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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

## **Clinical Collaboration with MSD**

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the Company has entered a clinical collaboration with MSD to evaluate the combination of APG-115, Ascentage Pharma's MDM2-p53 inhibitor, and KEYTRUDA<sup>®</sup> (pembrolizumab), MSD's anti-PD-1 therapy, for the treatment of patients with advanced solid tumors.

Under the agreement, Ascentage Pharma will sponsor an open-label, multicenter, phase Ib/II study (NCT03611868) is designed to evaluate the safety and efficacy of APG-115 with KEYTRUDA<sup>®</sup> in multiple cohorts of solid tumors (i, e., NSCLC, melanoma, Urothelial cancer, Liposarcoma, MPNST and ATM mutated/Tp53 WT tumors resistant or relapsed to PD-1/PD-L1 treatment or without previous PD-1/PD-L1 treatment). The Phase II portion of the study has initiated and is expected to enroll 80 patients at multiple sites in the United States. Ascentage Pharma and MSD will use a joint development committee to exchange information about the study.

Preclinical studies demonstrated that APG-115 promoted the production of proinflammatory cytokines in T cells, enhanced CD4+ T cell activation, and increased PD-L1 expression on various tumor cells. Enhanced antitumor activity was demonstrated in various tumor models after APG-115 was combined with PD-1 blockade. Results of the phase Ib trial was recently published at the ASCO annual meeting 2020 and demonstrated that APG-115 in combination with pembrolizumab is well-tolerated, with encouraging anti-tumor effects in several tumor types.

APG-115 is an orally administered, selective, small-molecule inhibitor of the MDM2-p53 PPI. APG-115 has strong binding affinity to MDM2 and is designed to activate p53 tumor suppression activity by blocking the MDM2-p53 PPI. Ascentage Pharma has commenced three clinical trials of APG-115 in the US, including a Phase I study as single agent, a Phase Ib/II study in combination with pembrolizumab for treatment of metastatic melanoma and other advanced solid tumors, and a Phase I/II study as a single agent or in combination with chemotherapy for treatment of salivary gland cancer. APG-115 is the first MDM2-p53 inhibitor to enter clinical studies in China. A Phase I study as a single agent, and a Phase Ib study as a single agent or in combination with chemotherapy for treatment of AML (acute myeloid leukemia) or MDS (myelodysplastic syndrome) are ongoing in China.

**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 successfully.

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

Suzhou, People's Republic of China, July 6, 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.