Enteris BioPharma Publishes Article Examining the Growing Utilization of the 505(b)(2) Regulatory Pathway in Drug Development

Paper Discusses the 505(b)(2) Pathway as a Vehicle for Innovation and Product Differentiation

BOONTON, N.J., Nov. 17, 2021 /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 article entitled, "The 505(b)(2) Pathway – Pharma's 'Goldilocks' Opportunity."

The article, authored by Gary Shangold, M.D., Chief Medical Officer of Enteris, is available through *Pharma Tech Outlook*; it provides insight into the growing utilization of the 505(b)(2) regulatory pathway by the biopharmaceutical industry and important issues drug makers face when considering whether to leverage the approval process, including potential market size, possible patent issues and how to demonstrate that the product brings added value by addressing an unmet medical need. Enacted as part of the 1984 Drug Price Competition and Patent Restoration Act (also known as the Hatch-Waxman Act), the 505(b)(2) pathway allows drug makers to introduce meaningful improvements to established drugs. It encourages innovation in drug development without requiring duplicative studies to demonstrate what is already known about a drug, while respecting the patent and exclusivity rights for the original approved drug.

"The 505(b)(2) regulatory pathway provides an appealing middle ground for drug developers – a time- and cost-efficient route to drug approval that fosters and rewards innovation and offers the potential to deliver to the market differentiated products with significant commercial value," stated Dr. Shangold. "By utilizing this process, the pharmaceutical industry has seen significant growth in innovative drug technologies, such as Enteris' Peptelligence® and ProPerma™, that enable the development of products that distinguish themselves by improving upon one or more attributes of the original innovator drug. By doing so, companies can expand the potential market and ideally provide better treatments to the patients who need these drugs, by addressing needs which remain unmet by the original products on which they are based. We are excited to share our knowledge in this article and welcome the chance to help both large pharmaceutical companies and smaller biotechs capitalize on the opportunity to introduce novel products that can extend the lifecycle of a drug already on the market or enhance the potential of a promising technology in development."

The article is available to view at https://drug-discovery-and-development.pharmatechoutlook.com/vendor/the-505b2-pathway-pharma-s--goldilocks--opportunity-cid-1597-mid-95.html .

About Gary A. Shangold
Dr. Shangold is Enteris BioPharma's Chief Medical Officer, joining the Company in January 2020. He brings more than 30 years of pharmaceutical industry and consulting experience in clinical research and regulatory affairs. He received a B.A. in Social Behavior from the University of Pennsylvania, and an M.D. from the Columbia University College of Physicians and Surgeons.

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.

SOURCE Enteris BioPharma, Inc.

For further information: For Enteris BioPharma: Kalpana Ramakrishnan, Ph.D., Manager, Business Development, +1.862.261.9125; Enteris Media Relations: Jason Rando, Tiberend Strategic Advisors, Inc., +1.212.375.2665, jrando@tiberend.com

---