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

APG-2575 granted the fifth 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 patients with follicular lymphoma (FL). This is the fifth ODD granted to APG-2575 by the US FDA, following the previous ODDs for the treatment of Waldenström macroglobulinemia (WM), chronic lymphocytic leukemia (CLL), multiple myeloma (MM), and acute myeloid leukemia (AML). Up to the date of this announcement, four of Ascentage Pharma's investigational drug candidates have been granted a total of ten ODDs by the US FDA, a record number for any Chinese biopharmaceutical company.

The term "orphan drugs" refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. FL is a heterogeneous disease and the second most common subtype of non-Hodgkin lymphoma (NHL) among patients in the US, accounting for about 20% of all NHL incidences. Defined as a proliferation of malignant germinal center B cells, FL is also the most common subtype of indolent B-cell lymphoma[1,2]. The ODD obtained from the FDA will be conducive to APG-2575 enjoying various policy support in its subsequent research and development, as well as commercialization in the US, including a tax credit on expenditures incurred in clinical studies, a waiver of the New Drug Application (NDA) fee, possible research grant, and most importantly, 7 years of market exclusivity in the US upon market approval of APG-2575.

APG-2575 is a novel, orally administered small-molecule Bcl-2-selective inhibitor being developed by Ascentage Pharma. APG-2575 is designed to treat various hematologic malignancies and solid tumors by selectively blocking antiapoptotic protein Bcl-2 to restore the normal apoptosis process in cancer cells (apoptosis), thereby killing the tumors. APG-2575 is the first China-developed Bcl-2 inhibitor entering the clinical stage in China. Previously, APG-2575 had received clearances and approvals for multiple Phase Ib/II clinical studies in the US, China and Australia, and is currently being clinically developed in a range of hematologic malignancies globally.

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, January 29, 2021

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. Kridel R, Sehn L, Gascoyne D. Pathogenesis of follicular lymphoma. J Clin Invest. 2012 Oct;122(10):3424–31.

2. Huet S, Sujobert P, Salles G. From genetics to the clinic: a translational perspective on follicular lymphoma. Nat Rev Cancer. 2018 Aspr;18(4):224-239.