Contraline Announces 24-Month Safety and Efficacy Results from First-in-Human Trial of ADAM™

CHARLOTTESVILLE, VA, UNITED STATES, April 24, 2025 /EINPresswire.com/ -- Contraline, a clinical-stage male contraception company, today announced that participants in the First-in-Human clinical trial of ADAM™ ("The ADAM Study") have reached a critical milestone, demonstrating both safety and efficacy at the 24-month mark.

ADAM™ is a water-soluble, biocompatible hydrogel implanted in the vas deferens to block sperm transport, leading to azoospermia (absence of sperm in the ejaculate). By offering a long-lasting yet reversible alternative to condoms and vasectomy, ADAM™ represents a potential breakthrough in male contraceptive options.

In The ADAM Study, two participants are the first to reach azoospermia at 24 months (from an average baseline sperm concentration of 81.5 million/mL), highlighting the product's long-term contraceptive potential. Additional participants remain in the trial, with ongoing efficacy observed at 12, 15, 18, and 21 months, measured by lab-based semen analysis and at-home sperm testing.

No treatment-related serious adverse events (SAEs) have been reported. All observed adverse events were consistent with the expected treatment profile (similar to no-scalpel vasectomy), and there were no unexpected safety concerns. These outcomes emphasize ADAM's safety and tolerability as a male contraceptive. Additional data from The ADAM Study will be presented at the American Urological Association (AUA) meeting on April 26th, 2025 (PD06-02).

"Our goal was to create a male contraceptive option lasting two years, responding directly to consumer needs," said Dr. Alexander Pastuszak, Contraline's Chief Medical Officer. "These findings confirm that ADAM, our novel water-soluble hydrogel, can achieve the intended lifespan. We remain optimistic about its safety, efficacy, and reversibility, and its potential to give

men and couples greater reproductive control."

Contraline also announced that it has received full regulatory approval to initiate its Phase 2 (Early Feasibility) clinical study in Australia, set to begin in Q3 2025. This approval marks a major milestone in the development of long-lasting, reversible male contraceptives, paving the way for accelerated progress and global momentum toward much-needed innovation in reproductive health. The upcoming study will build on the promising safety and feasibility results from the First-in-Human trial, further establishing Contraline as a leader in male contraception.

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.

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

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