Antengene Announces NDA Approval by NMPA for XPOVIO®, China's First XPO1 inhibitor, for the Treatment of Adults with Relapsed or Refractory Multiple Myeloma

XPOVIO® is Antengene's first product approval in China
XPOVIO® is the first and only XPO1 inhibitor approved in China

Antengene Corporation Limited (the "Company" or "Antengene") is pleased to announce that **ATG-010 (selinexor, brand name: XPOVIO®), a first-in-class, oral Selective Inhibitor of Nuclear Export (SINE) compound has received conditional approval for marketing by the National Medical Products Administration** (the "NMPA"), applicable in combination with dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received prior therapy including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. **XPOVIO® is China's first approved XPO1 inhibitor.** The conditional approval of XPOVIO® was based on the global Phase 2 STORM trial as well as the positive results from the Phase 2 MARCH trial. The ongoing, randomized Phase 3 BENCH study in China, evaluating selinexor in combination with bortezomib and low-dose dexamethasone for patients with multiple myeloma as early as first relapse, will serve as the confirmatory trial.

Antengene will host conference calls for investors on December 20, 2021 (China Standard Time).

Dr. Jay Mei, M.D., Ph.D., Chairman and Chief Executive Officer of Antengene commented, "Our mission is to bring first-in-class/best-in-class medicines to the market for patients with cancer and other life-threatening diseases. I am pleased that XPOVIO® is Antengene's first product to be approved in China and the first and only XPO1 inhibitor on the market in China."

Dr. Mei continued, "We believe the approval of XPOVIO® will bring important clinical benefits to Chinese patients with refractory or relapsed multiple myeloma. XPOVIO® is approved in three indications in the U.S., including in second line multiple myeloma, and the product has been widely adopted into practice guidelines by major oncology networks including the Chinese Society of Clinical Oncology (CSCO) in China, the National Comprehensive Cancer Network (NCCN) in the U.S. and the European Society for Medical Oncology (ESMO) in the EU. These are very positive steps to enabling product acceptance and adoption."

Dr. Kevin Lynch, M.D., Chief Medical Officer of Antengene commented, "With XPOVIO®'s approval in China, Antengene can offer a new, much needed therapeutic

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option to Chinese patients with RRMM. We believe selinexor has broad potential in oncology and are committed to advance further development of the product though our program of 10 clinical studies in China. These include the confirmatory Phase 3 BENCH study for multiple myeloma patients after at least one prior therapy, as well as studies in other oncology indications that have strong relevance for patients in China."

Dr. Lynch continued, "Antengene would like to thank all of the patients and investigators involved in the clinical study and the NMPA for their support during the priority review. Together, we are aiming to improve the care and lives of people with cancer in China and around the world."

Antengene Conference Call Details
Antengene management will hold conference calls on Monday, December 20, 2021 to discuss the approval in China of ATG-010/XPOVIO®:

Monday, December 20, 2021 at 9:00 a.m. Beijing Standard Time: In English
(Sunday, December 19, 2021 at 8:00 p.m. ET)
Registration Link:
https://goldmansachs.zoom.us/webinar/register/WN_wDleCuF4Qfij1xTNU3pAkg
Meeting ID: 981 2215 4695
Passcode: 253504

Monday, December 20, 2021 at 10:00 a.m. Beijing Standard Time: In Chinese
(Sunday, December 19, 2021 at 9:00 p.m. ET)

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Singapore： +65-6622 0840

UK：+44 20 3761 0113

USA：+1-646 357 8788

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Pivotal STORM and MARCH Trials
The conditional approval of XPOVIO® was based on results from the global Phase 2 STORM trial as well as the Phase 2 MARCH trial in China evaluating the efficacy and safety of selinexor plus dexamethasone in 82 patients with relapsed/refractory multiple myeloma (RRMM).

Results of the **STORM trial** showed that the overall response rate (ORR), the primary endpoint, as assessed by an Independent Review Committee (IRC), based on the International Myeloma Working Group (IMWG) Uniform Response Criteria, was 25.3% for the prespecified subgroup of 83 patients whose disease was refractory to bortezomib, carfilzomib, lenalidomide, pomalidomide, and daratumumab.

Results of the **MARCH trial** showed that the efficacy and safety in Chinese patients whose disease was refractory to both lenalidomide and bortezomib, as well as the last line of therapy (with some also refractory to anti-CD38 monoclonal antibody), were generally consistent with that seen in the global study. The overall response rate, the primary endpoint, as assessed by an Independent Review Committee (IRC), was 29.3%, for all treated patients in the MARCH trial and 25% for patients refractory to at least a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody.

The ongoing, randomized Phase 3 BENCH study evaluating selinexor in combination with bortezomib and low-dose dexamethasone will serve as the confirmatory trial.

About the SINE Compounds

SINE (Selective Inhibitor of Nuclear Export) compounds are inhibitors of the major nuclear export protein Exportin 1 (XPO1). Currently, there are three oral SINE compounds, ATG-010 (selinexor), ATG-016 (eltanexor), and ATG-527 (verdinexor), under clinical development. Antengene has an exclusive license from Karyopharm Therapeutics Inc. ("Karyopharm") to these compounds in certain APAC markets.

About ATG-010/Selinexor/ XPOVIO®

Selinexor is the first and only oral XPO1 inhibitor approved by the U.S. Food and Drug Administration (FDA). By blocking the nuclear export protein XPO1, selinexor can promote the intranuclear accumulation and activation of tumor suppressor proteins and growth regulating proteins, and down-regulate the levels of multiple oncogenic proteins. This induces apoptosis without affecting normal cells. Due to its novel mechanism of action, selinexor is being evaluated for use in multiple combination regimens to improve treatment efficacy.

Selinexor is approved by the U.S. FDA for the treatment of relapsed/refractory multiple myeloma (RRMM), second line multiple myeloma and relapsed/refractory diffuse large B–cell lymphoma.

Antengene obtained approval of selinexor in South Korea through a priority review process prior to the current approval by NMPA in China. Antengene is conducting 10 studies with selinexor in mainland China (3 in collaboration with Karyopharm) for relapsed/refractory/advanced hematological malignancies and advanced solid tumors.

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 cancer and other life-threatening diseases. Driven by its vision of "**Treating Patients Beyond Borders**", Antengene aims to provide the most advanced anti-cancer drugs to patients in the Asia Pacific Region and around the world. Since initiating operations in 2017, Antengene has obtained 20 investigational new drug (IND) approvals in the U.S. and in Asia, submitted 6 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for selinexor/ATG-010 in South Korea and mainland China 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.

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.

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