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ASIA EDITION

Ascentage Pharma collaborates with Junshi Bioscience for cancer therapy

09 April 2019 | News

Junshi Biosciences' self-developed toripalimab is the first anti-PD-1 monoclonal antibody marketed by a Chinese company that has been approved by China's National Medical Products Administration to be used to treat unresectable or metastatic melanoma that has failed previous systemic therapy.

Ascentage Pharma, a globally-focused, clinical-stage biotechnology company engaged in developing novel therapies for cancers, hepatitis B and age-related diseases has announced that it has entered into a strategic collaboration with Shanghai Junshi Biosciences Co., Ltd. to explore the synergies of Ascentage's Inhibitor of Apoptosis Proteins (IAP) inhibitor APG-1387, and Junshi Biosciences' anti-PD-1 therapy toripalimab in clinical trials in solid and hematological tumors in China.

APG-1387 is a novel, small molecule IAP inhibitor that induces apoptosis by mimicking the dimeric form of the SMAC protein, which is being developed to treat advanced solid tumors and chronic HBV infection. APG-1387 has completed dose-escalation Phase I trials as a single agent in solid tumors in both China and Australia. It is currently in Phase Ib trial in combination with anti-PD-1 therapy in patients with advanced solid tumors in the United States. APG-1387 is the first IAP-targeting investigational drug to enter clinical trials in China. In preclinical studies, the combination of APG-1387 and anti-PD-1 immuno-oncology therapy demonstrated strong antitumor activity, resulting in clinically relevant responses such as Complete Response (CR). These results suggest that the combination treatment may enhance the activity of PD-1 blockade therapy and warrant further investigation in humans.

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"We are delighted to be partnering with Junshi on evaluating this novel combination therapy. We are proud to be one of the first companies to bring this innovative combination therapy of an immune checkpoint inhibitor and a small molecule targeted treatment to the clinical stage of development in China," Dajun Yang, M.D., Ph.D., Chairman and CEO of Ascentage, said.

APG-1387 is a novel small molecule IAP inhibitor (Inhibitor of Apoptosis Protein), which was discovered and is being

developed by Ascentage Pharma. Ascentage is developing APG-1387 globally, and has completed dose escalation Phase I trials in advanced solid tumors in China and Australia, and a Phase I trial of APG-1387 is currently ongoing in the U.S. APG-1387 is also being investigated for the treatment of the Hepatitis B infection.

In March 2018, the New Drug Application ("NDA") for JS001, a recombinant humanized anti-PD-1 monoclonal antibody for injection, was accepted by the NMPA. On 17 December 2018, Junshi Biosciences' anti-PD-1 therapy toripalimab was conditionally granted marketing approval for use in the treatment of unresectable or metastatic melanoma that has failed previous systemic therapy by the NMPA, which is the first commercialized product of Junshi Biosciences. In the pivotal clinical trial, patients were observed with the ORR of 17.3% and the DCR of 57.5%, and the one-year overall survival rate is 69.3%. The NDA approval of toripalimab witnessed the pivotal step from pre-revenue biotech start-up to a commercial-stage biopharmaceutical company.

Ascentage Pharma is a globally-focused, clinical-stage biotechnology company engaged in developing novel therapies for cancers, hepatitis B and age-related diseases. The Company focuses on developing therapeutics that inhibit protein-protein interactions to restore apoptosis, or programmed cell death. Ascentage Pharma has built a rich pipeline of eight drug candidates in clinical development, including a novel, highly potent Bcl-2/Bcl-xL inhibitor, APG-1252, as well as candidates aimed at IAP and MDM2-p53 pathways, and next-generation tyrosine kinase inhibitors.

Junshi Biosciences was founded in December 2012 by a team graduated from renown universities in China and the United States with extensive experience in the industry and international transfer of technology.

Junshi Biosciences is mainly engaged in the research and development of therapeutic antibody. The company specializes in the R&D and industrialization of innovative monoclonal antibody drugs and other therapeutic proteins (TPs) drugs. With an impressive product pipeline including 16 innovative drugs and a biosimilar, Junshi Biosciences is the first Chinese company to have filed investigational new drug application (IND) and new drug application (NDA) for anti-PD-1 monoclonal antibody to National Medical Products Administration (NMPA). Junshi Biosciences is also the first company in China to have obtained approval for IND application for anti-PCSK9 monoclonal antibody and anti-BLyS monoclonal antibody from NMPA. Junshi Biosciences has more than 700 employees around the world, scattered in Los Angeles and Maryland in the United States, and Shanghai, Suzhou and Beijing in China.