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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**

#### **ASCENTAGE PHARMA'S LISAFTOCLAX GRANTED BREAKTHROUGH THERAPY DESIGNATION IN CHINA FOR TREATMENT-NAÏVE CLL/SLL**

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that Lisaftoclax (APG-2575), the Company’s novel Bcl-2 inhibitor, has been granted a Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of China’s National Medical Products Administration (NMPA), in combination with acalabrutinib, for the treatment of treatment-naïve adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).

BTDs are granted to innovative drugs or modified new drugs intended for the prevention or treatment of serious, life-threatening diseases or conditions that severely impair quality of life, for which there is no effective treatment, or where sufficient existing evidence demonstrates significant clinical advantages over currently available treatment options. Drug candidates that are granted BTDs receive priority from the CDE for communications and development guidance to accelerate drug development. Furthermore, if the applicant meets the relevant conditions after evaluation, it may apply for Priority Review status and conditional approval when submitting a New Drug Application (NDA) in China. Overall, the BTD pathway is designed to accelerate the development and review of innovative drugs and modified new drugs that offer significant clinical value or address urgent unmet clinical needs.

CLL/SLL is a clonal proliferative malignancy of B lymphocytes that predominantly affects older adults, with more than 100,000 new cases worldwide each year.<sup>1</sup> In recent years, the incidence of CLL/SLL in China has been increasing, with some patients presenting at a younger age and with more aggressive disease.<sup>2</sup>

In CLL/SLL, immunochemotherapy and BTK inhibitors have been used as first-line treatment options and have achieved favorable response rates and survival outcomes, although certain limitations remain. Immunochemotherapy has limited efficacy in some patients, particularly in those with high-risk features such as del(17p)/TP53 mutations, complex karyotypes, and unmutated IGHV. BTK inhibitor monotherapy also has limitations, including insufficient depth of response and concerns regarding long-term safety, and requires continuous treatment. Once treatment fails, patients have very limited subsequent treatment options, with generally poor outcomes. Therefore, there remains an urgent clinical need for fixed-duration combination strategies that improve efficacy and depth of response while reducing adverse events.

Lisaftoclax is a novel, oral, selective Bcl-2 inhibitor developed by Ascentage Pharma. In July 2025, Lisaftoclax was approved in China for the treatment of adult patients with CLL/SLL who had previously received at least one systemic therapy including a BTK inhibitor. Lisaftoclax is the first China-developed Bcl-2 inhibitor approved in China and the second Bcl-2 inhibitor approved globally. Ascentage Pharma is currently conducting four global registrational Phase III trials of Lisaftoclax. One of these studies, GLORA-2, is a global registrational Phase III trial evaluating the clinical potential of Lisaftoclax in combination with acalabrutinib as a first-line treatment for CLL/SLL.

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

Suzhou, People's Republic of China, October 21, 2026

*As at the date of this announcement, the Board comprises Dr. Yang Dajun as Chairman and executive Director, Dr. Wang Shaomeng and Dr. Lu Simon Dazhong<sup>Note 1</sup> as non-executive Directors, and Mr. Ye Changqing, Mr. Ren Wei, Dr. David Sidransky<sup>Note 2</sup>, Ms. Marina S. Bozilenko, Dr. Debra Yu and Dr. Marc E. Lippman, MD as independent non-executive Directors.*

*Notes:*

- 1. Dr. Lu Simon Dazhong satisfy the independence requirements of the U.S. Securities and Exchange Commission and Nasdaq corporate governance requirements*
- 2. Dr. David Sidransky is the Lead Independent Non-Executive Director of the Company.*

#### **References**

1. Yao, Y., Lin, X., Li, F., et al. The global burden and attributable risk factors of chronic lymphocytic leukemia in 204 countries and territories from 1990 to 2019: analysis based on the global burden of disease study 2019. Biomed Eng Online. 2022 Jan 11;21(1):4. DOI: 10.1186/s12938-021-00973-6
2. 劉澎. 復旦大學附屬中山醫院慢性淋巴細胞白血病／小淋巴細胞淋巴瘤診療規範(2018)[J].中國臨床醫學, 2018, 25(1): 157-160. DOI: 10.12015/j. issn.1008-6358.2018.20180