

**Pre-IND meeting to communicate the combination of recombinant fully human anti- PD-L1 monoclonal antibody injection ( ZKAB001 for short ) and vaccinia GM-CSF/TK inactivated virus ( Pexa-Vec , oncolytic virus)**

September 4, 2019, a pre-IND meeting to communicate the combination of recombinant fully human anti- PD-L1 monoclonal antibody injection ( ZKAB001 for short ) and vaccinia GM-CSF/TK inactivated virus ( Pexa-Vec , oncolytic virus) has been held at the Drug Evaluation Center (CDE) of NMPA. CDE representatives include Zhou Ming (Major reviewer) , Song Yuanyuan, Xia Lin, Chen Dongmei, Zhang Qian and others. Zhaoke (Guangzhou) Oncology Pharmaceutical Ltd. representatives include Benjamin Li, Michel Wong, Hande Ping, Li Yujie, Liu Jianfeng, Li Peizhi, Du Yifan.

The meeting focused on discussing the possibilities of carrying out the combination Ib / II trial of two drugs to treatment Melanoma. Introduction has been made by by Dr. Zhou Ming and Dr. Benjamin Li. Then, Michael Wong, the project lead from Zhaoke and Liu Jianfeng presented the background information of the two products the trial protocol. This was followed by a Q&A section. CDE and Zhaoke reached an agreement by the end of the meeting, This meeting provided sufficient scientific basis for the following IND application for the combination of the two drugs.

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