Oral KORSUVA™ in Phase 2 Trial for Pruritus Treatment

Enteris BioPharma's "Feasibility-to-Licensing" Partner, Cara Therapeutics, Initiates Second Pruritus Phase 2 Trial of Peptelligence®-Engineered Oral KORSUVA™
Study evaluating Oral KORSUVA (CR845/difelikefalin) for the treatment of pruritus in patients with primary biliary cholangitis (PBC)
Oral KORSUVA is also the subject of a separate, ongoing Phase 2 trial for the treatment of pruritus in stage III-V chronic kidney disease (CKD)

Boonton, NJ – June 27, 2019 – Enteris BioPharma, Inc. a biotechnology company developing innovative drug products built around its proprietary oral peptide delivery technologies, congratulates Cara Therapeutics (Nasdaq: CARA) on the successful initiation of its Phase 2 clinical trial of Oral KORSUVA™ (CR845/difelikefalin) for the treatment of pruritus in patients with hepatic impairment due to primary biliary cholangitis (PBC). The tablet formulation of Oral KORSUVA was engineered using Enteris' proprietary oral peptide delivery technology, Peptelligence®.

The Oral KORSUVA Phase 2 initiation in pruritis associated with PBC follows a Phase 1 trial in patients with hepatic impairment, which successfully established the Oral KORSUVA tablet strength. Building upon that study, the Phase 2 trial is a multicenter, randomized, double-blind, placebo-controlled 16-week trial designed to evaluate the safety and efficacy of 1 mg tablet of Oral KORSUVA taken twice daily (BID) versus placebo in approximately 60 patients with PBC and moderate-to-severe pruritus. The primary efficacy endpoint is the change from baseline in the weekly mean of the daily 24-hour Worst Itch Numeric Rating Scale (WI-NRS) score at Week 16 of the treatment period. Oral KORSUVA is currently the subject of a separate Phase 2 clinical trial for the treatment of pruritus in stage III-V chronic kidney disease (CKD).

The oral tablet formulation of CR845/difelikefalin was developed in accordance with a Manufacturing and Clinical Supply Agreement whereby Enteris utilized its Peptelligence technology to enable the active ingredient, which was initially formulated for I.V. or injection administration, to be delivered orally. Under the terms of the "Feasibility-to-Licensing" program, Enteris will continue to manufacture the oral tablet formulation of CR845/difelikefalin for current and potential future studies through Phase 2 that Cara Therapeutics elects to pursue. Cara Therapeutics has the opportunity to negotiate a Phase 3/commercial license to the Peptelligence technology for oral CR845/difelikefalin from Enteris at any time.

"We congratulate Cara Therapeutics on advancing Oral KORSUVA into a second pruritus Phase 2 clinical trial. This is another significant milestone for Cara and highlights the important, ongoing relationship between Cara and Enteris," said Joel Tune, chief executive officer and executive chairman of Enteris BioPharma. "With Cara now actively evaluating Oral KORSUVA in two separate Phase 2 clinical trials, while we advance our own Phase 2 program for Ovarest™ in endometriosis, evidence continues to mount suggesting that Peptelligence has the potential to enable the oral delivery of peptide therapeutics across multiple drug compounds and disease indications."

"We are pleased with our ongoing work with Enteris and are excited to advance a second Oral KORSUVA program in a pruritis setting into Phase 2," stated Derek Chalmers, Ph.D., D.Sc., president and chief executive officer of Cara Therapeutics. "Pruritus continues to be a significant comorbidity in patients with chronic cholestatic liver diseases and may be exacerbated by certain bile acid-related drugs. We believe that Oral KORSUVA may provide a potential new, first-in-class therapeutic approach to treat this unmet clinical need."

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors (KORs). Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In a Phase 3 trial and Phase 2 trials, KORSUVA Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP), and is currently being investigated in additional Phase 3 trials in hemodialysis patients with CKD-aP.

About Enteris BioPharma

Enteris BioPharma, Inc. is a privately held, New Jersey-based biotechnology company offering innovative formulation solutions utilizing its proprietary oral drug 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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