

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 I/II STUDY OF SELINEXOR (ATG-010) IN PATIENTS WITH NON-HODGKIN LYMPHOMA 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 China’s National Medical Products Administration (“**NMPA**”) has approved a single-arm dose-finding Phase I/II study designed to evaluate the safety of selinexor (ATG-010) in combination with the R2 regimen of lenalidomide plus rituximab for the treatment of relapsed/refractory diffuse large B-cell lymphoma (rrDLBCL) and relapsed/refractory indolent non-Hodgkin lymphoma (rriNHL).

This is a voluntary announcement made by the Company. The Group cannot guarantee that ATG-010 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, November 19, 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 IND Approval in China for a Phase I/II Study of Selinexor (ATG-010) in Patients with Non-Hodgkin Lymphoma

Shanghai and Hong Kong, PRC, November 19, 2021 – Antengene Corporation Limited (“**Antengene**”, SEHK: 6996.HK), a leading innovative global biopharmaceutical company dedicated to discovering, developing and commercializing first-in-class and/or best-in-class therapeutics in hematology and oncology, today announced that the **China National Medical Products Administration (NMPA) has approved a single-arm dose-finding Phase I/II study designed to evaluate the safety of selinexor (ATG-010) in combination with the R2 regimen of lenalidomide plus rituximab for the treatment of relapsed/refractory diffuse large B-cell lymphoma (rrDLBCL) and relapsed/refractory indolent non-Hodgkin lymphoma (rriNHL) (the “SWATCH” study).**

NHL is one of the most prevalent hematologic malignancies in China and in the world. In 2016, China reported 68,500 newly diagnosed NHL cases and 37,600 NHL-related deaths, which accounted for 14.9% and 15.7% of the NHL incidences and deaths reported globally. The age-standardized incidence rate, mortality rate, and prevalence of NHL in China are 4.29, 2.45, and 14.9 per 100,000, respectively, and both incidence and mortality rates have been on the rise with the increase in age. Although rituximab in combination with various chemotherapies can deliver significant improvement to the overall survival (OS) of patients with NHL, rriNHL represent an urgent unmet need. Further, while there have been promising advances in rrDLBCL treatment, effective treatment remains a challenge.

Ruijin Hospital of Shanghai Jiaotong University School of Medicine is the lead site in China for this 10-center study. The first segment of study will enroll patients with rrDLBCL in a dose-escalation phase, the second subsequent dose-expansion phase will enroll patients with either rrDLBCL (arm A) or rriNHL (arm B). Enrolled patients will be treated with selinexor in combination with the R2 regimen of lenalidomide plus rituximab (SR2). The objective of the Phase I/II study is to determine the treatment dose of the SR2 regimen, and evaluate the safety, tolerability, and preliminary efficacy of the combination regimen in patients with rrDLBCL or rriNHL who are not eligible for high-dose chemotherapy (HDC) or autologous stem cell transplantation (ASCT).

Prof. Weili Zhao, Chief Physician of the Hematology Department, Ruijin Hospital of Shanghai Jiaotong University School of Medicine, Vice Chair of the Chinese Society of Hematology, Vice Chair of the Lymphoma Alliance of the Chinese Society of Clinical Oncology, and the principal investigator of the study, commented: “With the current standard of care treatments, some patients with DLBCL or iNHL would still eventually relapse or become refractory, thus face a dismal prognosis. Therefore, we urgently need new therapies with novel mechanisms and fresh combination strategies that can bring this patient population greater survival benefits. This is the breakthrough we clinicians have been hoping for. Selinexor monotherapy has already been approved by the U.S. FDA for the treatment of rrDLBCL. In this Phase I/II study, we will evaluate the safety and tolerability of selinexor in combination with the R2 regimen in patients with rrDLBCL or rriNHL ineligible for HDC/ASCT. We hope the SR2 regimen will offer a more effective treatment option to patients with rriNHL.”

Dr. Jay Mei, Founder, Chairman and CEO of Antengene, noted: “We are pleased that the NMPA has approved the single-arm dose-finding Phase I/II study designed to assess the safety and efficacy of selinexor plus the R2 regimen for the treatment of rrDLBCL and rriNHL. Selinexor (ATG-010) is Antengene’s first commercial-stage program. This study highlight’s Antengene’s complementary approach of developing new regimen and the Company’s dedication to select diseases, such as rriNHL, an indication for which selinexor is not approved by the U.S. FDA yet but still represents an urgent unmet clinical need in the APAC region. We look forward to advancing this study under the supervision of the NMPA, in an effort to develop a safe and effective new treatment regimen for patients with rrDLBCL and rriNHL.”

About the SWATCH Study

This open-label, multicenter, single-arm Phase I/II study comprises a dose-escalation phase and a dose-expansion phase, and is designed to evaluate the safety, tolerability, and preliminary efficacy of selinexor in combination with lenalidomide and rituximab (R2) for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (rrDLBCL) and relapsed/refractory indolent non-Hodgkin lymphoma (rriNHL). The primary endpoints of the study are the maximum-tolerated dose (MTD) and the recommended Phase II dose (RP2D) determined by the dose-limiting toxicity (DLT) observed in the dose-escalation phase as well as other key safety measures including the frequency of adverse events (AEs) and severe adverse events (SAEs). Secondary endpoints include objective response rate (ORR), progression-free survival (PFS), and duration of response (DOR) of the SR2 regimen as assessed per the Lugano 2014 criteria for the assessment of lymphoma (Cheson, 2014).

About Antengene

Antengene Corporation Limited (“**Antengene**”, SEHK: 6996.HK) is a leading clinical-stage R&D-driven global biopharmaceutical company focused on innovative first-in-class/best-in-class therapeutic 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 beginning operation in 2017, **Antengene has obtained 19 investigational new drug (IND) approvals, submitted 6 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for selinexor (ATG-010) 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 15 clinical and pre-clinical assets. The Company has global rights on 10 programs and Asia Pacific rights, including the Greater China region, on 5 programs.** 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.