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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-115 and APG-1252 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 two Orphan Drug Designations (ODDs) to the novel drug candidates of the apoptosis-targeting pipeline being developed by the Company: the MDM2-p53 inhibitor, APG-115 and the Bcl-2/Bcl-xL inhibitor, APG-1252, for the treatment of acute myeloid leukemia (AML) and small-cell lung cancer (SCLC), respectively. As of the date of this announcement, Ascentage Pharma has obtained a total of six ODDs from the FDA for four of the Company’s novel drug candidates under development.

“Orphan drugs” refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. AML is a highly heterogenous hematologic malignancy that is more common in the elderly population with a median age at diagnosis of 68 years old<sup>1</sup>. The most recent data from the Surveillance, Epidemiology, and End Results Program (SEER) of the US National Cancer Institute (NCI) estimates that there will be 19,940 new cases of AML and an estimated 11,180 deaths from this disease in the US in 2020. Lung cancer is divided into two main histopathological types: non-small cell lung cancer (NSCLC) and SCLC, with 13–15% of lung cancers classified as SCLC<sup>2,3</sup>. SCLC is a rare and highly aggressive malignancy with a low 5-year survival rate<sup>3</sup>. AML and SCLC are currently considered as rare diseases in the US. The ODDs obtained from the FDA will be conducive to APG-115 and APG-1252 enjoying various development incentives in its subsequent research and development, 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 AML and SCLC.

APG-115 is an orally administered, selective, small-molecule inhibitor of the MDM2-p53 protein-protein interaction (PPI). APG-115 has strong binding affinity to MDM2 and is designed to activate tumor suppression activity of p53 by blocking the MDM2-p53 PPI. APG-115 is the first MDM2-p53 inhibitor entering clinical development in China, with multiple ongoing clinical studies in solid tumors and homologous malignancies in China and the US. APG-115 has shown promising results in preclinical studies for the treatment of gastric cancer.

APG-1252 is a novel small-molecule drug candidate being developed by Ascentage Pharma that restores apoptosis by selectively inhibiting Bcl-2 and Bcl-xL proteins. APG-1252 is currently being tested in Phase I dose-escalation studies in patients with advanced cancers in the US and Australia, a Phase Ib/II study of APG-1252 plus paclitaxel treatment in patients with relapsed/refractory SCLC in the US, and a Phase I dose-escalation study of single agent in patients with SCLC in China. The clinical data of APG-1252 generated thus far has shown a favorable safety profile and preliminary efficacy in patients with SCLC and other advanced solid tumors.

**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-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, October 9, 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. DeSantis CE, Lin CC, Mariotto AB, et al. Cancer Treatment and Survivorship Statistics, 2014. *CA Cancer J Clin* 2014; 64: 252-271.
2. Siegel R, Miller K, Jemal A. Cancer Statistics, 2020. American Cancer Society. *CA Cancer J Clin* 2020; 70: 7-30.
3. Lu T, Yang X, Huang Y, et al. Trends in the incidence, treatment, and survival of patients with lung cancer in the last four decades. *Cancer Manag Res.* 2019; 11: 943-953.