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Hutchison MediPharma receives approval of Fruquintinib capsules in China

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WuXi AppTec provided comprehensive support for the successful market launch of this innovative drug in China using its enabling platforms.

WuXi AppTec congratulates its partner Hutchison MediPharma (HMP) on receiving approval of fruquintinib capsules (Elunate) for metastatic colorectal cancer from the National Medical Products Administration of China ("NMPA") – formerly the China Food and Drug Administration. Fruquintinib is an innovative medicine that has not previously been launched in China or internationally.

The approval in China was completed using a priority review and approval process, thereby maximizing the number of potential patients who can benefit from this novel cancer treatment. This is the second innovative drug approval in China supported by WuXi STA, a subsidiary of WuXi AppTec, since the implementation of the Marketing Authorization Holder (MAH) pilot program.

Colorectal cancer is a commonly diagnosed cancer worldwide. Approximately 1.36 million new cases and nearly 700,000 deaths are reported each year globally, representing a significant global healthcare challenge. In China, the annual incidence of colorectal cancer tops 376,000 and continues to grow, and 50% of new cases will eventually develop into metastatic colorectal cancer (mCRC). VEGFR inhibitors play a pivotal role in tumor-related angiogenesis, cutting off the blood supply that a tumor needs to grow rapidly. Fruquintinib (HMPL-013) is a highly selective and potent small-molecule inhibitor of VEGFR 1, 2 and 3, providing a new therapeutic approach for metastatic colorectal cancer patients.

WuXi AppTec provided comprehensive support for the successful market launch of this innovative drug in China using its enabling platforms. WuXi STA, via its industry-leading process development and manufacturing technology platform and global standard quality system, supported the process optimization and process validation of its Active Pharmaceutical Ingredient (API), as well as the Elunate® NDA submission and approval. In June 2018, WuXi STA's Jinshan API manufacturing site passed the pre-approval inspection by NMPA as part of the Elunate ® NDA application process. WuXi STA also supported fruquintinib capsules' clinical trials in the United States. In addition, WuXi SMO, a subsidiary of WuXi AppTec, provided services from phase i to phase iii clinical research during the past six years. The entire clinical program of

this product was successfully completed, with high data quality and outstanding results obtained. Results of the phase iii study were published on the Journal of the American Medical Association (JAMA) with an impact factor of 47 points.

"We congratulate our partner Hutchison MediPharma on their tremendous achievement. This is the second innovative drug that WuXi STA provided API manufacturing for the approval and launch in China since the implementation of the Marketing Authorization Holder (MAH) pilot program." said Dr. Minzhang Chen, CEO of WuXi STA. *"The successful development of fruquintinib is further evidence of our commitment to enabling our partners with the most outstanding capabilities and cutting-edge technologies. We support them in the quest to bring better medicines to patients and strive to fulfill WuXi's dream that 'every drug can be made and every disease can be treated'."*