 Approval of Phase Ib/II Clinical Trial of APG-1387 for the Treatment of Advanced Pancreatic Cancer in Combination with Chemotherapy in China

Ascentage Pharma Group International (the “Company” or “Ascentage Pharma”) announced that it has received approval from the Center of Drug Evaluation (CDE) of China National Medical Products Administration (NMPA) for the Phase Ib/II clinical trial of APG-1387, Ascentage Pharma’s novel inhibitor of apoptosis proteins (IAP) inhibitor, in combination with chemotherapy for the treatment of advanced pancreatic cancer.

APG-1387 is a novel, small molecule IAP inhibitor and also the first IAP inhibitor to enter clinical trials in China. This is a multi-center, open-label clinical trial that comprised of a Phase Ib dose-escalation study and a Phase II efficacy study, and it is designed to evaluate the safety, pharmacokinetics (PK), and preliminary efficacy of APG-1387 in combination with the nab-paclitaxel plus gemcitabine doublet chemotherapy in advanced pancreatic cancer.

APG-1387 has completed Phase I clinical trials in advanced solid tumors in China and Australia, and it was shown to be well-tolerated. The preliminary result from the ongoing Phase I trial of APG-1387 in the U.S. was presented in a poster at the 2019 Annual Meeting of American Society of Oncology (ASCO). The data demonstrated APG-1387’s promising anti-tumor activity in advanced pancreatic cancer patients who had failed multiple prior lines of treatments. Among 10 advanced pancreatic cancer patients treated with APG-1387 monotherapy, 4 patients achieved SD (stable disease), including one patient has been treated for over 9 cycles with confirmed SD.
Pancreatic cancer is a highly aggressive form of gastrointestinal cancer. With a poor prognosis and an incidence rate at par with its mortality rate, the 2015 statistics shows a five-year survival rate of just 7.2%, making pancreatic cancer the malignancy with the lowest survival rate in China. Currently, the treatment landscape for pancreatic cancer remains unchanged with very limited options. The Company will carry forward clinical trials of APG-1387, striving for providing new treatment option for pancreatic cancer patients.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: We cannot guarantee that we will be able to obtain further approval for, or ultimately market, APG-1387 successfully.

By order of the Board
Ascentage Pharma Group International
Dr. Yang Dajun
Chairman and Executive Director

Suzhou, People’s Republic of China, February 24, 2020

As at the date of this announcement, the board of Directors of the Company comprises Dr. Yang Dajun as Chairman and executive Director, Dr. Wang Shaomeng, Dr. Tian Yuan, Mr. Zhao Qun, Dr. Lu Simon Dazhong and Mr. Liu Qian as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng and Mr. Ren Wei as independent non-executive Directors.