COVID–19 Conduct guidance. FDA's revisions include broadening the guidance's scope to apply during disasters and PHEs, removing several outdated questions, clarifying recommendations regarding use of risk-based approaches for monitoring clinical investigations, clarifying recommendations concerning charging for investigational products, and making other editorial changes to improve clarity and consistency.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (21 CFR 10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because disasters and PHEs may occur without notice and, as we have learned from experience during the COVID–19 PHE, may rapidly cause major disruptions to clinical trial conduct. It is thus important to public health to provide guidance on approaches to assure the safety of trial participants and minimize risks to trial integrity during such major disruptions. Moreover, portions of the guidance reflect a less burdensome approach that is consistent with public health and that can be used during a disaster or PHE when appropriate. Interested parties had an opportunity to comment on the recommendations in the COVID–19 Conduct guidance, and FDA considered those comments when revising the guidance to apply those recommendations to disasters and public health emergencies more broadly. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(D)).

The guidance represents the current thinking of FDA on ''Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 320 have been approved under OMB control number 0910–0630; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20474 Filed 9–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered T Cell Therapies for the Treatment of HPV-Positive Cancer(s)

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 Scarlet TCR, Inc. (''Scarlet''), presently headquartered in Kingston, New Jersey.

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 October 6, 2023 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. 62/004,335 filed May 29, 2014, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–US–01];

2. PCT Patent Application No. PCT/US2015/033129 filed May 29, 2015, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–PCT–02];

3. Australian Patent No. 2015266818 issued January 16, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–AU–03];

4. Brazilian Patent Application No. BR112016027805–4 effective filing date of May 29, 2015, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–BR–04];

5. Canadian Patent Application No. 2,950,192 effective filing date of May 29, 2015, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–CA–05];

6. Chinese Patent No. ZL201580031789.X issued May 4, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–CN–06];

7. European Patent No. 3149031 issued December 18, 2019, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–EP–07];

a. Validated in: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM and TR.

8. Israeli Patent No. 248797 issued September 1, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–IL–08];

9. Japanese Patent No. 6742991 issued August 19, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–JP–09];

10. Korean Patent No. 10–2445667 issued September 16, 2022, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–KR–10];

11. Mexican Patent No. 375379 issued September 25, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–MX–11];

12. Saudi Arabian Patent No. 7456 issued January 5, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–SA–12];

13. United States Patent No. 10,174,098 issued January 8, 2019, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–US–13];

14. Hong Kong Patent No. HK1236203 issued January 8, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–HK–14];

15. United States Patent No. 10,870,687 issued December 22, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–US–15];

16. European Patent Application No. 19217074.4 filed December 17, 2019, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–EP–16];

17. Australian Patent No. 2019283892 issued May 13, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–AU–17];

18. Japanese Patent No. 6997267 issued December 20, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–JP–53];

19. Saudi Arabian Patent Application No. 520412601 filed August 10, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–SA–54];

20. Hong Kong Patent Application No. 42020020661.3 filed November 24, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–HK–55];

21. Mexican Patent Application No. MX/a/2020/010035 filed September 24, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–MX–56];

22. United States Patent No. 11,434,272 issued September 6, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–US–57];

23. Australian Patent No. 2021202227 issued February 23, 2023, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–AU–58];

24. Chinese Patent Application No. 20210399056.9 filed April 14, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–CN–59];

25. Israeli Patent No. 282518 issued July 2, 2022, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–IL–60];

26. Hong Kong Patent Application No. 42022046605.6 filed January 19, 2022, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–HK–62];

27. Japanese Patent No. 7291196 issued June 6, 2023, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–JP–63];

28. Israeli Patent Application No. 290655 filed February 16, 2022, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–IL–64];

29. United States Patent Application No. 17/816,496 filed August 1, 2022, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–US–65];

30. Korean Patent Application No. 2022–7032043 filed September 15, 2022, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–KR–66];

31. Australian Patent Application No. 2023200608 filed February 6, 2023, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–AU–01]; and

32. Japanese Patent Application No. 2023–091878 filed June 2, 2023, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–JP–01].

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 autologous T cell therapy products that are genetically engineered to have stable expression of a T cell receptor (TCR) targeting human papillomavirus (''HPV'')–16 E7, as claimed in the Licensed Patent Rights, for the treatment of HPV-associated cancers and premalignant conditions in humans.''

The E–176–2014 patent family is primarily directed to an isolated TCR reactive to HPV 16 E7 antigen in the context of HLA–A*02. HPV describes a group of human viruses known to cause malignancy. Of the group, HPV–16 is the most prevalent strain. Approximately 90% of adults are estimated to have been exposed at some point in their lifetime. HPV drives transformation of infected cells through the expression of certain oncoproteins, chiefly E5, E6 and E7. The latter two are constitutively expressed in malignant cells and are necessary to maintain a transformed state, rendering them useful therapeutic targets.

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: September 18, 2023.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2023–20487 Filed 9–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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