



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Collaboration for Phase 3 Study

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention described below will be a first-in-class, reversible, hormonal contraceptive method for males and is co-owned by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health, and The Population Council, Inc., a New York not-for-profit corporation based in New York City (“Population Council”). The co-owners will complete the Phase 2b clinical stage of development in 2024 and are seeking a licensee and investor/collaborator for the Phase 3 clinical stage, anticipated to begin as early as 2024.

ADDRESSES: Inquiries relating to this licensing and collaboration opportunity should be directed to: Heather Gunas, JD, MPH, Senior Technology Transfer Manager, National Cancer Institute (NCI) Technology Transfer Center, 9609 Medical Center Drive, Room 1E446, Rockville, MD 20850 (*for overnight mail*) or Bethesda, MD 20892 (*for regular mail*), Telephone: (240) 276-5530; Facsimile: (240) 276-5504; E-mail: gunash@mail.nih.gov. A Confidential Disclosure Agreement will be required to receive copies of unpublished information regarding this invention.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are available for licensing: PCT Application No. PCT/US23/21154, filed May 5, 2023, and entitled “Progestin/Testosterone Transdermal Gel”. Government rights to this invention are consolidated to Population Council under an active Interinstitutional-Agreement Institution Lead. The invention

pertains to a combination of progestin and testosterone in a transdermal composition for use as male contraception. The transdermal gel is applied daily to the shoulders and upper arms, has had a low incidence of adverse events in early clinical trials, and its sperm suppression is reversible. There is currently no available highly effective reversible method of male contraception; the methods of condom and withdrawal are not highly effective, and vasectomy is not always reversible.

NICHD's Contraceptive Clinical Trials Network is currently conducting the Phase 2b clinical study, which will complete in 2024. The Phase 2b study had favorable interim results and high acceptability with subjects; some subjects requested to re-enroll or participate in a later phase trial. The co-owners are planning the Phase 3 stage and will finalize the protocol design in conjunction with a licensee and after Food and Drug Administration (FDA) feedback. A licensee and commercial collaborator for Phase 3 is desired -- the license will be established with Population Council as the technology lead, and if the NICHD Contraceptive Clinical Trials Network conducts the Phase 3 clinical program or a portion of it, the licensee would collaborate with NICHD under a Cooperative Research and Development Agreement (CRADA) to facilitate funding and conduct of the study.

The licensee needs the capacity to file and maintain an NDA (New Drug Application) with the US FDA and take responsibility for sales, marketing, and distribution of the approved product in the US and other territories to be determined.

Achieving expeditious commercialization of federally funded research and development is consistent with the goals of the Bayh-Dole Act, codified as 35 USC §200-212.

Potential Commercial Application: male contraceptive

Development Stage: Phase 2b study completes in 2024; Phase 3 study starts in 2024+

Dated: July 7, 2023.

Richard U. Rodriguez,

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[FR Doc. 2023-14761 Filed: 7/11/2023 8:45 am; Publication Date: 7/12/2023]