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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 Second 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 inhibitor being developed by the Company, an Orphan Drug Designation (ODD) for the treatment of chronic lymphocytic leukemia (CLL). This is the second ODD granted to APG-2575 by the FDA, following the first ODD received from the FDA in July this year for the treatment of Waldenström Macroglobulinemia (WM).

“Orphan drugs” refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. CLL is a form of leukemia among adults, characterized by progressive accumulation of abnormal lymphocytes cells in the peripheral blood, bone marrow and lymphoid tissues.

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 the US, China and Australia in a range of hematologic malignancies globally, including a global Phase Ib/II clinical study of APG-2575 as a single agent or in combination with other therapeutic agents to treat patients with relapsed/refractory CLL/SLL (small lymphocytic lymphoma). The study is currently recruiting patients in the US and Australia.

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 US upon approval for the treatment of 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, September 7, 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.*