

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

Announcement of updates on the clinical development of APG-2575, including an objective response rate of 70% in patients with relapsed/ refractory Chronic Lymphocytic Leukemia

Ascentage Pharma Group International (the “Company” or “Ascentage Pharma”) is pleased to announce updates on the clinical development of the class 1 novel Bcl-2 inhibitor APG-2575 being developed by the Company, further demonstrating the drug candidate’s higher therapeutic potential.

APG-2575 is a novel, orally administered small-molecule Bcl-2-selective inhibitor being developed by Ascentage Pharma, and is designed to treat hematologic malignancies and solid tumors by selectively blocking antiapoptotic protein Bcl-2 to restore the normal apoptosis process in cancer cells (apoptosis). APG-2575 has high selectiveness towards Bcl-2. After entering into cells through the cell membrane, APG-2575 selectively binds to anti-apoptosis protein Bcl-2 on the mitochondrial outer-membrane, disrupts the formation of Bcl-2:BIM complexes, and releases the proapoptotic protein BIM, which further activates a series of processes of apoptosis, and finally leading to the apoptosis of cancer cells. APG-2575 is the first China-developed Bcl-2 inhibitor having entered into clinical development in China. As a single agent, APG-2575 has potent antitumor activity in Bcl-2-dependent tumor cells, and has shown a broad range of antitumor activities when combined with other oncologic drugs. APG-2575 has already received clearances and approvals for multiple Phase Ib/II clinical studies in China, Australia, the U.S. and Europe, and is currently being clinically developed in a range of hematologic malignancies globally.

Highlights of the updates:

- In total, 9 clinical studies are ongoing globally, with over 100 patients who have been administered APG-2575 at doses ranging from 20 mg to 1200 mg for the treatment of chronic lymphocytic leukemia (CLL), follicular lymphoma (FL), mantle cell lymphoma (MCL), diffuse large B-cell lymphoma (DLBCL), multiple myeloma (MM), acute myeloid leukemia (AML), and high leukocyte acute leukemia (HCL), etc.
- Clinical studies of APG-2575 in the treatment of relapsed/refractory CLL (r/r CLL) have enrolled over 30 patients. Preliminary clinical study results show that an objective response rate (ORR) of 70% has been reached in evaluable patients.
- On safety:
 - Maximum tolerated dose (MTD) has not been reached, and no dose-limiting toxicity (DLT) was observed.
 - No clinical or laboratory tumor lysis syndrome (TLS) was observed.
 - Most treatment-related adverse events (TRAEs) were of Grade 1 or 2.
 - Limited cases of neutropenia and thrombocytopenia.
- APG-2575 has been granted three Orphan Drug Designations (ODDs) by the US Food and Drug Administration, for the treatment of CLL, MM, and Waldenström macroglobulinemia (WM).

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, December 10, 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.