New Licensing Agreement for Oral KORSUVA™ with Peptelligence®

Enteris BioPharma and Cara Therapeutics Enter into Licensing Agreement for Peptelligence® to Advance Development of Oral KORSUVA™
Deal Showcases the Potential of Peptelligence® as the "Gold Standard" Technology for Developing Oral Formulations of Peptide-Based Drugs
Oral KORSUVA™ is Currently the Subject of Three Separate Phase 2 Clinical Trials for Differing Indications of Pruritus

Boonton, NJ – August 21, 2019 – Enteris BioPharma, Inc., a biotechnology company developing innovative drug products built around its proprietary oral peptide delivery technologies, today announced its entry into a definitive licensing agreement with Cara Therapeutics (Nasdaq: CARA) for Enteris' Peptelligence® technology in the ongoing development of an oral formulation of Cara's first-in-class KOR agonist, CR845/difelikefalin (KORSUVA™). Peptelligence® is Enteris' proprietary platform for the oral delivery of peptides and BCS class II, III and IV small molecules.

The oral tablet formulation of KORSUVA™ (Oral KORSUVA™) was engineered using Peptelligence®. Oral KORSUVA™ is currently the subject of three separate Phase 2 clinical trials for pruritus in patients with hepatic impairment due to primary biliary cholangitis (PBC), stage III-V chronic kidney disease (CKD), and atopic dermatitis (AD). The agreement announced today will allow Cara to continue its Oral KORSUVA™ programs into Phase 3 and beyond.

Under the terms of the deal, Enteris granted to Cara Therapeutics a non-exclusive, royalty-bearing license to the Peptelligence® technology to develop, manufacture and commercialize Oral KORSUVA™ worldwide, excluding Japan and South Korea. In exchange, Enteris will receive an upfront payment equal to $8 million, with 50% payable in cash and 50% payable in shares of Cara's common stock. Cara is also obligated to pay Enteris milestone payments upon the achievement of certain development, regulatory and commercial milestones and low-single digit royalties based on net sales in the licensed territory. Cara retains the right to buy-out the royalty obligation for a period of two years under prespecified conditions.

"This is a watershed moment for Enteris and our Peptelligence® platform, and we greatly welcome the opportunity to deepen our relationship with Cara Therapeutics in the ongoing development of its Oral Korsuva™ pipeline," said Joel Tune, CEO of Enteris BioPharma. "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 peptide and small molecule-based drugs in development and on the market given the convenience and marketability of an orally administered tablet in comparison to an injection. With Cara now actively evaluating Oral KORSUVA™ in three separate Phase 2 clinical trials for differing pruritus indications, evidence continues to mount suggesting that Peptelligence® not only offers the ability to maximize the performance and patient-acceptance of peptide therapeutics, but that entire franchises could be developed around our technology."

"We are pleased to formalize our ongoing work with Enteris and look forward to the continued advance of our Oral KORSUVA™ program, which now includes three Phase 2 clinical trials in pruritus settings," stated Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "Effective treatment of pruritus remains a significant unmet need in patients with atopic dermatitis, liver disease and chronic kidney disease, adding to their discomfort and seriously impacting patients' quality of life, including sleep disruption, altered eating habits, anxiety and depression. We believe that KORSUVA may provide a potential, first-in-class therapeutic to treat pruritus across clinical populations, and the ability to deliver it via an oral tablet formulation expands patient accessibility to the benefits of the product, if approved."

About Enteris BioPharma

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

For Enteris BioPharma: Enteris Media Relations:

Brian Zietsman, President & CFO
+1.973.453.3527

Jason Rando
Tiberend Strategic Advisors, Inc.
+1.212.375.2665
jrando@tiberend.com

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