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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 First Third-Generation BCR-ABL Inhibitor in China Olverembatinib (HQP1351) Recommended for Breakthrough Therapy Designation**

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that the Center for Drug Evaluation (the “**CDE**”) of the National Medical Products Administration of the People’s Republic of China (the “**NMPA**”) has recommended the novel class I drug Olverembatinib (the determined English common name of HQP1351) of Guangzhou Healthquest Pharma Co., Ltd, a wholly-owned subsidiary of Ascentage Pharma, for a Breakthrough Therapy Designation (BTD) for the treatment of patients with chronic-phase chronic myeloid leukemia (CP CML) resistant and/or intolerant to first-and second-generation tyrosine kinase inhibitors (TKI). This BTD recommendation marks another major development for Olverembatinib following the “Priority Review” designation granted by the CDE in October 2020. The indication of BTD recommendation is an expansion from that of the “Priority Review” designation.

According to the Provisions for Drug Registration (State Administration for Market Regulation Order No. 27)\* (《藥品註冊管理辦法》(國家市場監督管理總局令第27號)) and the announcement of the NMPA in relation to the publication of three documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020)\* (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》(2020年第82號)) implemented by the NMPA on July 1, 2020, the breakthrough therapy review policy is designed to promote the research and creation of drugs with apparent clinical advantages, which are intended for the prevention or treatment of serious life-threatening diseases or diseases which severely impact the quality of life for which there is no existing treatment or where sufficient evidence indicates advantages of the novel drug over currently available treatment options. Drugs that have been granted the BTD are prioritized by the CDE in communications and exchange, and in receiving guidance to promote the drug development progress. Furthermore, BTD designated drugs will be eligible to the Priority Review status that will accelerate the review process at the stage of

application for commercialization. In conclusion, this measure will effectively accelerate the development and review of drugs presenting significant clinical value or addressing urgent clinical needs.

CML is a hematologic malignancy of the white blood cells. Following the commercialization of BCR-ABL TKIs, the treatment of CML has been revamped. However, despite clinical benefits offered by the first-generation BCR-ABL inhibitor imatinib (GLEEVEC®), and several second-generation TKIs, acquired resistance to TKIs remains a major challenge in the treatment of CML. BCR-ABL tyrosine kinase mutations represent a key mechanism of acquired drug resistance; T315I, which is the most common drug-resistant mutation, occurs in about 25% of patients with drug-resistant CML. Patients with T315I-mutant CML are resistant to both first-and second-generation BCR-ABL inhibitors, presenting an urgent need for an effective new generation treatment drug for patients with TKI resistance/intolerance in China, especially those who are resistant to both first-and second-generation TKIs.

Olverembatinib is a novel, orally active, potent third-generation BCR-ABL inhibitor designed to effectively target BCR-ABL mutants, including T315I, and the first China-developed third-generation BCR-ABL inhibitor targeting drug-resistant CML. In July 2019, Olverembatinib was cleared by the U.S. Food and Drug Administration (the “FDA”) to enter a Phase Ib clinical study. In May 2020, Olverembatinib was granted an Orphan Drug Designation and a Fast Track Designation by the FDA. In October 2020, Olverembatinib was granted “Priority Review” designation by the CDE in China for the treatment of adult patients resistant to TKI and with T315I-mutant chronic phase CML or accelerated phase CML. In December 2020, clinical trial results of Olverembatinib were selected for oral presentation at the American Society of Hematology Annual Meeting for the third consecutive year. These data further demonstrated the favorable safety and promising efficacy profiles of Olverembatinib.

**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, HQP1351 successfully.

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

Suzhou, People’s Republic of China, March 24, 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, 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.*

\* *For identification purposes only*