Enteris BioPharma's Licensing Partner, Cara Therapeutics, Announces Top Line Data from Phase 2 Trial of Peptelligence®-Engineered Oral KORSUVA™ for the Treatment of Pruritus in Patients with Advanced Chronic Kidney Disease (CKD)

Oral KORSUVA 1 mg met primary endpoint with statistically significant reduction in mean worst itching intensity NRS scores vs. placebo after 12-week treatment period (p=0.018)
Oral KORSUVA 1 mg was well-tolerated after 12 weeks of treatment

Boonton, NJ – December 6, 2019 – Enteris BioPharma, Inc., a biotechnology company developing innovative drug products built around its proprietary delivery technologies and a wholly-owned subsidiary of SWK Holdings Corporation (SWKH.OB), congratulates Cara Therapeutics on the successful completion of its Phase 2 clinical trial of Oral KORSUVA™ (CR845/difelikefalin) for the treatment of pruritus in patients with stage III-V (moderate-to-severe) chronic kidney disease (CKD).

Top line data from the Phase 2 study indicated that Oral KORSUVA 1 mg achieved the primary endpoint of statistically significant reduction in weekly mean of the daily Worst Itching Intensity Numeric Rating Scale (WI-NRS) scores vs. placebo after the 12-week treatment period (-4.4 KORSUVA vs. -3.3 placebo, p=0.018). The treatment effect was statistically significant after two weeks of treatment and sustained through the 12-week treatment period. Oral KORSUVA 1 mg was also deemed to be generally well-tolerated with a safety profile consistent with prior studies. Based on the Phase 2 results, Cara expects to initiate a Phase 3 clinical trial of Oral KORSUVA 1 mg in 2020.

The tablet formulation of Oral KORSUVA was engineered using Enteris' proprietary oral delivery technology, Peptelligence®. In August, Enteris and Cara entered into a licensing agreement for Peptelligence to advance the ongoing development of Oral KORSUVA. In addition to the CKD program, Oral KORSUVA is currently the subject of two separate, ongoing Phase 2 trials for the treatment of pruritus in patients with primary biliary cholangitis and atopic dermatitis.

"We congratulate Cara Therapeutics on the completion of its Phase 2 trial of Oral KORSUVA for the treatment of pruritis in patients with advanced CKD and are pleased to see that Oral KORSUVA 1 mg met the primary efficacy endpoint and was well-tolerated over the 12-week treatment regimen," said Brian Zietsman, President and CFO of Enteris BioPharma. "With publicly stated plans to advance Oral KORSUVA 1 mg into a Phase 3 clinical trial in 2020, we welcome the opportunity to actively support Cara as per our recently enacted licensing agreement. Cara is an important partner for Enteris, and the continued success of its Oral KORSUVA program highlights the significant potential of Peptelligence to enable safe and efficacious oral delivery of peptides and other molecules with low oral bioavailability."

About Enteris BioPharma

Enteris BioPharma, Inc. is a wholly-owned subsidiary of SWK Holdings Corporation (SWKH.OB) offering innovative formulation solutions utilizing its proprietary 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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Announces-Top-Line-Data-from-Phase-2-Trial-of-Peptelligence-R-Engineered-Oral-KORSUVA-TM-for-the-Treatment-of-Pruritus-in-Patients-with-Advanced-Chronic-Kidney-Disease-CKD