



## **Antengene Announces NDA Submission for XPOVIO® in Indonesia**

Shanghai and Hong Kong, PRC, May 17, 2023 — 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 Indonesia National Agency of Drug and Food Control (BPOM)** for the treatment of relapsed/refractory multiple myeloma (R/R MM) and relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL). **In Q4 2022, Antengene also submitted NDAs for XPOVIO® in Malaysia and Thailand.**

“In just six months, we have submitted NDAs for XPOVIO® in three ASEAN countries, Malaysia, Thailand and Indonesia, supporting our plans to expand commercial presence in the APAC region,” said **Thomas Karalis, Antengene’s Corporate Vice President, Head of Asia Pacific Region.** “In a region characterized by countries with large populations and in many cases a lack of access to novel therapeutics, patients with R/R MM or DLBCL have urgent unmet needs for innovative, effective treatments. We



hope XPOVIO® can address this unmet need and bring a new treatment option to patients with R/R MM and R/R DLBCL in these underserved markets.”

“Established in China with a growing presence in the APAC region and a clear roadmap for global expansion, Antengene is striving to build up strong commercial capabilities in the ASEAN countries that has a total population exceeding 600 million and establish a global commercial infrastructure that will allow us to bring more breakthrough therapies to patients around the world,” said **Dr. Jay Mei, Antengene’s Founder, Chairman and CEO**. “In the past six months, we submitted NDAs for XPOVIO® in three key ASEAN countries. This achievement is a testament to the effective execution by our teams and the company’s commitment to bringing more innovative drugs to patients around the world. Moving forward, we will continue to excel in execution and maintain close contacts with the regulatory authorities of these countries for the approval of XPOVIO®.”

### **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, in realizing its vision of **“Treating Patients Beyond Borders”** .

Since 2017, Antengene has built a pipeline of 9 oncology assets at various stages going from clinical to commercial, including 6 with global rights, and 3 with rights for the APAC region. To date, Antengene has obtained 28 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 10 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 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. For a further discussion of these and other factors that could cause future results to differ materially from any forward-looking statement, see the other risks and uncertainties described in the Company's Annual Report for year-end December 31, 2022, and subsequent filings with the Hong Kong Stock Exchange.