ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

Ascentage Pharma Obtained its 9th Orphan Drug Designation from the US FDA in 2020, Setting a Record among Chinese Biopharmaceutical Companies

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 acute myeloid leukemia (AML). This is the fourth ODD granted by the US FDA for APG-2575, following the previous ODDs for the treatment of Waldenström macroglobulinemia (WM), chronic lymphocytic leukemia (CLL), and multiple myeloma (MM). As at the date of this announcement, four of Ascentage Pharma's investigational drug candidates have been granted a total of nine ODDs by the US FDA in 2020, a record number among all Chinese biopharmaceutical companies.

AML is a highly heterogenous hematologic malignancy that is more common in the elderly population with a median age at diagnosis of 68 years[1]. The most recent data from the Surveillance, Epidemiology, and End Results Program (SEER) of the US National Cancer Institute (NCI) estimated 19,940 new cases of AML and 11,180 deaths from this disease in the US in 2020. Despite the significant advances in AML therapeutics in recent years, the five-year survival rate of AML remains at 25%–30%, which still represents a significant unmet clinical need for therapies with more durable efficacy and a better safety profile.

The term "orphan drugs" refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. In the US, a rare disease refers to a disease or condition which affects less than 200,000 patients in the country. Since the Orphan Drug Act was passed in 1983, the US government has provided relevant policy support to relevant corporations to encourage the research and development of orphan drugs. 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, research grant, and most importantly, seven years of market exclusivity in the US upon approval of APG-2575 for treating the particular indication.

As a result of the rise of biopharmaceutical innovation in China, a growing number of Chinese biopharmaceutical companies are forging ahead with their global strategies. Obtaining regulatory approvals such as the ODD from the FDA is widely regarded as a key indicator of a company's strength in global innovation, and by that, Ascentage Pharma is a clear leader in the field. As at the date of this announcement, four of Ascentage Pharma's investigational drug candidates have been granted a total of nine ODDs by the FDA in 2020 (see table below), a leading number among all Chinese biopharmaceutical companies so far according to public information.

Compound	**Target**	**Indication**
HQP1351	BCR-ABL	Chronic Myeloid Leukemia (CML)
APG-2575	Bcl-2	Waldenström Macroglobulinemia (WM)
		Chronic Lymphocytic Leukemia (CLL)
		Multiple Myeloma (MM)
		Acute Myeloid Leukemia (AML)
APG-115	MDM2-p53	Gastric Cancer (GC)
		Acute Myeloid Leukemia (AML)
		Soft Tissue Sarcoma
APG-1252	Bcl-2/Bcl-xL	Small Cell Lung Cancer (SCLC)

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, HQP1351. APG-115 and APG-1252 successfully.

By order of the Board
Ascentage Pharma Group International
Dr. Yang Dajun
Chairman and Executive Director

Suzhou, People's Republic of China, January 5, 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. DeSantis CE, Lin CC, Mariotto AB, et al. Cancer Treatment and Survivorship Statistics, 2014. CA Cancer J Clin 2014;64:252-271.