www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On August 13, 2025, the Committee will discuss a new indication for use for dermal filler devices in the décolletage area and will make recommendations regarding risks associated with new indications for use such as in the décolletage area, the potential impact of filler material on imaging studies and clinical exams (*e.g.,* breast cancer screening), pre-market and post-market study assessments for benefit and risk, removal of dermal filler implant material, and patient preference.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference and/or video conferencing meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.html.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before July 23, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled on August 13, 2025, between approximately 11:30 a.m. and 12:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 14, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 15, 2025.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343. FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: June 27, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12421 Filed 7–2–25; 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: The Development of an *in vivo* Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment or Prevention of B Cell Mediated Autoimmune Diseases

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 applications listed in the Supplementary Information section of this notice to Capstan Therapeutics, Inc. (Capstan), a company located in San Diego, California, the United States of America.

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 July 18, 2025 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Abritee Dhal, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276–6154; Email: *abritee.dhal@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application 62/006,313 (HHS Reference E–042–2014–0–US–01), filed 2 June 2014;
2. PCT Application PCT/US2015/033473 (HHS Reference E–042–2014–0–PCT–02), filed 1 June 2015;
3. Australian Patent 2015270912 (HHS Reference E–042–2014–0–AU–03), issued 17 December 2020;
4. Canadian Patent Application 2951045 (HHS Reference E–042–2014–0–CA–04), filed 1 June 2015;
5. Chinese Patent ZL201580033802.5 (HHS Reference E–042–2014–0–CN–05), issued 31 August 2021;
6. European Patent 3149044 (HHS Reference E–042–2014–0–EP–06), issued 21 October 2020 and validated in the following jurisdictions:
   a. Germany (HHS Reference E–042–2014–0–DE–19);
   b. Spain (HHS Reference E–042–2014–0–ES–20);
   c. France (HHS Reference E–042–2014–0–FR–21);
   d. The United Kingdom (HHS Reference E–042–2014–0–GB–22);
   e. Italy (HHS Reference E–042–2014–0–IT–23); and
   f. Ireland (HHS Reference E–042–2014–0–IE–24);
7. Israeli Patent 249305 (HHS Reference E–042–2014–0–IL–07), issued 1 October 2021;
8. Indian Patent 406961 (HHS Reference E–042–2014–0–IN–08), filed 19 May 2022;
9. Japanese Patent 6797693 (HHS Reference E–042–2014–0–JP–09), issued 20 November 2020;
10. South Korean Patent 2016–7036828 (HHS Reference E–042–2014–0–KR–10), issued 20 May 2024;
11. Mexican Patent 383150 (HHS Reference E–042–2014–0–MX–11), issued 3 June 2021;
12. New Zealand Patent 727167 (HHS Reference E–042–2014–0–NZ–12), issued 8 October 2024;

13. Saudi Arabian Patent 8651 (HHS Reference E–042–2014–0–SA–13), issued 15 September 2021;
14. Singapore Patent 11201609960Q (HHS Reference E–042–2014–0–SG–14), issued 28 September 2021;
15. United States Patent 10,287,350 (HHS Reference E–042–2014–0–US–15), issued 14 May 2019;
16. Hong Kong Patent HK 1234420 (HHS Reference E–042–2014–0–HK–16), issued 4 June 2021;
17. United States Patent 11,236,161 (HHS Reference E–042–2014–0–US–17), issued 1 February 2022;
18. New Zealand Patent 764530 (HHS Reference E–042–2014–0–NZ–18), issued 8 October 2024;
19. European Patent Application 20197459.9 (HHS Reference E–042–2014–0–EP–25), filed 22 September 2020;
20. Australian Patent 2020267211 (HHS Reference E–042–2014–0–AU–26), issued 15 August 2024;
21. Japanese Patent 7004470 (HHS Reference E–042–2014–0–JP–27), issued 6 January 2022;
22. Mexican Patent Application MX/a/2021/006239 (HHS Reference E–042–2014–0–MX–28), filed 27 May 2021;
23. Israeli Patent 283423 (HHS Reference E–042–2014–0–IL–29), issued 2 July 2022;
24. Hong Kong Patent Application 42021038427.7 (HHS Reference E–042–2014–0–HK–30), filed 8 September 2021;
25. United States Patent Application 17/557,845 (HHS Reference E–042–2014–0–US–31), filed 21 December 2021;
26. Japanese Patent 7485650 (HHS Reference E–042–2014–0–JP–32), issued 6 January 2022;
27. United States Patent Application 17/696,249 (HHS Reference E–042–2014–0–US–33), filed 16 March 2022;
28. Israeli Patent Application 291292 (HHS Reference E–042–2014–0–IL–34), filed 13 March 2022;
29. Indian Patent Application 202248047256 (HHS Reference E–042–2014–0–IN–35), filed 19 August 2022;
30. South Korean Patent Application 10–2024–7016401 (HHS Reference E–042–2014–0–KR–01), filed 17 May 2024;
31. Japanese Patent Application 2024–074954 (HHS Reference E–042–2014–0–JP–01), filed 2 May 2024; and
32. Australian Patent Application 2024205043 (HHS Reference E–042–2014–0–AU–01), filed 24 July 2024.

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 the following:

''The commercial development, production, and sale of a T cell-directed, non-viral, synthetic nanoparticle-based system comprised of lipids, polymers and/or lipopolymers that encapsulates an mRNA that encodes a chimeric antigen receptor (CAR) that binds to CD19 via the CDR polypeptide sequences of the anti-CD19 antibody known as Hu19, for the treatment or prevention of B cell mediated autoimmune diseases.

The following are specifically excluded from the Licensed Field of Use:

(1) anti-CD19 targeting CAR-based immunotherapy using CRISPR/Cas9-edited allogeneic (where donor and recipient are different) T lymphocytes.

(2) the development of CAR-expressing cells generated ex vivo (both autologous and allogeneic cell therapies).

(3) viral-based nucleic acid systems or viral vectors to express the CAR.''

This technology discloses the development of chimeric antigen receptors that recognize the CD19 cell surface protein. CD19 is expressed primarily on B cells, including autoreactive B cells which drive the development of autoimmune disorders such as System Lupus Erythematosus, Immune-mediated myositis, and Antisynthestase Syndrome. For many autoimmune diseases there are no FDA-approved therapies, underscoring that there is an unmet need. The development of a new anti-CD19 CAR-based therapy can potentially meet the needs of patients that currently do not have any treatment options.

The scope of exclusivity for this license will be limited to the development of a specific class of molecules (CARs) which use a specific binding domain (Hu19), wherein the CARs are transfected via a specific methodology (non-viral transfection, *in vivo*) into specific types of cells (T cells). The scope is further limited for autoimmune diseases. Other fields of use will still be available if this license is granted, including use of Natural Killer cells instead of T cells to express the CAR product.

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.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. 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.

Dated: June 30, 2025.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2025–12409 Filed 7–2–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM).

SACATM is a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations. SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM.

This meeting will be held as a virtual meeting and open to the public. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below. TTY users should contact the Federal TTY Relay Service at 800–877–8339. All requests should be made at