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## **Antengene Corporation Limited**

**德琪醫藥有限公司**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 6996)**

### **VOLUNTARY ANNOUNCEMENT**

#### **APPROVAL OF THE PHASE II STUDY OF SELINEXOR BY NMPA FOR THE TREATMENT OF MYELOFIBROSIS IN CHINA**

Antengene Corporation Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) hereby informs the shareholders and potential investors of the Company of the attached press release that the National Medical Products Administration (“**NMPA**”) has approved a Phase II study of selinexor (XPOVIO®) for the treatment of patients with myelofibrosis in China.

This is a voluntary announcement made by the Company. The Group cannot guarantee that selinexor will ultimately be successfully marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board  
**Antengene Corporation Limited**  
**Dr. Jay Mei**  
*Chairman*

Hong Kong, August 23, 2021

*As at the date of this announcement, the board of directors of the Company comprises Dr. Jay Mei, Mr. John F. Chin, Dr. Kevin Patrick Lynch and Mr. Donald Andrew Lung as executive directors; Mr. Yanling Cao and Dr. Kan Chen as non-executive directors; and Mr. Mark J. Alles, Ms. Jing Qian and Mr. Sheng Tang as independent non-executive directors.*

## **Antengene Announces Approval of the Phase II Study of Selinexor for the Treatment of Myelofibrosis in China**

Shanghai and Hong Kong, PRC, August 23, 2021 – Antengene Corporation Limited (“Antengene”, SEHK: 6996.HK), a leading innovative biopharmaceutical company dedicated to discovering, developing and commercializing global first-in-class and/or best-in-class therapeutics in hematology and oncology, today announced that **China’s National Medical Products Administration (NMPA) has approved a Phase II study of selinexor (XPOVIO®) for the treatment of patients with myelofibrosis (MF).**

MF is a clonal bone marrow neoplasm which can emerge either as primary MF (PMF), polycythemia vera (PV) or essential thrombocythemia (ET). The disease is primarily characterized by fibrosis in the bone marrow, extramedullary hematopoiesis, anemia, splenomegaly, constitutional symptoms, and possible progression to leukemia that would shorten patients’ survival. Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is currently the only curative treatment for MF. However, such treatment is commonly associated with a high rate of complications and treatment-related deaths. According to the National Comprehensive Cancer Network (NCCN®) Guidelines for the Treatment of MF, patients with intermediate-2 or high-risk MF ineligible for allo-HSCT and with a platelet count of  $\geq 50 \times 10^9/L$  should be treated with JAK inhibitors ruxolitinib or fedratinib (2020 NCCN® Guidelines). Due to the poor prognosis of patients who have failed or developed resistance to these targeted therapies, MF still represents an urgent unmet medical need.

**This randomized, open-label, global multicenter Phase II study will be conducted at 15 centers across China, including the primary trial center at the First Affiliated Hospital of Soochow University, and enroll approximately 20 patients in total. The study is designed to evaluate the safety and efficacy of selinexor versus physician’s choice (PC) in patients with MF who had received at least six months of treatment with a JAK1/2 inhibitor.** Enrolled patients will be randomized in a 1:1 ratio into one of the two treatment arms, to receive either single agent selinexor or PC treatment. The primary endpoint of the study is the proportion of patients with a  $\geq 35\%$  spleen volume reduction from baseline (SVR35), as assessed by the independent radiographic review committee (IRC).

**Prof. Depei Wu, Director of Hematology Department at the First Affiliated Hospital of Soochow University, and the principal investigator of the study,** noted: “MF is a relatively rare form of proliferative neoplasm in the bone marrow that has long lacked effective treatment options before the emergence of targeted therapies. Allo-HSCT is currently the only curative treatment for patients with MF, yet not all patients with MF are eligible to or tolerant of the treatment. Although ruxolitinib has already been approved in China for the treatment of MF, patients who have failed on or developed resistance to the therapy still have very limited treatment options. This randomized, open-label, global multicenter Phase II study is designed to assess the safety and efficacy of selinexor versus physician’s choice (PC) in patients with MF who had received at least six months of treatment with a JAK1/2 inhibitor. We are very hopeful that this study will provide additional evidence supporting the exploration of effective treatments for MF and ultimately provide a new treatment option to patients with MF in China.”

**Dr. Jay Mei, Founder, Chairman and CEO of Antengene**, commented: “The NMPA’s approval for this clinical trial of selinexor in patients with MF marks another major milestone in our effort in developing selinexor in a broad range of diseases, and a big step towards expanding potential indications for this candidate drug. We are confident that selinexor will demonstrate its clinical utility in the treatment of MF as we progress with this clinical development program. We look forward to advancing this study under the oversight of the NMPA, and aim to achieve a clinical breakthrough for patients with MF in China.”

### **About Selinexor (XPOVIO®)**

Selinexor is a first-in-class oral selective inhibitor of nuclear export (SINE) compound discovered and developed by Karyopharm Therapeutics Inc. (NASDAQ: KPTI), Selinexor is currently being developed by Antengene, which **has the exclusive development and commercial rights in certain Asia-Pacific markets, including Greater China, Korea, Australia, New Zealand and the ASEAN countries, and already obtained an NDA approval in South Korea through a priority review process.**

In July 2019, the US Food and Drug Administration (FDA) approved selinexor in combination with low-dose dexamethasone for the treatment of relapsed/refractory multiple myeloma (rrMM) and in June 2020 approved selinexor as a single-agent for the treatment of relapsed/refractory diffuse large B-cell lymphoma (rrDLBCL). In December 2020, selinexor also received FDA approval as a combination treatment for multiple myeloma after at least one prior therapy. In February 2021, selinexor was approved by the Israeli Ministry of Health for the treatment of patients with rrMM or rrDLBCL and in March 2021, the European Commission (EC) has granted conditional marketing authorization for selinexor (XPOVIO) for the treatment of adult patients with rrMM.

Selinexor is so far the first and only oral SINE compound approved by the FDA and is the first drug approved for the treatment of both MM and DLBCL. Selinexor is also being evaluated in several other mid- and later-phase clinical trials across multiple solid tumor indications, including liposarcoma and endometrial cancer. In November 2020, at the Connective Tissue Oncology Society 2020 Annual Meeting (CTOS 2020), Antengene’s partner, Karyopharm, presented positive results from the Phase III randomized, double blind, placebo controlled, cross-over SEAL trial evaluating single agent, oral selinexor versus matching placebo in patients with liposarcoma. Karyopharm also announced that the ongoing Phase III SIENDO trial of selinexor in patients with endometrial cancer passed the planned interim futility analysis and the Data and Safety Monitoring Board (DSMB) recommended the trial should proceed as planned without any modifications. Top-line SIENDO trial results are expected in the second half of 2021.

Antengene is currently conducting multiple clinical trials of selinexor for the treatment of MM, DLBCL, endometrial cancer, and peripheral T and NK/T-cell lymphoma, and five of these trials are at late-stages (Phase II/III).

## About Antengene

Antengene Corporation Limited (“Antengene”, SEHK: 6996.HK) is a leading clinical-stage R&D – driven biopharmaceutical company focused on innovative medicines for oncology and other life-threatening diseases. Antengene aims to provide the most advanced anti-cancer drugs to patients in the Asia Pacific Region and around the world. Since its official operation in 2017, **Antengene has obtained 16 investigational new drug (IND) approvals, submitted 6 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for selinexor in South Korea already approved through a priority review process. Leveraging partnerships as well as in-house drug discovery, Antengene has built a broad and expanding pipeline of 13 clinical and pre-clinical assets, comprising 8 global rights assets and 5 assets with rights for Asia Pacific markets including the Greater China region.** Driven by its vision of “**Treating Patients Beyond Borders**”, Antengene is committed to addressing significant unmet medical needs by discovering, developing, manufacturing and commercializing first-in-class/best-in-class therapeutics.

## Forward-looking statements

The forward-looking statements made in this article relate only to the events or information as of the date on which the statements are made in this article. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this article completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this article, statements of, or references to, our intentions or those of any of our Directors or our Company are made as of the date of this article. Any of these intentions may alter in light of future development.