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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 Granted Orphan Drug Designation by the US FDA

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that the US Food and Drug Administration (FDA) has granted APG-2575, a novel Bcl-2 selective inhibitor being developed by the Company, an Orphan Drug Designation (ODD) for the treatment of Waldenström Macroglobulinemia (WM). This is the first ODD granted to APG-2575, and the second ODD obtained by Ascentage Pharma from the FDA.

“Orphan drugs” refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. WM is a type of lymphocytic lymphoma characterized by the bone marrow infiltration of lymphoplasmacytic cells with elevated monoclonal immunoglobulin M (IgM). WM is a rare disease that accounts for less than 2% of all non-Hodgkin’s lymphoma (NHL) patients in the US¹.

APG-2575 is a novel, orally administered Bcl-2 selective inhibitor being developed by Ascentage Pharma. APG-2575 has received clearances and approvals for multiple Phase Ib/II clinical studies in China and the United States in a range of hematologic malignancies.

The ODD obtained from the FDA qualifies APG-2575 for various development incentives, 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 United States upon approval for the treatment of 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, July 15, 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.

Reference:

¹ Datamonitor, Market Spotlight: WM published on April 17, 2020.