

## **Enteris BioPharma Highlights 2019 Achievements and 2020 Outlook**

### **A transformational 2019 positions Enteris to capitalize on potential of Peptelligence®**

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- Acquired by SWK Holdings Corporation; Now Operating as a Wholly Owned Subsidiary Focused on Advancement of Peptelligence-Driven External Partnerships and Internal Drug Development Pipeline
- Entered into Licensing Agreement with Cara Therapeutics for Peptelligence to Advance Development of Oral KORSUVA™
  - Oral KORSUVA Currently the Subject of Three Separate, Ongoing Clinical Programs Focused on Distinct Pruritis Indications
  - Phase 2 Clinical Trial of Oral KORSUVA for Treatment of Pruritis in Patients with Advanced Chronic Kidney Disease Met Primary Efficacy Endpoint (1 mg dose); Cara Therapeutics Expects Phase 3 Trial to Begin in 2020
- Initiated Expansion of Manufacturing Facility to Enable Phase 3 and Commercial Scale Production
  - Phase 3 Manufacturing Upgrade Expected to be Completed in Q2 2020

[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), provided a review of its 2019 key business achievements and development activities as the company anticipates multiple growth opportunities during 2020 involving its industry-leading Peptelligence® oral peptide delivery technology.

"The past year has been transformative for Enteris as we completed two transactions – the acquisition by SWK Holdings and the licensing agreement with Cara Therapeutics – which, combined, served to demonstrate the significant business and development potential of our Peptelligence platform, while providing a springboard for growth during 2020 and beyond," said Brian Zietsman, President and CFO of Enteris BioPharma. "Since our founding in 2013, Enteris has established itself as *the* industry leader in enabling the safe and efficacious oral delivery of peptides and other molecules with low oral bioavailability. Our accomplishments in 2019 will enable us to maximize this very sizable opportunity through the advancement of new and existing external development agreements, as well as our own internal development pipeline."

### **Acquisition by SWK Holdings**

The signature event for Enteris in 2019 was its acquisition by SWK Holdings in August. Per the terms of the agreement, Enteris now operates as a wholly owned subsidiary of SWK and continues to be led by its existing management team. As a result, Enteris is now able to focus on the advancement of the external partnerships built around Peptelligence, as well as its internal 505(b)(2) drug development pipeline, both of which have the potential to deliver lucrative near- and longer-term licensing opportunities. Moreover, SWK, through its specialty financing activities, has the ability to introduce Enteris to companies that could benefit from its ability to develop oral formulations of peptide and small molecule therapeutics.

Mr. Zietsman continued, "With SWK as our parent company, we are on sounder operational and financial footing and enjoy greater agility to pursue value-creating opportunities as we expand our external partnerships and advance our internal R&D pipeline. Additionally, SWK is fueling an expansion of our manufacturing capabilities to enable Enteris to produce compounds for Phase 3 clinical trials and beyond to commercialization. Based on our estimates, we expect to have the capabilities in place for Phase 3 manufacturing in the second half of 2020. This is an important growth opportunity for Enteris, not only for our existing partners but in our efforts to secure new, high-value relationships."

### **Cara Therapeutics Licensing Agreement and Oral KORSUVA Phase 2 Trial Results**

Shortly before its acquisition by SWK, Enteris announced the entry into a definitive licensing agreement with Cara Therapeutics for Peptelligence in the ongoing development of an oral formulation of Cara's first-in-class KOR agonist, CR845/difelikefalin (Oral KORSUVA). Under the terms of the deal, Enteris granted to Cara Therapeutics a non-exclusive, royalty-bearing license to Peptelligence to develop, manufacture and commercialize Oral KORSUVA worldwide, excluding Japan and South Korea. In exchange, Enteris received an upfront payment equal to \$8 million.

Oral KORSUVA is currently the subject of three separate clinical programs for pruritus in patients with stage III-V chronic kidney disease (CKD), hepatic impairment due to primary biliary cholangitis (PBC), and atopic dermatitis

(AD). In December, Cara announced the successful completion of its Phase 2 clinical trial of Oral KORSUVA for the treatment of pruritus in patients with advanced CKD. Top line data from the Phase 2 study indicated that Oral KORSUVA 1 mg achieved the primary efficacy endpoint and that the drug was generally safe and well-tolerated. Based on these results, Cara expects to initiate a Phase 3 clinical trial of Oral KORSUVA 1 mg in 2020.

Mr. Zietsman continued, "The licensing agreement with Cara was a watershed moment for Enteris as it showcased our ability to monetize our Peptelligence platform via the development of oral peptide formulations for partner companies. This is a cornerstone of Enteris' business strategy, and we expect the success of Cara, including the positive Phase 2 clinical trial of Oral KORSUVA, to incentivize other companies to entrust their peptide therapeutics with us. We are excited by Cara's progress with Oral KORSUVA and look forward to the initiation of the Phase 3 clinical trial in 2020, per Cara's estimates, as well as the advancement of the two additional Oral KORSUVA Phase 2 programs."

### **Foreseeing Multiple Growth Drivers in 2020 and Beyond**

Zietsman concluded, "We expect 2020 to build on the momentum from 2019 with multiple business drivers anticipated during the year, including progress with our external partners as well as our internal pipeline, led by Ovarest® and Tobrate®. Our ability to develop oral tablet formulations of peptides and other molecules with low oral bioavailability offers boundless opportunities for growth, and it is our intent, with the support of SWK, to maximize this potential to the fullest."

### **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 <http://www.EnterisBioPharma.com>.

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