Oral KORSUVA™ in Phase 2 Clinical Trial for Atopic Dermatitis

Enteris BioPharma's "Feasibility-to-Licensing" Partner, Cara Therapeutics, Initiates Phase 2 Trial of Peptelligence®-Engineered Oral KORSUVA™ for Pruritus in Patients with Atopic Dermatitis
Oral KORSUVA is now the subject of three separate, ongoing Phase 2 clinical trials

Boonton, NJ – July 11, 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 atopic dermatitis (AD). The tablet formulation of Oral KORSUVA, which was engineered using Enteris' proprietary oral peptide delivery technology, Peptelligence®, is now the subject of three separate, pruritus-focused Phase 2 clinical trials.

The Oral KORSUVA Phase 2 clinical trial in pruritus associated with AD is a multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of Oral KORSUVA for moderate-to-severe pruritus in approximately 240 adult subjects with AD. Subjects will be randomized to three tablet strengths of Oral KORSUVA: 0.25 mg, 0.5 mg and 1 mg taken twice daily (BID) vs. placebo for 12 weeks followed by a 4-week active extension phase. The primary efficacy endpoint is the change from baseline in the weekly mean of the daily 24-hour Itch Numeric Rating Scale (I-NRS) score at Week 12 of the treatment period. Cara is also investigating Oral KORSUVA in two additional Phase 2 clinical trials for the treatment of pruritus in patients with hepatic impairment due to primary biliary cholangitis (PBC) and pruritus in patients with stage III-V chronic kidney disease (CKD).

"We commend Cara Therapeutics on the continued expansion of its Oral KORSUVA pipeline, which now boasts three ongoing Phase 2 clinical trials in separate pruritus indications. There is much to be excited about in the potential of Oral KORSUVA, and we welcome the opportunity to continue our successful work with Cara to advance these important studies," said Joel Tune, chief executive officer and executive chairman of Enteris BioPharma. "Given the convenience and marketability of an orally administered tablet in comparison to an injection, the ability of our Peptelligence® platform to enable the oral delivery of peptide therapeutics, such as CR845/difelikefalin, is a potential game-changer for numerous drugs in development and on the market. Cara's recent successes, alongside the advancement of our internal pipeline, highlighted by Ovarest®, epitomize this vast potential."

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 as needed by Cara's development plans. 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 are excited to initiate this latest Phase 2 trial of Oral KORSUVA and the opportunity to extend our work with Enteris to the development of a potential novel oral therapeutic option for the treatment of pruritus in patients with AD," stated Derek Chalmers, Ph.D., D.Sc., president and chief executive officer of Cara Therapeutics. "Pruritus affects nearly all atopic dermatitis patients, significantly impacting patients' quality of life, including sleep disruption, altered eating habits, anxiety and depression. Like our other pruritus programs, 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 both Phase 3 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). KORSUVA Injection is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Oral KORSUVA is currently in Phase 2 trials for the treatment of pruritus in patients with CKD, as well as in patients with primary biliary cholangitis (PBC).

The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory

authority.

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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