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

Clinical Collaboration with Acerta Pharma, the Hematology Research and Development Center of Excellence of AstraZeneca

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the Company has entered a clinical collaboration with Acerta Pharma, the hematology research and development center of excellence of AstraZeneca (LSE/STO/NYSE: AZN). Under the terms of the collaboration, Ascentage Pharma will sponsor a clinical trial to study the combination of Ascentage Pharma's APG-2575, a selective BCL-2 inhibitor, and Acerta Pharma's CALQUENCE® (acalabrutinib), a Bruton's Tyrosine Kinase (BTK) inhibitor, evaluating the efficacy and safety of this combination therapy in patients with relapsed/refractory (r/r) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).

This global, multicenter, open-label Phase Ib/II dose-escalation and dose-expansion study is designed to evaluate the safety, tolerability, and anticancer activity of APG-2575 as a single agent or in combination with CALQUENCE® in patients with r/r CLL/SLL. The study has already initiated in US with the dosing of first patient, and planned to expand in Europe, and Australia.

CLL/SLL is a hematologic malignancy caused by mature B-cell neoplasms and constitutes the most common form of adult leukemia in North America and Europe, accounting for about 30% of all new leukemia cases. Despite significant initial responses to current first-line treatments, many patients with CLL need ongoing treatment to maintain these responses, and relapse often portends a poor prognosis. Recent studies in CLL showed that combining a BTK inhibitor with another BCL-2 inhibitor can deepen responses and even shorten cyclic treatment, enabling patients to achieve complete remission and therefore discontinue treatment.[1, 2]

APG-2575 is a novel, orally administered BCL-2–selective inhibitor being developed by Ascentage Pharma. APG-2575 is designed to treat a variety of hematologic malignancies by selectively blocking BCL-2 to restore the normal apoptosis process in cancer cells. Since March 2020, the Company has received approvals and clearances for several Phase Ib/II studies of APG-2575 in China and the US.

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-2575 successfully.

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

Suzhou, People's Republic of China, June 22, 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 Jain N, Keating M, Thompson P, et al. Ibrutinib and venetoclax for first-line treatment of CLL. N Engl J Med 2019;380:2095-2103.

2 Wiestner A. Ibrutinib and venetoclax — doubling down on CLL. N Engl J Med 2019;380:2169-2171.