meeting notes of the November 14–15, 2024 ACMH open meeting; and (2) recommendations on the implementation of the updated Office of Management and Budget (OMB) Federal race and ethnicity data collection standards (SPD 15) that is focused on opportunities for engagement with racial, ethnic, and Tribal community level organizations to support increased awareness of OMB SPD 15 and their intended goals within their communities. The final recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to engagement with racial, ethnic, and Tribal community level organizations to support increased awareness of OMB SPD 15 and their intended goals within their communities.

Any individual who wishes to attend the meeting must register via the Zoom registration link, *https://www.zoomgov.com/webinar/register/WN_iZGnp8BWRQORITiqVcThzA,* by 5 p.m. EST on December 12, 2024. Each registrant should provide their name, affiliation, phone number, email address, if they plan to provide either written or verbal comment, and whether they have requests for special accommodations, including sign language interpretation. After registering, registrants will receive an automated email response with the meeting connection link. The meeting connection link is unique to each registrant and should not be shared.

Members of the public will have an opportunity to provide comments at the meeting. Individuals should indicate during registration whether they intend to provide written or verbal comment. Public comments will be limited to two minutes per speaker during the time allotted. Individuals of the public may also submit and distribute electronic or printed statements or material(s) related to this meeting's topic. Written statements or material(s) should be double-spaced with one-inch margins and not exceed two pages in length. Any content beyond the two-page limit will not be presented to the Committee. Registered members of the public who plan to submit electronic and distribute electronic or printed public statements or material(s) related to the meeting's topic should email the material to *OMH-ACMH@hhs.gov* at least two (2) business days prior to the meeting.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2024–28167 Filed 11–29–24; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Vaccine Augmented Tumor Infiltrating Lymphocytes for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer 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 the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Iovance Biotherapeutics, Inc. (''Iovance''), headquartered in San Carlos, CA.

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 December 17, 2024 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)–276–5484; Email: *andy.burke@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 63/295,762 filed December 31, 2021, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–US–01];

2. International Patent Application No. PCT/US2022/082579 filed December 29, 2022, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–PCT–02];

3. Australian Patent Application No. 2022425620 filed June 25, 2024, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–AU–01];

4. Canadian Patent Application No. 3241588 filed June 18, 2024, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–CA–01];

5. Chinese Patent Application No. 202280092973.5 filed August 30, 2024, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–CN–01];

6. European Patent Application No. 22854399.7 filed June 25, 2024, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–EP–01];

7. Japanese Patent Application No. 2024–539628 filed June 28, 2024, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–JP–01]; and

8. United States Patent Application No. 18/720,347 filed June 14, 2024, entitled ''T Cell Therapy with Vaccination as a Combination Immunotherapy Against Cancer'' [HHS Reference No. E–046–2022–0–US–02].

The patent rights in these inventions have been assigned and/or exclusively licensed 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 the following:

''Development, manufacture and commercialization of combination immunotherapies for the treatment of cancer in humans, comprising at least the following elements:

1. An autologous tumor infiltrating lymphocyte (TIL) T cell product; and

2. A neoantigen cancer vaccine.''

The E–046–2022 patent family is primarily directed to a combination immunotherapy comprising a population of antigen-specific immune cells (*e.g.,* T cells) and a vaccine targeting the same antigen(s). In oncology, many adoptive cell therapies rely on antigen-specific T cells isolated from the patient in need of treatment. However, these cells often exist in a terminally differentiated and exhausted state and are unable to mount a robust immune response following reinfusion. Recent evidence suggests that administration of a vaccine in parallel with the T cell product can ameliorate this performance defect when the vaccine targets antigen(s) recognized by the T cells. This two-part approach may enhance treatment efficacy.

It is noted that the exclusive field of use which may be granted to Iovance applies to only certain autologous T cell products and vaccination strategies and does not include, for example, any non-TIL-based applications. Accordingly, the scope of rights which may be conveyed under the proposed license

covers a portion of the possible applications of E–046–2022.

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 from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 25, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–28081 Filed 11–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) publishes a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the **Federal Register** during the first week of each month, in accordance with section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and section 9.17 of the Mandatory Guidelines using Oral Fluid. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list.*

HHS separately notifies Federal agencies of the laboratories and IITFs currently certified to meet the standards of the Mandatory Guidelines using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70768).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020, and subsequently revised in the **Federal Register** on October 12, 2023 (88 FR 70814).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved to Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid effective October 10, 2023 (88 FR 70814), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare *, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories).

HHS-Certified Laboratories Approved to Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine effective February 1, 2024 (88 FR 70768), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823. (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)