Antengene Announces XPOVIO® Regulatory Approval in Taiwan for the Treatment of Relapsed and/or Refractory Multiple Myeloma and Diffuse Large B-Cell Lymphoma

- *XPOVIO® is the **first and only exportin 1 (XPO1) inhibitor** approved in **Taiwan***
- *Antengene plans to submit for **national health insurance reimbursement in Taiwan for XPOVIO®** in Q4 2022*

Shanghai and Hong Kong, PRC, October 21, 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 **the Taiwan Food and Drug Administration (TFDA) has approved a New Drug Application (NDA) for XPOVIO® (selinexor) for three indications:** (1) in combination with dexamethasone (Xd) for the treatment of adult patients with relapsed/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

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antibody; or (2) in combination with bortezomib and dexamethasone (XVd) for the treatment of adult patients with MM who have received at least one prior therapy; and (3) as a monotherapy for the treatment of adult patients with relapsed/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 the world's first oral selective inhibitor of the nuclear export protein XPO1, with regulatory approvals in 13 countries and regions including the United States, Israel, the United Kingdom, the European Union, Canada, Norway, Iceland, Lichtenstein, South Korea, Mainland China, Taiwan,China, Singapore and Australia**. To date, multiple XPOVIO® regimens have been added to the clinical guidelines of major oncology societies in the U.S., the EU, and APAC,** including 5 regimens for the treatment of myeloma and 1 regimen for the treatment of lymphoma added to the guidelines of the National Cancer Care Network (NCCN); 4 regimens for the treatment of myeloma and 1 regimen for the treatment of lymphoma added to the guidelines of the Chinese Society of Clinical Oncology (CSCO); 4 regimens for the treatment of myeloma added to the Guidelines for the Diagnosis and Management of Multiple Myeloma in China; 2 regimens for the treatment of myeloma added to the guidelines

of the European Society of Medical Oncology (ESMO); and 1 regimen for the treatment of myeloma added to the guidelines of the International Myeloma Working Group (IMWG).

"Antengene is very pleased to receive regulatory approval for XPOVIO® in Taiwan for R/R MM and R/R DLBCL. There remains an unmet need to extend survival for patients with these life-threatening diseases and XPOVIO® presents Taiwan physicians and patients with a new novel addition to existing therapies. We continue to build our Antengene presence across APAC markets and in Taiwan. We also look forward to introducing XPOVIO® and securing reimbursement in order to extend access to this first in class therapy for our physicians and patients." said **Thomas Karalis, Antengene's Corporate Vice President, Head of Asia Pacific Region.**

"XPOVIO® is approved in multiple markets in the APAC region. This novel product fulfills Antengene's mission to bring first-in-class/best-in-class medicines to patients with cancer in APAC markets and beyond," said **Mr. John Chin, Antengene's Chief Business Officer.** "Antengene is currently conducting eight clinical studies of XPOVIO® in mainland China for the treatment of patients with relapsed/refractory hematologic malignancies

or solid tumors, and the drug's safety and efficacy have already been validated in five registrational trials. Moving forward, we will strive to develop and commercialize more first-in-class and best-in-class drugs for patients with cancer or other life-threatening diseases."

About Multiple Myeloma

Multiple myeloma (MM) is caused by the dysregulated proliferation of plasma cells. It is the second most common hematologic malignancy in many countries and regions. Despite availability of a number of treatments for relapsed patients, MM is prone to relapse and most patients still succumb to their disease. MM is the second most common hematologic malignancy in Taiwan, with an estimated about 700 to 800 new MM patients and 400 deaths per year[1].

About Diffuse Large B-Cell Lymphoma

Diffuse large B-cell lymphoma (DLBCL) is an aggressive hematologic malignancy and the most common subtype of lymphoma in Taiwan[2].

While there have been promising advances in therapy, options are limited, and effective treatment remains a challenge. Indeed, it is reported approximately 50% of patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) continue to lack effective treatment options[3].

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]).

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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 on 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 broad and expanding pipeline of 15 clinical and preclinical assets, of which 10 are global rights assets, and 5 came with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 24 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 6 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 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.

References

1. 2019 Cancer Registry Annual Report, Health Promotion Administration of Taiwan Ministry of Health and Welfare

2. Subtype- specific epidemiology of lymphoid malignancies in Taiwan compared to Japan and the United States, 2002- 2012

Cancer Medicine. 2018;1-12

3. Wang Z, Zhou C, Feng X, Mo M, Shen J, Zheng Y. Comparison of cancer incidence and mortality between China and the United States, Precis

Cancer Med 2021; 4:31

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