



REPRONOVO ANNOUNCES FIRST PARTICIPANT INCLUDED IN U.S. PHASE 2 TRIAL OF RPN-001 FOR MALE INFERTILITY

- RPN-001 is a novel orally administered aromatase inhibitor being developed for the treatment of infertility in men with low serum testosterone
- No FDA-approved oral therapies currently exist for this underserved population

Lausanne, Switzerland and Copenhagen, Denmark, July 1, 2025 - ReproNovo, a company dedicated to developing innovative treatments for reproductive medicine and women's health, today announced that the first participant has been included in the company's Phase 2 clinical trial of its lead candidate RPN-001 (leflutrozole), an orally administered aromatase inhibitor in development for the treatment of male infertility

(<https://clinicaltrials.gov/study/NCT06993155?term=Leflutrozole&rank=1>).

The randomized, placebo-controlled trial is evaluating the safety and efficacy of three dose levels of RPN-001 in men with low testosterone and impaired semen quality. The study plans to enroll approximately 200 men across multiple clinical sites in the U.S.

"Initiating this Phase 2 study marks a significant milestone in our efforts to bring forward new solutions for the many couples affected by male-factor infertility," said **Jean Duvall, Chief Executive Officer of ReproNovo**. "Low testosterone levels are becoming more prevalent, even in younger men, highlighting the urgent demand for new treatments. Our goal is to develop a targeted, well-tolerated therapy that expands options for men and reduce the burden on female partners."

Male-factor infertility is implicated in up to half of infertility cases worldwide. Currently, no FDA-approved oral therapies exist for men with this diagnosis. RPN-001 is the first candidate in its class developed specifically for this indication and has demonstrated a promising profile in early clinical studies. RPN-001 is being studied to show improvements in testicular function and promotion of sperm production (spermatogenesis).

"RPN-001 has the potential to offer clinicians a new way to increase the amount of functional sperm available for fertility treatments based on a well-understood biological pathway," said **Joan-Carles Arce, MD, PhD, Chief Scientific and Medical Officer of ReproNovo**. "With this Phase 2 study now underway, we are taking the next step toward addressing a clear and growing unmet need in reproductive medicine."

This milestone builds on momentum from ReproNovo's recent \$65 million Series A financing to advance its multiple Phase 2 clinical programs in reproductive medicine and women's health.

ABOUT REPRONOVO:

ReproNovo is a cutting-edge biopharmaceutical company developing innovative solutions to address critical gaps in reproductive medicine and women's health. Our team is composed of proven experts with deep experience in reproductive medicine, drug development, regulatory affairs and business development who have throughout their careers successfully brought multiple therapies to market. Lead clinical compound, RPN-001 (leflutrozole), is being developed to treat male infertility. RPN-002 (nolasiban) is a first-in-disease and first-in-class molecular entity being developed to manage adenomyosis and increase the probability of



embryo implantation in women undergoing assisted reproductive technology (ART) treatments. Both assets are Phase 2 ready. ReproNovo is financed by Jeito Capital, AXA IM Alts, founding investor M Ventures, Ysios Capital and ALSA Ventures. Headquartered in Lausanne, Switzerland, the company has its primary development team in Copenhagen, Denmark, and an additional development site in Barcelona, Spain. For more information, visit the Company's website at www.repronovo.com or follow us on [LinkedIn](#).

ABOUT RPN-001 (leflutrozolet):

RPN-001 is a novel orally administered compound being developed for the treatment of infertility in men with low serum testosterone. The small molecule inhibits the enzyme aromatase, suppressing testosterone conversion to estradiol, thereby normalizing testosterone levels. Low testosterone levels are becoming more prevalent, even in younger men, highlighting the urgent demand for new treatments. ReproNovo has an exclusive global license agreement with Mereo BioPharma for the development and commercialization of leflutrozolet.

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