

Enteris BioPharma Presents Data from Two Clinical Studies Involving Oral Formulations of Leuprolide at ENDO 2022 Annual Conference

Data suggest that oral formulations of leuprolide developed utilizing Enteris' Peptelligence® platform successfully deliver meaningful circulating drug concentrations and achieve hormonal suppressive effects which are comparable to parenteral administration

BOONTON, N.J., June 13, 2022 /PRNewswire/ -- [Enteris BioPharma, Inc.](#), a biotechnology company developing innovative drug products based on its proprietary delivery technologies, and a wholly-owned subsidiary of SWK Holdings Corporation (Nasdaq: SWKH), announced today that two posters describing clinical studies of oral formulations of leuprolide developed utilizing Enteris' proprietary Peptelligence® platform are being presented at the annual meeting of The Endocrine Society (ENDO 2022) taking place June 11-14, 2022, in Atlanta.

Peptelligence is a novel formulation technology designed to enhance the oral delivery and bioavailability of selected drugs by enhancing the permeation of such compounds that are typically injected, including peptides and BCS class III and IV small molecules, and preventing their breakdown in the digestive tract. [Leuprolide](#) is a gonadotropin-releasing hormone analogue that is used to treat endometriosis and uterine fibroids in women, prostate cancer in men, and central precocious puberty in boys and girls.

The first poster, titled, "*Systemic Delivery of Leuprolide via Oral Administration*," details the results from a randomized, four-period, four-treatment, crossover pharmacokinetic and food effect study to determine whether Enteris' Peptelligence enteric coating and permeation enhancement is able to deliver therapeutically relevant doses of an oral formulation of leuprolide. The study assessed the PK profiles of 14 healthy female volunteers following single administrations of 1 and 4 mg of leuprolide and compared these profiles to that of a single subcutaneous injection of 1 mg of leuprolide acetate. Data from the study confirmed the successful systemic delivery of leuprolide by the oral route with measures of bioavailability and dose proportionality, as well as revealing an acceptable safety and tolerability profile.

The second poster, titled "*Effective Suppression of Gonadotropins and Gonadal Steroids Following Oral Administration of Leuprolide*," highlights the results from a study testing whether orally delivered low doses of leuprolide could achieve key pharmacodynamic measures, including suppressive effects on luteinizing hormone (LH), follicle-stimulating hormone (FSH), estradiol, and progesterone. Estradiol suppression is noted as a key indicator for effectiveness in treating hormone-dependent benign gynecologic conditions such as endometriosis. Across all measures, orally administered leuprolide effectively suppressed the gonadal steroids at levels comparable to that of a one-month depot injection of leuprolide (an active comparator in this study), as well as to an approved, marketed dose of a GnRH antagonist. Further, there were no serious or severe adverse events related to the oral formulation of leuprolide.

"We are excited to share the results of our studies at ENDO 2022. Both studies have shown positive data on key measures related to the pharmacokinetics and pharmacodynamics of our oral formulation of leuprolide," said Enteris Chief Medical Officer Dr. Gary Shangold. "This is a significant milestone in developing effective oral delivery of leuprolide and there are meaningful applications for underserved patient populations. The depot injection method requires time for its effects to reverse upon discontinuation and may be associated with tolerability issues related to the injection site. Endometriosis can result in multiple painful surgeries, and an orally delivered gonadotropin-releasing hormone (GnRH) agonist could offer significant benefits to patients."

In addition to their live presentation at the meeting on Monday June 13th, the full poster presentations will also be available in the virtual format starting on June 11, at 10:00 a.m. ET. Information about ENDO 2022 may be accessed at <https://endo2022.endocrine.org/Home>.

About Enteris BioPharma

Enteris BioPharma, Inc. is a wholly-owned subsidiary of SWK Holdings Corporation (Nasdaq: SWKH) offering total integrated contract development and manufacturing (CDMO) services including innovative formulation solutions utilizing its proprietary drug delivery technologies, Peptelligence® and ProPerma®. The technologies have been the subject of numerous feasibility studies and active development programs, several of which are in clinical development. Additionally, Enteris BioPharma is advancing an innovative internal product pipeline of drug products that address significant unmet clinical needs for which there is no satisfactory treatment option. For more information on Enteris BioPharma and its proprietary oral drug delivery technologies, please visit <http://www.EnterisBioPharma.com>.

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