



**Antengene Announces NDA Submission for XPOVIO® in  
Macau, China, Malaysia and Thailand for  
Relapsed/Refractory Multiple Myeloma and  
Relapsed/Refractory Diffuse Large B-cell Lymphoma**

Shanghai and Hong Kong, PRC, December 23, 2022 — Antengene Corporation Limited ( **“Antengene”** SEHK: 6996.HK), a leading innovative, commercial-stage 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 **it has submitted New Drug Applications (NDAs) for XPOVIO® (selinexor) to the Pharmaceutical Administration Bureau of Macau, Malaysian National Pharmaceutical Regulatory Agency and Thai Food and Drug Authority** for the treatment of relapsed/refractory multiple myeloma (R/R MM) and relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL). **The Company also plans to submit an NDA for XPOVIO® in Indonesia in the first half of 2023.**

“Filing these NDAs in Macau, China, Malaysia and Thailand is an important step in the next wave of geographic expansion for XPOVIO® and Antengene,” said **Thomas Karalis, Antengene’s Corporate Vice President, Head of Asia Pacific Region.** “With limited access to novel



agents in these markets and with large populations, a high unmet medical need exists in management of both patients with MM and DLBCL. When approved, XPOVIO® will offer an important novel treatment option in the care of patients with these life threatening diseases in Macau, China, Malaysia and Thailand.”

“Antengene is executing on our strategy to bring transformative medicines to patients around the world. The APAC/ ASEAN markets are an important cornerstone of our commercial strategy and so we are very pleased to complete the NDA filings for XPOVIO® in Macau, China, Malaysia and Thailand,” said **Dr. Jay Mei, Antengene’s Founder, Chairman and CEO.** “Based on our robust clinical data package and positive commercial experience to date, we feel that, if approved in these markets, we will be well prepared to effect a successful launch of XPOVIO® in order to support patient uptake and enable improved outcomes for patients with R/R MM and R/R DLBCL. We look forward to working with each regulatory agency as the reviews progress.”

### **About XPOVIO® (selinexor)**

XPOVIO® is the world’s first approved orally-available, selective inhibitor of the nuclear export protein XPO1. **It offers a novel**



**mechanism of action, synergistic effects in combination regimens, fast onset of action, and durable responses.**

By blocking the nuclear export protein XPO1, XPOVIO® can promote the intranuclear accumulation and activation of tumor suppressor proteins and growth regulating proteins, and down-regulate the levels of multiple oncogenic proteins. XPOVIO® delivers its antitumor effects through three mechanistic pathways: 1) exerting antitumor effects by inducing the intranuclear accumulation of tumor suppressor proteins; 2) reducing the level of oncogenic proteins in the cytoplasm by inducing the intranuclear accumulation of oncogenic mRNAs; 3) restoring hormone sensitivity by activating the glucocorticoid receptors (GR) pathway. To utilize its unique mechanism of actions, XPOVIO® is being evaluated for use in multiple combination regimens in a range of indications. At present, Antengene is conducting 8 clinical studies of XPOVIO® in mainland China for the treatment of relapsed/refractory hematologic malignancies and solid tumors (3 global clinical studies of these are being jointly conducted by Antengene and Karyopharm Therapeutics Inc. [Nasdaq:KPTI]).

**XPOVIO® is approved in South Korea for the following two indications:**

- In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) 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.
- As a monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

**XPOVIO® is approved in mainland China for the following indication:**

- In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) who have received prior therapies and whose disease is refractory to at least one proteasome inhibitor, at least one



immunomodulatory agent, and an anti-CD38 monoclonal antibody.

**XPOVIO® is approved in Taiwan, China for the treatment of the following three indications:**

- In combination with dexamethasone (Xd) for the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors (PIs), at least two immunomodulatory agents (IMiDs), and an anti-CD38 monoclonal antibody.
- In combination with bortezomib and dexamethasone (XVd) for the treatment of adult patients with MM who have received at least one prior therapy.
- As a monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

**XPOVIO® is approved in Australia for the following two indications:**

- In combination with bortezomib and dexamethasone (XVd) for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy.
- In combination with dexamethasone (Xd) for the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) who have received at least three prior therapies and whose disease is refractory to at least one proteasome inhibitor (PI), at least one immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (mAb).

**XPOVIO® is approved in Singapore for the following three indications:**

- In combination with bortezomib and dexamethasone for treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy.
- In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (R/R MM) 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.



- As a monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy who are not eligible for haematopoietic cell transplant.

### **About Antengene**

Antengene Corporation Limited ( **“Antengene”** , SEHK: 6996.HK) is a leading commercial-stage R&D-driven global biopharmaceutical company focused on the discovery, development, manufacturing and commercialization of innovative first-in-class/best-in-class therapeutics for the treatment of hematologic malignancies and solid tumors, driven by its vision of **“Treating Patients Beyond Borders”** .

Since its founding in 2017, Antengene has built a broad and expanding pipeline of 13 clinical and preclinical assets, including 10 assets with global rights and 3 with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 27 investigational new drug (IND) approvals in Asia and



the U.S., and submitted 9 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in mainland China, Taiwan, China, South Korea, Singapore and Australia.

### **Forward-looking statements**

The forward-looking statements made in this document relate only to the events or information as of the date on which the statements are made in this document. Except as required by law, Antengene undertakes 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 document completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this document, 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 document. Any of these intentions may be altered in light of future development. For a further discussion of these and other factors that could cause future





results to differ materially from any forward-looking statement, see the section titled “Risk Factors” in our periodic reports filed with the Hong Kong Stock Exchange and the other risks and uncertainties described in the Company’s Annual Report for year-end December 31, 2021, and subsequent filings with the Hong Kong Stock Exchange.