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 Passes GMP Compliance Audit by EU QP with Zero Deficiency, Signaling Global Recognition of the Company's Quality Management System

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that it recently received a zero-deficiency report from the GMP compliance audit of Ascentage Pharma's Global Manufacturing Center by a Qualified Person (QP) of the European Union (EU). This successful audit indicates that the Company's Global Manufacturing Center and quality management system implemented at the site are now compliant with the standards of the EU GMP, marking the achievement of a major milestone that will pave the way for the Company's continued global expansion.

In March 2023, a QP of the EU carried out an inspection at Ascentage Pharma's Global Manufacturing Center over a four-day period. Under the guidance of the EudraLex Volume 4 regulations (Guidelines for Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Volume 4), the audit covered aspects including quality assurance, manufacturing processes, laboratory control, material management, facilities and equipment, data integrity, and IT systems of the manufacturing site.

The auditor spoke highly of Ascentage Pharma's Global Manufacturing Center during the course of the entire audit, and confirmed that the site possesses a high-standard quality management system, facilities, equipment, as well as experienced staff that make the site completely compliant with the requirements of the EU GMP. As a result, Ascentage Pharma received a zero-deficiency audit report from the EU QP that will pave the way for the manufacturing and global commercialization of the Company's innovative drugs.

About the EU QP system

The EU GMP first adopted the QP system in 1975. In the near 50 years that followed, it was proven to be an advanced system for pharmaceutical quality management and has thus become a core element of the EU GMP.

The EU has strict requirements for QPs and has clearly defined the legal status, required qualifications and responsibilities of QPs in the European Council Directive (2001/83/EC) and the EU GMP Annex 16 on the Certification by a Qualified Person and Batch Release. These high requirements make QPs some of the most authoritative experts in pharmaceutical manufacturing.

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

Suzhou, People's Republic of China, April 25, 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.