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 received CDE Approval for the Phase III Registrational Study of APG-2575 in Treatment-naïve CLL/SLL patients

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the Center for Drug Evaluation (CDE) of National Medical Products Administration of the PRC (NMPA) has approved the global Phase III pivotal registrational study of Bcl-2 selective inhibitor APG-2575 (Lisaftoclax), one of the key product candidates of the Company, in combination with Bruton Tyrosine Kinase (BTK) inhibitor Acalabrutinib versus chemoimmunotherapy in treatment-naïve patients with chronic lymphocytic leukemia/ small lymphocytic lymphoma (CLL/SLL), aiming to validate the combination regimen as a first-line treatment for CLL/SLL. This is another important milestone after the drug received clearance from the U.S. Food and Drug Administration (FDA) in August 2023 to initiate global registrational phase III clinical trial in previously treated patients with CLL/SLL.

The study is a global, multi-center, randomized-controlled, open-label, Phase III pivotal registrational clinical study (APG2575CC301) designed to evaluate the efficacy and safety of APG-2575 (Lisaftoclax) in combination with Acalabrutinib versus chemoimmunotherapy in treatment-naïve patients with CLL/SLL.

CLL/SLL is a hematologic malignancy caused by mature B-cell neoplasms that often affects elderly patients and is one of the most common types of adult leukemia, with over 100,000 new cases per year globally[1]. In China, the incidence of CLL/SLL has shown a significant upward trend and is characterized by younger age of onset and higher aggressiveness[2]. With the continuous breakthrough of basic research and targeted therapy, the survival of CLL/SLL patients has been prolonged. However, there remain many challenges in this field of treatment, and there is an urgent need to introduce new therapies with good efficacy and safety.

APG-2575 (Lisaftoclax) is a novel, oral Bcl-2 selective inhibitor developed by Ascentage Pharma. APG-2575 (Lisaftoclax) is designed to treat patients with a variety of malignancies by selectively blocking the Bcl-2 protein to restore the normal apoptosis process in cancer cells. APG-2575 (Lisaftoclax) is a potentially best-in-class drug globally, and is the second Bcl-2 inhibitor in the world and the first Bcl-2 inhibitor in China entering the pivotal registrational clinical stage. Previously, interim data from a global Phase II clinical study demonstrated promising efficacy of APG-2575 (Lisaftoclax) in combination with Acalabrutinib. The data showed that the combination therapy achieved an objective response rate (ORR) of 98% in patients with relapsed/refractory (R/R) CLL/SLL, an ORR of 100% in patients with initially treated CLL/SLL, and still maintained favorable safety profile comparable to monotherapy. In the study, APG-2575 (Lisaftoclax) was initiated on a daily dose ramp-up approach with simple and convenient dosing regimen, which allowed patients to receive treatment dose earlier[3]. Moreover, the study adopted a dosing regimen that was improved on that of existing Bcl-2 inhibitor plus BTK inhibitor combinations as it eliminated the lead-in for the BTK inhibitor, thus allowing patients to begin receiving the combination therapy more quickly. Those results were released as an Oral Presentation at the 2022 American Society of Hematology (ASH) Annual Meeting.

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 (Lisaftoclax) successfully.

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

Suzhou, People's Republic of China, October 13, 2023

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 and Dr. Lu Simon Dazhong as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.

References

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2. Liu Peng. Diagnostic and therapeutic guidelines for chronic lymphocytic leukocyte/small lymphocytic lymphoma in Zhongshan Hospital affiliated with Fudan University (v1.2018)[J]. Chinese Journal Of Clinical Medicine, 2018, 25(1) (劉澎. 復旦大學附屬中山醫院慢性淋巴細胞白細胞／小淋巴細胞淋巴瘤診療規範(v1.2018)[J].中國臨床醫學, 2018, 25(1)).

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