亞盛醫藥
Ascentage Pharma

ASCENTAGE PHARMA GROUP INTERNATIONAL
亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

APG-115 Granted Orphan Drug Designation by the FDA for the Treatment of Gastric Cancer

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the US Food and Drug Administration (FDA) has granted APG-115, a novel MDM2-p53 inhibitor being developed by the Company, an Orphan Drug Designation (ODD) for the treatment of gastric cancer (GC). This is the first ODD granted by the FDA for APG-115.

"Orphan drugs" refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. According to the latest data from the US National Cancer Institute's Surveillance, Epidemiology, and End Results Program, in 2017, there was an estimated 116,525 people living with GC in the US[1]. GC is currently considered as a rare disease in US. The ODD obtained from the FDA will be conducive to APG-115 enjoying various policy support in its subsequent research and development, including a tax credit on expenditures incurred in clinical studies, a waiver of the New Drug Application (NDA) fee, research grant awarded by the FDA, and 7 years of market exclusivity in the US upon approval for the treatment of GC.

APG-115 is an orally administered, selective, small-molecule inhibitor of the MDM2-p53 protein-protein interaction (PPI). APG-115 has strong binding affinity to MDM2 and is designed to activate tumor suppression activity of p53 by blocking the MDM2-p53 PPI. APG-115 is the first MDM2-p53 inhibitor entering clinical development in China, with multiple ongoing clinical studies in solid tumors and homological malignancies in China and the US. APG-115 has shown promising results in preclinical studies for the treatment of GC.

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-115 successfully.

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

Suzhou, People's Republic of China, September 14, 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.

References:

1. 2020 Cancer Incidence Data, Surveillance, Epidemiology, and End Results Program, National Cancer Institute.