# Antengene Corporation Limited
# 德琪醫藥有限公司

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

**(Stock Code: 6996)**

## VOLUNTARY ANNOUNCEMENT

## NMPA APPROVAL OF IND APPLICATION FOR A PHASE III CLINICAL TRIAL OF SELINEXOR IN ADVANCED OR RECURRENT ENDOMETRIAL CANCER

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 Company has received the approval of the investigational new drug ("**IND**") application by the National Medical Products Administration ("**NMPA**") for a Phase III clinical trial of Selinexor in advanced or recurrent endometrial cancer in China.

This is a voluntary announcement made by the Company. The Group cannot guarantee that Selinexor will ultimately be successfully developed and 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, May 12, 2021

*As at the date of this announcement, the board of directors of the Company comprises Dr. Jay Mei, Mr. John F. Chin and Mr. Yiteng Liu as executive directors; Mr. Yanling Cao, Mr. Zhen Li 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 IND Approval in China for a Global Phase III Trial of Selinexor in Advanced or Recurrent Endometrial Cancer**

Shanghai and Hong Kong, PRC, May 12, 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 the Investigational New Drug (IND) application for a Phase III clinical trial designed to evaluate the safety and efficacy of selinexor (XPOVIO®) in the treatment of advanced or recurrent endometrial cancer (the SIENDO trial).

Endometrial cancer is a common gynecologic malignancy which frequently occurs in women of reproductive age. With a high incidence rate that has continued to rise in recent years, endometrial cancer has become the most prevalent malignancy of the female reproductive tract. Pregnancy, obesity, diabetes and reproductive system diseases are the main risk factors for endometrial cancer[1]. There is a lack of treatment options and curative care for patients with advanced or recurrent endometrial cancer, so effective novel treatments are increasingly important.

Selinexor (XPOVIO®) is an US Food and Drug Administration (FDA) approved oral selective inhibitor of nuclear export that has been included in five regimens recommended by the National Comprehensive Cancer Network (NCCN®) Guidelines and multiple regimens recommended by the Chinese Society of Clinical Oncology (CSCO) Diagnosis and Treatment Guidelines, for the treatment of multiple myeloma (MM) and diffuse large B-cell lymphoma (DLBCL). Selinexor inhibits XPO1, the only clinically proven nuclear export protein target. Based on its unique mechanism of action, selinexor can be combined with various other drugs in order to potentially enhance efficacy. The SIENDO trial is a global trial being conducted at over 80 centers across North America, Europe and Asia.

"This IND approval for selinexor in China marks a major milestone in achieving our mission to transform patients' lives," said Dr. Jay Mei, founder, Chairman and CEO of Antengene. "The successful initiation of the SIENDO trial is a further step in helping us to explore additional solid tumor indications for the drug candidate. We believe that selinexor has the potential to play an important role in improving treatment options for patients with endometrial cancer. We look forward to working with sites and our partners to execute this trial. If data are positive, we will soon make this innovative therapy available to patients in China and around the world."

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[1] Reference: Qingliang ZENG, China Maternal and Child Health, 2021, 36(08), 1723-1725 DOI:10.19829/j.zgfybj.issn.1001-4411.2021.08.006

**About Selinexor (XPOVIO®)**

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

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 with bortezomib and dexamethasone for patients with 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. In March 2021, the European Commission (EC) has granted conditional marketing authorization for selinexor (NEXPOVIO®) 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, including five late-stage clinical trials, of selinexor in China for the treatment of MM, DLBCL, endometrial cancer, non-small cell lung cancer, and peripheral T and NK/T-cell lymphoma. Furthermore, Antengene has submitted New Drug Applications (NDAs) for selinexor in multiple Asia Pacific markets including China, Australia, South Korea, and Singapore, and was granted the Priority Review status by China's NMPA and an Orphan Drug Designation by the Ministry of Food and Drug Safety of South Korea (MFDS).

## 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 establishment in 2017, Antengene has built a broad and expanding pipeline of clinical and pre-clinical stage assets through partnerships as well as in-house drug discovery, and obtained 14 investigational new drug (IND) approvals and submitted 5 new drug applications (NDA) in multiple markets in Asia Pacific. Antengene's vision is to "Treat Patients Beyond Borders". Antengene is focused on and committed to addressing significant unmet medical needs by discovering, developing 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.

* *XPOVIO® and NEXPOVIO® are registered trade mark of Karyopharm Therapeutics Inc..*