

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

APG-2575 completed dosing of the first patient in Europe in Phase Ib/II clinical study

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that a Phase Ib/II clinical study of the novel class 1 Bcl-2 inhibitor APG-2575 being developed by the Company, as a single agent or in combinations for the treatment of patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (r/r CLL/SLL) (Number: APG2575CU101; EudraCT registration number: 2020-002736-73), has completed dosing of the first patient in Ukraine. This is the first global clinical study conducted by Ascentage Pharma in Europe.

This global multicenter Phase Ib/II study was designed to evaluate the safety and efficacy of APG-2575 as a single agent or in combinations for the treatment of patients with r/r CLL/SLL. The study has recently obtained Clinical Trial Application (CTA) approvals from the Ministry of Health of Ukraine and the Ministry of Health of the Russian Federation.

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 leukemia cases. The annual incidence rate of CLL/SLL is around 2–6 cases per 100,000 individuals, and 12.8 cases per 100,000 individuals in the population aged 65 years old or above. Despite significant initial responses to current first-line treatments, many patients with CLL/SLL need ongoing treatment to maintain these responses, and relapse often portends a poor prognosis. Recent studies in CLL/SLL showed that combining a BTK inhibitor with a Bcl-2 inhibitor can deepen responses and shorten treatment durations from long-term to cyclic treatments, making it possible for CLL/SLL patients to achieve complete remission and therefore discontinue treatment^{1,2}. These findings have undoubtedly provided a basis for exploring APG-2575 in combination with BTK inhibitors.

APG-2575 is a novel, orally administered small molecule Bcl-2-selective inhibitor being developed by Ascentage Pharma. APG-2575 is designed to treat several hematologic malignancies by selectively blocking Bcl-2 protein to restore the normal apoptosis mechanism in cancer cells (apoptosis), thereby destroying the tumour. APG-2575 is the first China-developed Bcl-2 selective inhibitor having entered into clinical stage in China. APG-2575 has received clearances and approvals for multiple Phase Ib/II clinical studies in the US, China and Australia, and its clinical development in a range of hematologic malignancies is being progressed concurrently on a global basis. This year, APG-2575 has been granted two Orphan Drug Designations from the US Food and Drug Administration for the treatment of Waldenström macroglobulinemia (WM) and CLL.

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, November 25, 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. Cancer Statistics 2020, American Cancer Society
2. 2020 Cancer Incidence Data, Surveillance, Epidemiology, and End Results Program, US National Cancer Institute