

NEWS RELEASE

Contraline & Population Council Announce Option-to-License Agreement for a Revolutionary Male Contraceptive

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Contraline is poised to advance the NES/T Gel, a groundbreaking late-stage male contraceptive

CHARLOTTESVILLE, Va.--(BUSINESS WIRE)-- Contraline, Inc., a clinical-stage biotechnology company, proudly announces the signing of an exclusive option-to-license agreement with the Population Council for the Nestorone/Testosterone Transdermal Gel (NES/T) for male contraception. Upon exercising the option, Contraline will spearhead the global development and commercialization of NES/T, positioning Contraline as the world's preeminent biotechnology company in male contraception. Contraline's pipeline now includes two revolutionary, clinical-stage, investigational male contraceptives: NES/T, a daily-use topical gel, and ADAM™, an implantable, reversible device.

Illustration of NES/T. Credit: Population Council

NES/T is an investigational short-acting, transdermal, and

reversible hormonal contraceptive, developed by the Population Council and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the US National Institutes of Health. The NES/T gel, containing Nestorone® (segesterone acetate) and testosterone, is formulated for men to apply daily to their shoulders to decrease sperm production. Over 750 men have been dosed with NES/T across Phase 1 and 2 clinical trials, with preliminary data suggesting NES/T has the potential to be a highly effective male contraceptive with an acceptable side-effect profile.

Globally, nearly 50 percent of all pregnancies are unplanned, amounting to over 120 million unintended

pregnancies each year.^{1,2} Beyond condoms and vasectomy, men lack reliable and acceptable contraceptive options. Market research estimates that 15-17 million men in the United States would use novel male contraceptives.^{3,4}

"Since founding Contraline in 2015, our vision has been to pioneer new male contraceptives and establish the industry from the ground up. With no new male contraceptives introduced since the vasectomy in 1897, our products, NES/T and ADAM™, have the potential to change the paradigm by providing men with reliable, reversible, and appealing options. Our goal is to offer a 'toolbox' of choices to fit each individual's lifestyle. This partnership with the Population Council and NICHD marks a major leap forward in our mission to transform global contraceptive solutions and promote reproductive equality," said Kevin Eisenfrats, CEO and Founder of Contraline.

"Contraline is a leader in the male contraceptive field, making them a natural potential partner for the NES/T gel," said Jim Sailer, Executive Director of the Population Council Center for Biomedical Research. "Contraline's goal to offer new methods of male contraception fits with our mission to provide women and men more contraceptive options."

This announcement comes as NES/T is completing a Phase 2b trial, enrolling over 460 couples across 17 global sites to assess safety and contraceptive efficacy (pregnancy prevention).⁵ Upon exercising the option and an end-of-Phase 2 meeting with the FDA, Contraline will launch a Phase 3 program for NES/T. This would be the first Phase 3 trial conducted in the United States for a novel male contraceptive drug product, marking a significant milestone in the field.

"The acceptability of NES/T in the Phase 2b trial was very high," said Regine Sitruk-Ware, MD, distinguished scientist at the Population Council and co-director of the Phase 2b trial. "Men in the trial were asking when the method will be available or whether they could re-enroll in the study to continue using the gel. Their female partners indicated that this method was much better than the female oral contraceptive pill."

"We believe NES/T can be a game-changer, with the potential to offer a novel male contraceptive option that provides a comparable pregnancy prevention rate as some of the most widely used female contraceptives today. We commend the Population Council and NICHD for their 20 years of dedication to developing NES/T," said Dr. Alexander Pastuszak, Chief Medical Officer of Contraline.

Contraline is dedicated to transforming the contraception industry by providing men with diverse, effective, and reversible contraceptive choices that enhance reproductive freedom and responsibility.

Disclaimer ADAM™

ADAM™ is an investigational device and is not yet authorized by the U.S. Food and Drug Administration (FDA) or any

other regulatory authority worldwide. As such, ADAM™ is not available for commercial use at this time and it is currently available only for investigational use in approved clinical trials.

Disclaimer NES/T

The NES/T gel is a US. FDA-Regulated Investigational Drug Product not yet authorized by the US FDA or any other regulatory authority worldwide. It is currently available only for investigational use in approved clinical trials.

About Contraline, Inc.

Contraline, Inc. is a venture-backed, clinical-stage, biotechnology company focused on innovation in reproductive health. The company's mission is to develop novel male contraceptives that are safe, effective, appealing, and reversible. Visit www.contraline.com

About the Population Council

The Population Council confronts critical health and development issues - from stopping the spread of HIV to improving reproductive health and ensuring that young people lead full and productive lives. Through biomedical, social science, and public health research in 50 countries, they work with partners to deliver solutions that lead to more effective policies, programs, and technologies that improve lives around the world. Over 170 million women around the world use contraceptives developed by the Population Council. Established in 1952 and headquartered in New York, the Council is a nongovernmental, nonprofit organization governed by an international board of trustees. Visit: www.popcouncil.org .

References

- 1 <https://www.guttmacher.org/fact-sheet/induced-abortion-worldwide>
- 2 <https://www.guttmacher.org/report/adding-it-up-investing-in-sexual-reproductive-health-2019>
- 3 <https://www.sciencedirect.com/science/article/pii/S001078242400101X>
- 4 https://www.malecontraceptive.org/uploads/1/3/1/9/131958006/mci_consumerresearchstudy.pdf
- 5 <https://clinicaltrials.gov/study/NCT03452111>

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