News Release

Junshi Biosciences Obtains NMPA's NDA Approval for anti-PD-1 Monoclonal Antibody JS001 (Toripalimab)

December 17, 2018 - Junshi Biosciences is pleased to announce that the National Medical Products Administration of China (NMPA) has conditionally granted approval for the new drug application (NDA) in respect of the Group's drug candidate, JS001, or Tuoyi (toripalimab), for use in the treatment of unresectable or metastatic melanoma that has failed previous systemic therapy.

JS001 is the first commercialized product of Junshi Biociences, and is honored to be the first anti-PD-1 monoclonal antibody injection developed by a PRC company to launch in the PRC market.

As JS001 was admitted in NMPA's fast-track regulatory review, the NDA was conditionally approved based on the completion of efficacy and safety data of a Phase II clinical trial. JS001 will be subjected to a commitment Phase III clinical trial being carried out subsequently evidencing the long-term clinical benefit of JS001 to patients in China for a full approval from the NMPA in the future.

Junshi Biosciences has also obtained from the FDA approval to conduct clinical trials in the United States for JS001 in January 2018 and the Group started Phase I clinical trial in the United States for JS001 in March 2018.

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