

WuXi STA's Integrated CMC Platform Supports InnoCare Orelabrutinib Approved by NMPA

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STA Pharmaceutical, a WuXi AppTec Company (WuXi STA), announces their partner InnoCare has received approval by the National Medical Products Administration of China (NMPA) for Orelabrutinib. Under the Marketing Authorization Holder (MAH) policy, WuXi STA provided an integrated and end-to-end support including drug substance, amorphous solid dispersion, tablet and packaging for this product. Just a couple months ago, with four WuXi STA's sites inspected at the same time, WuXi STA successfully passed the pre-approval inspection (PAI) for Orelabrutinib from NMPA.

From September 15 to October 3 in 2020, this comprehensive 18-day PAI involved four WuXi STA's sites in China spanning drug substance manufacturing (Shanghai Jinshan), amorphous solid dispersions manufacturing using spray dried dispersion (SDD) (Changzhou), tablet manufacturing (Wuxi city), and drug substance process R&D, drug product R&D and clinical materials manufacturing (Shanghai Waigaoqiao). All of them successfully passed the inspection without major observations and key observations. As a critical success factor, WuXi STA's integrated quality system across all sites ensured streamlined process and efficient collaboration among different functional teams in different locations.

The success of this PAI also demonstrated a new high for WuXi STA's drug product platform. In the year of 2020 alone, the drug product platform had delivered over 1,200 clinical batches to the global customers. The NDA approval for Orelabrutinib once again proved its comprehensive capability from technology to quality. As a key technology of WuXi STA's bioavailability enhancing technology platform, SDD platform provides an end-to-end solution from preclinical R&D in tens of milligram scale to commercial manufacturing in metric ton scale, and now successfully supported Orelabrutinib launch.

InnoCare co-founder, chairman, and CEO Dr. Jasmine Cui said: "We are excited that Orelabrutinib was approved by NMPA. As our important partner of this innovative drug, WuXi STA has provided CMC support from clinical trials to commercialization, and successfully passed PAI for Orelabrutinib. We look forward to working with WuXi STA to address more unmet medical needs."

Dr. Minzhang Chen, CEO of WuXi STA, commented: “We sincerely congratulate our partner InnoCare on the approval of Orelabrutinib. The successful PAI is the result of close team collaboration between WuXi STA and our partner InnoCare. We will continue to leverage our industry-leading technical capabilities, along with our end-to-end CMC platform to empower our partners to accelerate their pathway to market for the benefit of global patients.”

About InnoCare

InnoCare Pharma is a leading biopharmaceutical company committed to the discovery, development, and commercialization of first-in-class and/or best-in-class drugs for the treatment of cancer and autoimmune diseases. We strategically focus on lymphoma, solid tumors, and autoimmune diseases with highly unmet medical needs in China and worldwide. InnoCare has branches in Beijing, Nanjing, Shanghai, Guangzhou, New Jersey, and Boston.

About WuXi STA

STA Pharmaceutical Co., Ltd., a subsidiary of WuXi AppTec (WuXi STA), is a leading pharmaceutical development and manufacturing capability and technology platform company serving the life sciences industry, with operations in China and the United States. As a premier Contract Development and Manufacturing Organization (CDMO), WuXi STA offers our worldwide partners efficient, flexible, and high-quality solutions for integrated CMC (Chemical, Manufacturing, and Control) solutions from preclinical to commercial uses. For more information, please visit: <http://www.STApharma.com> and follow us on [LinkedIn](#).