

WuXi STA, Ark Biosciences sign CMC development agreement

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STA Pharmaceutical Co., Ltd., (WuXi STA), a subsidiary of WuXi AppTec, and Ark Biosciences, a global biotech company focusing on innovative drug discovery and development, especially in the area of viral infection and respiratory disease, have announced a strategic partnership for CMC (Chemistry, Manufacturing and Control) development and manufacturing.

Under the terms of the collaboration, Ark Biosciences will utilize the Marketing Authorization Holder (MAH) scheme to accelerate drug development and WuXi STA will provide an integrated solution in process R&D and manufacturing.

Ark Biosciences' pipeline includes active discovery programs of its own, those of its partners, as well as in-licensed drug assets for clinical development. Ark's leading program, a novel respiratory syncytial virus (RSV) F-protein inhibitor Ziresovir (AK0529), has completed three phase I clinical trials and is currently in global multi-center phase II clinical trial. The company also entered into a license agreement with Roche in August 2018 for the global rights of a potential new standard-of-care treatment for idiopathic pulmonary fibrosis.

WuXi STA was selected as the strategic partner thanks to its industry leading "end-to-end" CMC platform for new drug development from preclinical to commercial – for both API and finished dosage forms – as well as its expertise and track record for meeting global quality standards. The company is at the forefront of implementing China's MAH pilot program and is helping many domestic innovative drug development partners. By using WuXi STA, partners are able to optimize manufacturing processes, significantly reduce commercial production costs, mitigate business risk, and improve operational efficiency.

"We're delighted to partner with such a well-respected, world-class CDMO such as WuXi STA," said Dr. Jim Wu, CEO of Ark Biosciences. "WuXi STA's enabling end-to-end CMC platform, scale, and innovation capabilities will help us to move our drug candidates from the clinical-stage to commercialization more efficiently."

Dr. Minzhang Chen, CEO of WuXi STA, commented: "Our mission is to empower and accelerate customers to develop innovative drugs from clinical to commercial – faster and more efficiently. We are delighted to become the strategic partner of Ark Biosciences and look forward to helping them advance their drug candidates towards the clinic, bringing innovative

medicines for the benefit of patients around the world.”