these licensing and/or collaboration opportunities should be directed to: Hiba Alsaffar, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: hiba.alsaffar@nih.gov or Phone: 240-276-7489.

SUPPLEMENTARY INFORMATION:

Researchers at the NEI seek licensing and/or co-development research collaborations for improved methods of cryopreservation of cells, tissues, and organs via FOXO1 activation. The cornea is a critical part of the eye that helps prevent debris from entering and refracts light for proper vision. Corneal disorders such as keratoconus, Fuchs dystrophy, and infectious keratitis require corneal transplantation to restore vision. Approximately 185,000 corneal transplants are performed annually worldwide to treat corneal disorders. Corneas for those transplants are supplied by donor eyes that are stored at eye banks in select countries. Currently, Optisol-GS™ is the corneal preservation solution that is most widely used to store donated corneas at eye banks. Per NEI guidelines, corneas preserved in Optisol-GS™ have a 12-day shelf life. With the high demand for corneal transplantations worldwide, a 12-day shelf life cannot meet the requirement for long term cryogenic storage of corneas at large eye banks. Scientists at the NEI have developed improved methods for cryopreservation of cells, tissues, and organs (with focus of corneal tissue/cells) that increases