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EMA completes inspection of cGMP DS and DP facilities at WuXi Biologics

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WuXi Biologics completed EMA GMP Inspection, the first biologics company in China

WuXi Biologics, a leading global open-access biologics technology platform company offering end-to-end solutions for biologics discovery, development and manufacturing, announced that the European Medicines Agency (EMA) has completed the Pre-Approval Inspection (PAI) of the company's cGMP Drug Substance (DS) and Drug Product (DP) manufacturing facilities for the production of TaiMed Biologics' Trogarzo™ with no critical findings. WuXi Biologics will submit responses to the EMA inspection report in March 2019 and expects to obtain GMP certification for its facilities in May 2019.

This is the first such inspection of its kind in China, marking yet another critical milestone for WuXi Biologics, further endorsing the quality operations and the reputation of the company as a global leading biomanufacturing player. Upon completion of this inspection, WuXi Biologics will be honored to have the first cGMP biologics DS facility, the first cGMP biologics DP facility and the first cGMP cell banking facility in China to be approved by the EMA for commercial manufacturing. The DS and DP facilities also made headlines in March 2018 for being the first in China to pass the U.S. FDA inspection enabling the facilities to supply biologics globally.