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Alphamab inks oncology deal with Simcere and 3D Medicines

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To Develop and Commercialize Subcutaneous Injectable anti-PD-L1 Antibody for Oncology Indications in Mainland China

Alphamab Oncology has announced that Jiangsu Alphamab Biopharmaceuticals Co., Ltd., a wholly-owned subsidiary of the Company, has established strategic partnership with Simcere and 3D Medicines (Beijing) Co., Ltd. (3DMed) to advance the development and commercialization of KN035 (also known as envafolimab), a checkpoint inhibitor for programmed cell death ligand-1 (PD-L1), for oncology indications in mainland China.

Under the terms of the agreement, Alphamab Oncology is the exclusive manufacturer of KN035 and responsible for the production and supply of KN035. 3DMed will oversee KN035's clinical development, registration and commercialization. Simcere will exclusively market KN035 in mainland China upon the product's registration, and charge a marketing fee to 3DMed.

Invented by Alphamab Oncology, KN035 is a recombinant anti-PD-L1 single domain antibody fused with human Fc. In 2016, Alphamab Oncology and 3DMed reached an agreement to co-develop KN035 which is on track to be the first subcutaneous injectable anti-PD1/PD-L1 antibody to be approved globally. Compared to other marketed PD1/PD-L1 antibodies, KN035 has demonstrated distinctive advantages in safety, convenience and patient compliance, which may further improve patients' quality of life. KN035 is undergoing clinical trials in China, the United States, and Japan for multiple cancer indications, with more than 900 patients enrolled, including a pivotal Phase II clinical trial investigating the treatment of advanced solid tumors with microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR). Additionally, KN035 is undergoing pivotal Phase III clinical trials for advanced biliary tract cancer (BTC) in China. On January 18, 2020, KN035 was granted FDA Orphan Drug Designation (ODD) for the treatment of advanced biliary tract cancer (BTC).