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

Ascentage Pharma to Announce Results from Four Clinical Studies at 2021 ASCO Annual Meeting, with Data of Two of Its Drug Candidates Including Lisaftoclax (APG-2575) to Be Released in Oral Presentations for the First Time

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that results from four clinical studies of the Company's three apoptosis-targeted drug candidates have been selected for presentations at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. These include two oral presentations: one based on a global Phase I clinical study of the Bcl-2 inhibitor Lisaftoclax (APG-2575); and the other based on a global Phase II clinical trial of the MDM2-p53 inhibitor Alrizomadlin (APG-115) in combination with pembrolizumab.

Convening on June 4 to June 8, 2021, the ASCO Annual Meeting showcases the most cutting-edge research results in clinical oncology and the most advanced cancer therapies, and is the world's most influential and prominent academic exchange gathering of the clinical oncology community.

At this year's ASCO Annual Meeting, Ascentage Pharma will present results from four clinical studies of the Company's three drug candidates under development as follows:

The novel Bcl-2 inhibitor Lisaftoclax (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 hematologic malignancies and solid tumors by selectively blocking antiapoptotic protein Bcl-2 to restore the normal apoptosis process in cancer cells. APG-2575 is the first China-developed Bcl-2 inhibitor entering clinical development in China.

- **Selected study**: A global Phase I clinical study of APG-2575, a novel Bcl-2 inhibitor in patients with relapsed/refractory chronic lymphocytic leukemia (R/R CLL) and other hematologic malignancies (HMs)

  Format: Oral Presentation

This global multi-center, single-agent, open-label Phase I clinical study is designed to assess the safety, pharmacokinetics (PK), pharmacodynamic (PD), and efficacy of APG-2575, and to determine its maximum tolerated dose (MTD)/recommended Phase II dose (RP2D) in patients with R/R CLL and other HMs.

In the preliminary data released by Ascentage Pharma in December 2020, APG-2575 has demonstrated an objective response rate (ORR) of 70%, with favorable tolerability and manageable safety profiles in patients with R/R CLL. Detailed updated results will be released in an oral presentation at the ASCO Annual Meeting during June 4 to June 8, 2021.

The novel MDM2 inhibitor Alrizomadlin (APG-115)

Being developed by Ascentage Pharma, APG-115 is an orally administered, selective, small-molecule inhibitor of the MDM2 protein. Alrizomadlin has strong binding affinity to MDM2 and is designed to activate tumor suppression activity of p53 by blocking the MDM2-p53 protein-protein interaction. Alrizomadlin is the first MDM2-p53 inhibitor entering clinical development in China, and is currently being investigated in multiple Phase Ib/II clinical studies in solid tumors and HMs in China, the US and Australia.

- **Selected study**: A Phase II study of APG-115 in combination with pembrolizumab in patients with unresectable or metastatic melanoma or advanced solid tumors that have failed immuno-oncologic drugs

  Format: Oral Presentation

This study is designed to evaluate the efficacy and safety of APG-115 in combination with pembrolizumab in patients with unresectable or metastatic melanoma or advanced solid tumors that have failed immuno-oncologic drugs.

The results of this Phase Ib study released at the 2020 ASCO Annual Meeting demonstrated that APG-115 in combination with pembrolizumab is well-tolerated, with preliminary antitumor activity in advanced solid tumors.

- **Selected study**: A Phase I/II trial of APG-115, with or without platinum chemotherapy, in patients with p53 wild-type salivary gland carcinoma

  Format: Poster Presentation

This multi-center, open-label Phase I/II study in the US is designed to evaluate the efficacy of APG-115, with or without platinum chemotherapy, in patients with p53 wild-type salivary gland carcinoma.

The Bcl-2/Bcl-xL inhibitor Pelcitoclax (APG-1252)

APG-1252is a novel, highly potent, small molecule drug developed by Ascentage Pharma which is designed to restore apoptosis through selective inhibition of Bcl-2 and Bcl-xL proteins.

- **Selected study**: A multi-center Phase Ib/II study of APG-1252 plus paclitaxel in patients with relapsed or refractory small-cell lung cancer (R/R SCLC)

  Format: Poster Presentation

This multi-center, open-label Phase Ib/II study is designed to evaluate the safety and preliminary efficacy of combination therapy with APG-1252 plus paclitaxel in patients with R/R SCLC.

Information on Ascentage Pharma

Ascentage Pharma is a China-based, globally focused, clinical-stage biotechnology company engaged in developing novel therapies for cancers, CHB (Chronic hepatitis B), and age-related diseases. On October 28, 2019, Ascentage Pharma became listed on the Main Board of The Stock Exchange of Hong Kong Limited with the stock code: 6855.HK.

Ascentage Pharma has its own platform for developing therapeutics that inhibit protein-protein interactions to restore apoptosis or programmed cell death. The company has built a pipeline of eight type I small molecule clinical drug candidates which have entered the clinical development stage, including novel, highly potent Bcl-2 inhibitors, as well as candidates aimed at IAP and MDM2-p53 pathways, and next-generation tyrosine kinase inhibitors (TKIs). Ascentage Pharma is also the only company in the world with active clinical programs targeting all key apoptosis regulators. The Company is conducting more than 40 Phase I/II clinical trials in China, the US and Australia. HQP1351, the Company's core drug candidate developed for the treatment of drug-resistant chronic myeloid leukemia (CML), has been granted an Orphan Drug Designation (ODD) and a Fast Track Designation (FTD) by the US FDA, and a New Drug Application (NDA) for the drug candidate has been submitted and subsequently granted Priority Review by the Center for Drug Evaluation (CDE) in China. As at the date of this announcement, Ascentage Pharma has obtained a total of eleven ODDs from the US FDA for four of the Company's investigational drug candidates.

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, 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, April 21, 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, Dr. Lu Simon Dazhong and Mr. Liu Qian as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.