Enteris BioPharma Announces Successful Completion of Phase 1 Clinical Trial of Optimized Peptelligence® Oral Leuprolide

Data indicates optimized Peptelligence oral leuprolide formulation delivers comparable or greater drug levels than subcutaneous or depot injection

BOONTON, N.J., Oct. 4, 2021 /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 the successful completion of a Phase 1 clinical trial investigating its optimized Peptelligence oral tablet formulation of leuprolide. Data from the 22-patient study indicate that the optimized Peptelligence oral formulation is able to safely deliver a higher dose of leuprolide that enables blood concentrations comparable to subcutaneous or intramuscular depot injections.

The optimized oral tablet leuprolide was developed utilizing Enteris' proprietary Peptelligence platform, a novel formulation technology that enables oral delivery of molecules that are typically injected, including peptides and BCS class II, III and IV small molecules. Drug product for the Phase 1 clinical trial was manufactured by Enteris at its state-of-the-art 32,000-square-foot manufacturing facility, which has capacity to produce clinical trial material in quantities required along the entire clinical trial spectrum, from Phase 1 to Phase 3, as well as initial commercial production.

"Based on every measure, the Phase 1 clinical trial of our optimized oral tablet leuprolide formulation was a success, and we now look forward to further developing the product to address diseases in which gonadotropin-releasing hormone (GnRH) agonists are known to provide benefit and for which an oral format can improve patient compliance," stated Rajiv Khosla, Ph.D., Chief Executive Officer of Enteris BioPharma. "Importantly, the success of this Phase 1 clinical trial clearly demonstrates Enteris' comprehensive pharmaceutical CMC and clinical development capabilities both for our internal pipeline and for our partnered programs."

"Data from this Phase 1 clinical trial of our optimized oral tablet formulation of leuprolide demonstrate that the product can safely deliver a higher dose of leuprolide that elicits blood concentrations greater or equal to leuprolide delivered via injection," added Gary A. Shangold, M.D., Chief Medical Officer of Enteris. "We now look forward to advancing our Peptelligence-based oral leuprolide into the next round of clinical development."

The Phase 1 trial was designed as an open-label study to determine the safety and evaluate the pharmacokinetics (PK) of several dose regimens of an optimized Peptelligence oral tablet formulation of leuprolide in comparison to historical data from subcutaneous and intramuscular depot leuprolide formulations. Oral leuprolide represents Enteris' most clinically advanced internal product candidate and underscores the company's rapidly advancing clinical development pipeline targeting underserved patient populations where oral delivery can enable competitive and patient compliance advantages.

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 delivery technology, please visit http://www.EnterisBioPharma.com.

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