WuXi STA Passes the First U.S. FDA Drug Product Pre-Approval Inspection at its Shanghai Waigaoqiao site

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WuXi STA – a subsidiary of WuXi AppTec, announced that its Waigaoqiao site in Shanghai, China, successfully passed the first drug product pre-approval inspection (PAI) by the US FDA.

During the 5-day inspection from Oct. 22 - 26, 2021, the FDA inspector conducted a comprehensive onsite assessment including manufacturing facility and equipment, laboratories, quality management system, tablet production, material handling, computer control systems, and data integrity. Within the same week, the site also successfully passed two additional drug product PAIs by the China NMPA for two innovative drugs from its partners. Three successful drug product PAIs during one single week is a testimony to WuXi STA's robust and reliable quality system.

WuXi STA's drug product services at the Shanghai Waigaoqiao site include solid-state development, pre-formulation, formulation development, and clinical to commercial manufacturing for a broad range of oral dosage forms.

WuXi STA has passed over 40 inspections from all major regulatory agencies including US FDA, EMA, China NMPA and Japan PMDA. All eight sites across North America, Europe and Asia, follow the same quality system ensuring high-quality products manufactured for its partners worldwide. To date, WuXi STA has supported 34 new drug approvals globally. Products manufactured by WuXi STA have been launched in 105 countries around the world.

Dr. Minzhang Chen, Co-CEO of WuXi AppTec and CEO of WuXi STA, commented: "I am very pleased that our drug product platform in Waigaoqiao has successfully passed its first PAI by the US FDA. It is another milestone that the site starts to provide commercial drug product manufacturing services to the US market. With our industry-leading global CMC platform and proven quality system, we strive to empower more partners to accelerate their innovative medicines to market for patients worldwide."