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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**

#### **THE SUBMISSION OF NDA FOR SELINEXOR IN TAIWAN FOR THE TREATMENT OF THREE INDICATIONS IN HEMATOLOGIC MALIGNANCIES**

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 in respect of the submission of new drug application (“**NDA**”) for selinexor in Taiwan for the treatment of three indications in hematologic malignancies.

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, July 14, 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 Submits New Drug Application for Selinexor in Taiwan for the Treatment of Three Indications in Hematologic Malignancies**

- In July 2019, selinexor (XPOVIO®) was approved by the U.S. FDA and became the first and only XPO1 inhibitor indicated for the treatment of hematologic malignancies.
- Selinexor has been approved in the U.S., Israel, UK, and EU countries.

Shanghai and Hong Kong, PRC, July 14, 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 it has submitted a New Drug Application (NDA) to the Taiwan Food and Drug Administration (TFDA) for selinexor, a first-in-class XPO1 inhibitor, for three indications: in combination with bortezomib and dexamethasone (XVd), or in combination with dexamethasone (Xd) for the treatment of patients with relapsed and/or refractory multiple myeloma (RRMM); and as monotherapy in adult patients with relapsed and/or refractory diffuse large B-cell lymphoma (rrDLBCL), including DLBCL arising from follicular lymphoma, who have received at least two lines of systemic therapy.

Antengene has submitted New Drug Applications (NDAs) for selinexor in multiple Asia Pacific markets including China, Australia, South Korea, and Singapore, and was granted Priority Review status by China’s National Medical Products Administration (NMPA) and Orphan Drug Designation by the Ministry of Food and Drug Safety of South Korea (MFDS). This NDA submitted in Taiwan marks another milestone in Antengene’s expansion in the APAC markets and the company’s effort to address the unmet clinical needs of patients with hematologic malignancies.

Dr. Jay Mei, Founder, Chairman and CEO of Antengene, commented: “Within just nine months, we have submitted NDAs in six APAC markets, demonstrating our commitment to addressing the unmet needs of patients in the APAC region. Our seasoned team has a wealth of experience and depth of insight in product registration and commercialization in the Asia Pacific markets. I am confident that Antengene will deliver on our promise to bring our portfolio of innovative therapies to patients in the APAC markets.”

“Selinexor is an anti-tumor drug with a highly novel mechanism of action. It has been approved by the FDA for three indications in two tumor types (MM and DLBCL) in less than two years, demonstrating its broad anti-tumor effects,” said Kevin Lynch, Chief Medical Officer of Antengene. “Selinexor treatment in combination with dexamethasone still has 25.3% overall response rate (ORR) in patients who have failed five established therapies (penta-refractory) myeloma; and for patients with multiple myeloma who received at least one prior line of treatment, the median progression-free survival (PFS) is 13.9 months, which is significantly higher than that of the control group receiving bortezomib-based standard of care. In the subgroup analysis, patients who are 65 years or older, with renal insufficiency or high-risk cytogenetics can still achieve significant benefits from the XVd regimen. These are patients who are otherwise very difficult to treat. Finally, selinexor monotherapy can enable patients with rrDLBCL to obtain deep and durable responses with a median duration of response of 23.0 months for patients with complete response. We are therefore very optimistic about the potential efficacy benefits of selinexor combination regimens in DLBCL.”

Antengene and Karyopharm Therapeutics Inc. (NASDAQ: KPTI) have entered into an exclusive collaboration and license agreement for the development and commercialization of selinexor and other two XPO1 inhibitors, and a PAK4/NAMPT inhibitor in 17 APAC markets including Mainland China.

### **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, 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 RRMM and in June 2020 approved selinexor as a single-agent for the treatment of rrDLBCL. In December 2020, selinexor also received FDA approval as a combination treatment (XVd) for MM 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 (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 five late-stage clinical trials of selinexor in China for the treatment of MM, DLBCL, non-small cell lung cancer, and peripheral T and NK/T-cell lymphoma.

## **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 15 investigational new drug (IND) approvals and submitted 6 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.