

## **Enteris BioPharma Highlights 2020 Achievements and 2021 Outlook**

### **Enteris poised to capitalize on multiple value building opportunities involving Peptelligence® and ProPerma™ platforms**

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- Rajiv Khosla, Ph.D., named Chief Executive Officer
- Gary A. Shangold, M.D., appointed Chief Medical Officer
- Received two milestone payments totaling \$5 million from Cara Therapeutics per licensing agreement for Peptelligence to advance development of Oral KORSUVA™
  - Additional potential milestone payments expected over the next several quarters, subject to the achievement of certain development milestones for Oral KORSUVA
  - Oral KORSUVA currently the subject of three separate, ongoing clinical programs focused on distinct pruritis indications
- Expansion of manufacturing facility to enable Phase 3 and small volume commercial scale production, including dedicated containment for High Potency Active Pharmaceutical Ingredients (HPAPIs), is expected to be operational within the first few months of 2021

[Enteris BioPharma, Inc.](#), a biotechnology company developing innovative drug products based on its proprietary delivery technologies, and a wholly-owned subsidiary of SWK Holdings Corporation (Nasdaq: SWKH), provided a review of its 2020 business achievements and development activities as the company anticipates growth opportunities during 2021 involving its industry-leading Peptelligence® and ProPerma™ oral peptide and small molecule delivery technologies, and extensive pharmaceutical expertise.

"2020 was a year unlike any in recent times with the COVID-19 pandemic impacting all aspects of business and society. Despite the challenges, Enteris persevered, and we are now positioned for a variety of growth opportunities built around our transformative oral delivery technologies, Peptelligence and ProPerma," said Rajiv Khosla, Ph.D., Chief Executive Officer of Enteris. "Key to our success in 2020, and our ongoing optimism, is the strong, collaborative relationship between Enteris and SWK Holdings. With SWK's support, we have enacted and are beginning to see the results of a multi-pronged strategy to establish Enteris as *the* industry leader in enabling the safe and efficacious oral delivery of peptides and other molecules with low oral bioavailability. The foundation we built in 2020, including a reconstitution of our senior leadership, will enable us to maximize this very sizable opportunity through the advancement of external development agreements, our own internal development pipeline, and implementation of our manufacturing capability."

### **Executive Appointments - New Chief Executive Officer and Chief Medical Officer**

During 2020, Enteris significantly enhanced the company's executive leadership with the appointment of Dr. Khosla as Chief Executive Officer and Gary A. Shangold, M.D., as Chief Medical Officer. Collectively, Drs. Khosla and Shangold bring more than 60 years' industry experience to Enteris with expertise in business development, intellectual property monetization, drug development, regulatory relations and product commercialization. Importantly, both executives possess a deep knowledge of several drug delivery systems technologies, which will be critical to Enteris as the company seeks to capture more value-creating opportunities and maximize the potential of its comprehensive pharmaceutical proficiency.

Dr. Khosla continued, "Since being appointed CEO in May 2020, I have worked closely with Enteris' leadership, including Gary Shangold, and the SWK team to implement several measures focused on strengthening the company's internal and external operations. Namely, we have initiated an aggressive business development and marketing program designed to identify and secure potential licensing opportunities with pharmaceutical companies seeking to develop orally delivered versions of their peptide and small molecule products. We have made significant inroads with several companies, which we will continue to advance during 2021."

"Additionally, under the direction of our Chief Operating Officer, Paul Shields, Enteris has completed the physical construction of our expanded manufacturing facility. We now have the ability to produce clinical trial material (CTM) through to Phase 3, including dedicated containment for HPAPIs. Having a manufacturing facility of this sophistication is an important growth opportunity for Enteris, not only for our existing partners, but also in our efforts to secure new, high-value relationships. Remarkably, Paul and his team were able to advance the construction of this facility on schedule despite disruptions caused by COVID-19."

### **Cara Therapeutics Milestone Payments and Oral KORSUVA Clinical Advancements**

Enteris advanced its work with Cara Therapeutics per the definitive licensing agreement for Peptelligence in the

ongoing development of an oral formulation of Cara's first-in-class KOR agonist, CR845/difelikefalin (Oral KORSUVA). During the fourth quarter of 2020, Enteris received two separate milestone payments from Cara totaling \$5 million. Enteris is eligible to receive additional potential milestone payments, subject to the achievement of certain development milestones for Oral KORSUVA in 2021.

Oral KORSUVA is currently the subject of three separate late-stage 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). Previously, Cara announced positive top-line results from its Phase 2 clinical trial of Oral KORSUVA for the treatment of pruritus in patients with stage III-IV (moderate-to-severe) chronic kidney disease. Since then, Cara announced it intends to complete an End of Phase 2 Meeting with the FDA in the first quarter of 2021. Separately, Cara announced that it has completed full enrollment of its KARE Phase 2 dose-ranging clinical trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in atopic dermatitis patients.

Dr. Khosla continued, "The licensing agreement with Cara is an important value driver for Enteris as it showcases our ability to monetize our Peptelligence and ProPerma platforms via the development of oral formulations for partner companies. Additionally, the comprehensive nature of the collaboration, has clearly demonstrated the depth and breadth of pharmaceutical expertise at Enteris, including analytical method development, GMP manufacture, and novel formulation development.

### **Foreseeing Multiple Growth Drivers in 2021 and Beyond**

Dr. Khosla concluded, "We expect 2021, subject to any COVID-19 constraints, to be a positive year for Enteris, with the continued support of SWK, as we implement several initiatives started in 2020, and which have positioned us very well for our future growth. We will advance our activities to secure partnerships with pharmaceutical and biotech companies to develop oral tablet formulations of molecules with low oral bioavailability utilizing our novel technology. In addition, we will actively pursue partnership discussions with companies seeking US domestic CDMO capabilities, such as manufacture of clinical trials material (CTM), formulation development, and analytical method development, including for HPAPIs."

### **About Enteris BioPharma**

Enteris BioPharma, Inc. is a wholly-owned subsidiary of SWK Holdings Corporation (Nasdaq: SWKH) offering innovative formulation solutions utilizing its proprietary drug delivery technologies, Peptelligence® and ProPerma™. The technologies have 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 endocrine disorders. 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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For further information: For Enteris BioPharma: Amos J. Sanchez, Director, Business Development and Partnering, +1.973.453.3518; Enteris Media Relations: Jason Rando, Tiberend Strategic Advisors, Inc., +1.212.375.2665, [jrando@tiberend.com](mailto:jrando@tiberend.com)

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