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WuXi STA's Jinshan site passes fourth U.S. FDA inspection

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STA Pharmaceutical Co., Ltd., (WuXi STA), a subsidiary of WuXi AppTec, announces that its Active Pharmaceutical Ingredient (API) manufacturing facility at Jinshan (Shanghai, China) has successfully passed its fourth inspection from the U.S. Food and Drug Administration (USFDA) – with no Form 483s issued. The site previously passed three FDA inspections in 2013, 2014 and 2016.

WuXi STA is the first CDMO in China that is approved to supply commercial APIs for innovative drugs by regulatory agencies in the USA, China, EU, Canada, Switzerland, Australia, and New Zealand. The Jinshan site – opened in 2004 – is equipped with 100+ modern reactors ranging from 5L to 20,000L, as well as industry-leading technology platforms such as flow chemistry, biocatalysis and high potency APIs. The Jinshan facility is dedicated to the manufacture of small molecule innovative APIs and advanced intermediates, from kilo to metric ton scale – from preclinical and clinical development through to global commercial launch. In addition, WuXi STA recently initiated the site expansion project in Jinshan, adding more than 30,000 square meters of laboratory space and 500 scientists. Upon completion, the expanded Jinshan campus will be able to offer an integrated one-site solution for process development and manufacturing of innovative APIs and advanced intermediates, further strengthening WuXi STA’s global leading platform focusing on small molecule innovative drug process development and manufacturing.

“We are very proud of successfully passing the FDA inspection once more.” commented Ms. Mei Hao, Vice President of Quality at WuXi STA, “Quality is ingrained throughout our culture and, whilst fully expected, further demonstrates our commitment to customers and patients worldwide.”

Dr. Minzhang Chen, CEO of WuXi STA commented, “It is an integral part of the company’s culture to exceed global standards. We will continue to put quality first for all of our worldwide partners and offer them integrated efficient and flexible solutions, accelerating the process of new drug launches.”