BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

WuXi STA opens oligonucleotide large-scale manufacturing facility

January 3, 2020 | News

State-of-the-art facility expands WuXi STA's capacity and capability for this novel modality, providing a one-stop shop from preclinical to commercial



STA Pharmaceutical Co., Ltd., (WuXi STA) – a subsidiary of WuXi AppTec has announced the opening of its large-scale oligonucleotide active pharmaceutical ingredient (API) manufacturing facility in Changzhou, China. This significant milestone marks WuXi STA's establishment of a comprehensive one-stop platform to support the process R&D and manufacture of oligonucleotide APIs from preclinical to commercial. It enables customers around the world to advance promising new oligonucleotide therapies more rapidly to market for the benefit of patients.

Nucleic acid drugs have gradually become a hot area in the global innovative drug industry and many nucleic acid drugs have been approved by the U.S. FDA in recent years. To help customers accelerate new drugs to market, WuXi STA is continuously strengthening its oligonucleotide platform. The new facility, with over 30,000 square feet, is located at WuXi STA's Changzhou site. With its operation, the Changzhou site can manufacture oligonucleotide APIs up to 1 mol/synthesis run, to better meet the increasing demand of our customers.

WuXi STA's comprehensive platform covers the development and manufacturing of a variety of oligonucleotide modalities including DNA, RNA, Morpholino oligonucleotide (PMO) and peptide conjugates (PPMO). In addition, the company's industry-leading small molecule process chemistry organization adds further value in handling complex conjugation chemistry that involves oligonucleotide and other molecular modalities, as well as a combination of solid and solution phase chemistry to support next-generation oligonucleotide manufacturing technology development.

By leveraging our small-molecule CMC (Chemical, Manufacturing, and Control) technology and capability platform as well as global standard quality system, WuXi STA provides a robust one-stop shop for oligonucleotide innovators. The opening of this large scale manufacturing facility will empower more global partners to expedite the development and commercialization of oligonucleotide drugs to benefit patients worldwide," commented Dr. Minzhang Chen, CEO of WuXi STA.

WuXi STA's Changzhou site can now provide services involving small molecule, oligonucleotide and peptide process R&D and manufacturing from laboratory to commercial scales. During the past years, it has successfully passed multiple inspections from the U.S. Food and Drug Administration (FDA) and the National Medical Products Administration (NMPA), adhering to the highest regulatory standards.