Enteris BioPharma Publishes White Paper on Best Practices for Ensuring Content Uniformity in Solid Oral Dosage Manufacturing with HPAPI

Paper examines barriers to achieving optimal content uniformity with HPAPIs and the techniques manufacturers should use with low-dose drug products

BOONTON, N.J., March 7, 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), announced today the publication of a new white paper entitled, "HPAPI Drug Solid Oral Dosage (SOD) Manufacturing – Ensuring Content Uniformity."

The paper, co-authored by Thomas Daggs, Vice President of Product Development & Quality Control, and Angelo Consalvo, Director of Manufacturing, Enteris BioPharma, provides insight into the variables that impact content uniformity with high potency active pharmaceutical ingredients (HPAPIs), the benefits of dry production techniques over wet granulation when manufacturing HPAPI tablets, and the criteria drugmakers should consider when selecting a contract development and manufacturing organization (CDMO). The whitepaper is available to download via *Drug Development & Delivery* at https://drug-dev.com/whitepapers/white-paper-hpapi-drug-solid-oral-dosage-sod-manufacturing-ensuring-content-uniformity/

"The HPAPI market is a growing and increasingly important segment of the overall pharmaceutical industry that could, by 2026, generate sales that exceed $32 billion," stated Paul Shields, Ph.D., Chief Operating Officer for Enteris. "These are medicines that are more potent than a traditional pharmaceutical agent but use a fraction of the drug substance, thereby lowering the cost of goods. Despite the benefits that HPAPIs offer, manufacturing comes with considerable challenges, chief among them ensuring content uniformity, and often require specialized formulating technologies. Drugmakers are increasingly looking to outsource this work to CDMOs, but it is imperative that any prospective manufacturing partner is equipped to work with such challenging APIs, including both the expertise and tools to ensure safe, efficient, and precise production. This is especially the case when developing solid oral dosage (SOD) forms containing HPAPIs."

Dr. Shields continued, "Enteris BioPharma completed the renovation of its Boonton, NJ manufacturing plant, which now encompasses a 32,000-square-foot, state-of-the-art facility with multiple suites dedicated to HPAPI handling/containment and SOD manufacturing. This technical capacity is complemented by our experience and knowledge working with HPAPIs and low-dose formulations to achieve excellent content uniformity. We are excited to share our knowledge in this white paper and welcome the opportunity to work with both large pharmaceutical companies and smaller biotechs to service their HPAPI needs."

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 for innovative formulation solutions utilizing its proprietary drug delivery technologies, Peptelligence® and ProPerma®, and contract manufacturing (CMO) services using non-proprietary technologies. The company's proprietary technologies have been the subject of numerous feasibility studies and active development programs, some 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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