Enteris BioPharma Highlights 2021 Achievements and 2022 Outlook

Enteris continues to capitalize on multiple value building opportunities involving Peptelligence® and ProPerma® platforms

-- Received two milestone payments totaling $15 million from Cara Therapeutics per license agreement for Peptelligence® to advance development of Oral KORSUVA™

-- Oral KORSUVA currently the subject of four late-stage clinical programs focused on distinct pruritis indications

-- Launched expanded manufacturing facility and CMO business in May 2021

-- New manufacturing capabilities allow for the manufacture of clinical trial material (CTM) for all phases of clinical development and small volume commercial-scale production, including a dedicated containment for High Potency Active Pharmaceutical Ingredients (HPAPIs)

-- Successful completion of Phase 1 clinical trial of optimized Peptelligence® oral tablet formulation of leuprolide

BOONTON, N.J., Jan. 5, 2022 /PRNewswire/ -- 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 2021 business achievements and development activities as the company anticipates growth opportunities during 2022 involving its industry-leading Peptelligence® and ProPerma® oral peptide and small molecule delivery technologies, and extensive pharmaceutical expertise.

"2021 marked a year of important achievements for Enteris, highlighted by the significant expansion of our suite of manufacturing, formulation and development services and important advancements with our external and internal development programs built around our transformative oral delivery technologies, Peptelligence and ProPerma," said Rajiv Khosla, Ph.D., Chief Executive Officer of Enteris. "We enter 2022 well positioned to continue executing on our multi-prong strategy to build Enteris into *the* partner of choice for developing oral BCS-III and BCS-IV drug products, including oral peptides, peptidomimetics, and small molecules. We expect to advance several of our proprietary CDMO partnerships and our internal development programs and harness our CMO manufacturing capabilities to expand our reach within the pharmaceutical industry."

Expanded Manufacturing Capabilities Provide Firm Foundation for Enhanced CDMO Services and Launch of CMO Operations

During 2021, Enteris announced the expansion of its Boonton, NJ manufacturing facility and the expansion of its proprietary CDMO business segment, which provides custom solutions for the formulation, development and manufacturing of solid oral doses for difficult to formulate BCS III and IV compounds, including peptides and highly potent compounds. In addition, Enteris now provides CMO services that includes the manufacture, testing and release of Phase 1 to Phase 3 clinical trial supplies, and commercial production at a 32,000-square-foot facility that includes 6,000 square feet of cleanroom space with approximately 2,500 square feet dedicated to the containment and processing of high potency API (HPAPI).

Dr. Khosla continued, "The expansion of our manufacturing facility and the launch of our CMO operations marked a major milestone for Enteris and plays a vital role in our business development activities. Having a manufacturing facility of this sophistication allows Enteris to deepen our existing manufacturing partnerships by providing custom solutions from bench to market and also secure new, high-value relationships. Whether a company requires proof of concept regarding our proprietary development of its peptide or small molecule for oral tablet delivery and subsequently harnesses our CDMO expertise for the development and manufacture of their pharmaceutical product, including HPAPI, Enteris possesses the technologies and capabilities necessary for a successful outcome."

Dr. Khosla added, "We believe that market conditions will drive a sharp increase in demand for U.S.-based CMOs with the ability to handle complex manufacturing needs for specialty pharmaceutical and biotechnology companies. The disruption brought on by COVID-19, which is continuing as we speak, has highlighted the need to return more of the industry's manufacturing and supply chain to domestic shores and reduce the overreliance on overseas markets for key starting materials, intermediates and APIs needed to produce drugs, as well as the actual manufacturing of medications prescribed to millions of Americans."

Cara Therapeutics' Oral KORSUVA™ Advancements Highlight Potential of Enteris' "Oral Feasibility" Program

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™). In June and December 2021, Enteris announced the receipt of two separate milestone payments

from Cara totaling $15 million. Enteris is eligible to receive additional potential milestone payments, subject to the achievement of certain development milestones for Oral KORSUVA, of which Enteris will retain half.

Cara's Oral KORSUVA program is currently the subject of four separate late-stage clinical trials for pruritus in patients with hepatic impairment due to primary biliary cholangitis (PBC), stage III-V non-dialysis dependent (NDD) chronic kidney disease (CKD), atopic dermatitis (AD) and notalgia paresthetica.

Dr. Khosla continued, "The milestone payments we received from Cara in 2021 provide further confirmation of the considerable value Enteris derives from our collaboration with Cara in its Oral KORSUVA program. Since its inception, the licensing agreement with Cara has provided a revenue source and a showcase for the potential of the Peptelligence and ProPerma platforms."

Dr. Khosla added, "Moreover, the success of Oral KORSUVA provides undeniable validation of our oral feasibility program. During this process, Enteris partners with companies to conduct initial proof-of-concept research to determine the potential of developing Peptelligence and ProPerma oral tablet formulations. We provide clients with optimized tablet prototypes, specifically tailored to the client's API, which are evaluated in preclinical PK studies. If successful, we then enter a licensing agreement, which allows Enteris to recoup the initial feasibility expenses via the achievement of certain development milestones, as is the case now with Cara. During 2021, we initiated six oral feasibility programs, and we anticipate several of these transitioning to partnering agreements in the near future."

Internal Development Pipeline Advances

In September 2021, Enteris announced the successful completion of a 22-patient Phase 1 clinical trial investigating its optimized Peptelligence oral tablet formulation of leuprolide. Data from the study indicated that the optimized Peptelligence oral formulation is able to safely deliver a higher dose of leuprolide that enables blood concentrations comparable to subcutaneous or intramuscular depot injections. The optimized oral tablet leuprolide was developed utilizing Enteris' proprietary Peptelligence platform, and drug product for the trial was manufactured by Enteris at its state-of-the-art manufacturing facility.

"The success of the Phase 1 clinical trial provides further validation of the potential of our Peptelligence platform and optimized oral tablet formulation of leuprolide," stated Dr. Khosla. "Oral leuprolide represents Enteris' most clinically advanced internal product candidate and underscores our rapidly advancing clinical development pipeline targeting underserved patient populations where oral delivery can improve market potential and provide patient compliance advantages. We look forward to advancing the product into the next round of clinical development and exploring its potential to address diseases in which gonadotropin-releasing hormone (GnRH) agonists are known to provide benefit."

Foreseeing Multiple Growth Drivers in 2022 and Beyond

Dr. Khosla concluded, "As we look back on what we achieved in 2021 and consider what we can achieve in 2022, we anticipate a year of continued growth for Enteris. We are confident that we can build on the momentum of the past year by advancing our internal development programs and furthering our efforts to secure new partnerships and deepen our existing relationships with pharmaceutical and biotech companies to develop oral tablet formulations of molecules with low oral bioavailability utilizing our novel technology. In addition, we will continue to pursue partnership discussions with companies seeking domestic CMO capabilities, such as the manufacture of clinical trial material (CTM), 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 total integrated contract development and manufacturing (CDMO) services including 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 clinical development. Additionally, Enteris BioPharma is advancing an innovative internal product pipeline of drug products that address significant unmet clinical needs for which there is no satisfactory treatment option. For more information on Enteris BioPharma and its proprietary oral drug delivery technologies, please visit http://www.EnterisBioPharma.com.

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