

Enteris BioPharma Supports Endometriosis Awareness Month

Enteris' lead program, Ovarest®, is designed to address a key endometriosis patient need by enabling the oral delivery of leuprolide

Boonton, NJ - March 5, 2019 - [Enteris BioPharma, Inc.](#), a biotechnology company developing innovative drug products built around its proprietary oral peptide delivery technologies, announced its support for Endometriosis Awareness Month, designated as the month of March. Recognizing the work that is being done by nearly a dozen U.S. organizations and associations to raise awareness of endometriosis, Enteris joins with these groups in exploring patient treatment options to help relieve symptoms and find a cure for this debilitating disease.

According to recent reports, more than six million women in the United States suffer from endometriosis. With limited approved therapeutic options to treat the discomfort and pain, the most effective approved treatment option for endometriosis entail GnRH agonists, with leuprolide being the most widely used agent in this class of drug.

Leuprolide, while effective, has significant limitations in both convenience and tolerability, which are largely attributable to its depot injection delivery method (Lupron Depot®). Utilizing its proprietary [Peptelligence®](#) technology, Enteris is developing an oral tablet formulation of leuprolide called [Ovarest®](#) that offers the convenience of a pill, while addressing the significant limitations in convenience and tolerability attributable to the depot injection delivery method. Data from the most recent Phase 2a clinical study indicated that Ovarest enabled significant suppression of estradiol (E2), demonstrating a measurable pharmacodynamic effect that is tightly correlated with efficacy in endometriosis.

“Endometriosis remains an underserved market due to the challenges women face with currently-approved injectable treatments,” said Joel Tune, CEO and Executive Chairman of Enteris BioPharma. “We believe that Ovarest has the potential to meet a critical patient need by enabling leuprolide to be delivered as an oral tablet instead of a depot injection. With the added flexibility of daily oral dosing and rapid reversibility, we believe more patients could benefit from this drug, and we are looking forward to advancing Ovarest® into a Phase 2b trial.”

About Endometriosis

Endometriosis is an estrogen-dependent, chronic, inflammatory disease characterized by the appearance and growth of endometrial cells or tissues in locations outside the uterus. Sources suggest endometriosis affects millions of women in the United States, with the vast majority of patients remaining undertreated due to the limitations of current options. There is no cure for endometriosis, and the associated pain is currently managed with oral contraceptives, progestins, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and GnRH agonists of which Lupron Depot® is the standard of care.

About Ovarest®

Ovarest®, an oral formulation of leuprolide for the treatment of endometriosis, leverages Enteris' proprietary Peptelligence® technology, which the company uses to develop innovative oral drug formulations for clients in addition to advancing its own internal product pipeline of oral tablet reformulations of drug products that address significant treatment opportunities.

[Positive results from their most recent Phase 2a clinical trial](#), indicate that the optimized formulation and dose achieved estradiol suppression in line with Lupron Depot®, the current standard-of-care injectable formulation, as well as other pharmaceutical products with proven efficacy in the treatment of endometriosis. All subjects met the estradiol suppression target (estradiol \leq 40 pg/mL) during the dosing period. Based on these positive results, Enteris plans to advance Ovarest into the next stage of clinical development.

About Enteris BioPharma

Enteris BioPharma, Inc. is a privately held, New Jersey-based biotechnology company offering innovative formulation solutions utilizing its proprietary oral peptide drug delivery technology, Peptelligence®. The technology has been the subject of numerous feasibility studies and active development programs, several of which are in late stage clinical development.

Additionally, Enteris BioPharma is advancing an internal product pipeline of oral tablet reformulations of drug products that address significant treatment opportunities for which there is no oral delivery option. Enteris BioPharma's most advanced internal product candidate, Ovarest® (oral leuprolide tablet), is an oral peptide being developed for the treatment of endometriosis. [Tobrate®](#) (oral tobramycin tablet) is also being developed by Enteris BioPharma for the treatment of uncomplicated urinary tract infection (uUTI). A third internal

compound, octreotide, is currently in preclinical development. For more information on Enteris BioPharma and its proprietary oral delivery technology, please visit <https://enterisbiopharma.com>.

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