# 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 NDA BY THE MFDS FOR ATG-010 (SELINEXOR) FOR THE TREATMENT OF RELAPSED OR REFRACTORY MULTIPLE MYELOMA AND DIFFUSE LARGE B-CELL LYMPHOMA

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 South Korean Ministry of Food and Drug Safety ("**MFDS**") has approved the Company's New Drug Application ("**NDA**") for the orphan drug-designated first-in-class oral inhibitor of XPO1, ATG-010 (selinexor), in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma and as a monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma.

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, July 30, 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 the Approval of First-in-Class Oral XPO1 Inhibitor Selinexor in South Korea for the Treatment of Relapsed or Refractory Multiple Myeloma and Diffuse Large B-Cell Lymphoma**

Shanghai and Hong Kong, PRC, July 30, 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 through a priority review process, the South Korean Ministry of Food and Drug Safety (MFDS) has approved the company's New Drug Application (NDA) for the Orphan Drug-designated first-in-class oral inhibitor of XPO1, selinexor (XPOVIO®), in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (rrMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody (penta-refractory); and as a monotherapy for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (rrDLBCL) who have received at least two prior lines of treatment.

**Introduction of a practice-changing therapy for MM and DLBCL patients**

Most patients with MM eventually suffer from relapse or become refractory diseases. For patients who have failed in one therapy, diffuse large B-cell lymphoma (DLBCL) has poor prognosis and the chance of cure or long-term disease-free survival declined every time getting worse after treatment. At present, there is no cure for rrMM and rrDLBCL and it is in dire need for safer and more effective therapies.

In October 2020, selinexor was granted an Orphan Drug Designation (ODD) in South Korea, where the term "Orphan Drug" is defined by the MFDS as therapies used to treat diseases affecting 20,000 or fewer patients and therapies used to treat diseases for which no appropriate therapy has been developed, or therapies that have demonstrated significant improvement in safety and/or efficacy compared to existing treatments.

**A new mechanism of action with a broad therapeutic window**

Selinexor's novel mechanism of action (MoA) which is based on the selective inhibition of the nuclear export protein XPO1, is different from that of all currently approved therapies. The drug can be combined with various therapies to deliver improved treatment outcomes in these diseases. To date, five selinexor-based regimens have been added to the National Comprehensive Cancer Network (NCCN®) Guidelines.

In addition, a number of international multicenter clinical trials in respect of selinexor are jointly carried out in places such as North America, Europe, Australia, Asia. These include the study of XPORT-DLBCL-030 in international multicenter clinical trials in combination with R-GDP for the treatment of rrDLBCL, and the study of SIENDO in international multicenter clinical trials of monotherapy of endometrial neoplasms.

Minyoung Kim, General Manager of Antengene, commented: "We are very encouraged by the MFDS' approval of selinexor. I am confident that this oral selective inhibitor of nuclear export protein, with its practice-changing therapeutic utility, will improve the quality of life of patients with rrMM and rrDLBCL in South Korea, and bring renewed hope to this patient population."

**About Selinexor**

Selinexor is a currently first-in-class and only-in-class oral selective inhibitor of nuclear export (SINE) compound approved by the US Food and Drug Administration (FDA), also the first drug approved for the treatment of multiple myeloma and diffuse large B-cell lymphoma. Selinexor promotes nuclear storage and activation of tumor-suppressor proteins and other growth-regulating proteins by selectively inhibiting of the nuclear export protein XPO1, and induces the apoptosis of tumor cells by down-regulating the intracytoplasmic levels of various oncogenic proteins without affecting normal cells. Based on this novel mechanism of action, selinexor can be combined with various therapies for improved treatment outcomes.

**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, 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.