# Antengene Announces XPOVIO® Regulatory Approval in Hong Kong for the Treatment of Relapsed and/or Refractory Multiple Myeloma

- *XPOVIO® (selinexor) is the **first and only XPO1 inhibitor** approved in **Hong Kong***
- XPOVIO® **has received regulatory approvals in 41 countries and regions** including the United States, Israel, the United Kingdom, the European Union (the 27 member countries including France and Italy), Canada, Norway, Iceland, Lichtenstein, South Korea, mainland of China, Taiwan China, Hong Kong China, Singapore, Australia and Northern Ireland.

Shanghai and Hong Kong, PRC, July 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 **the Department of Health, the Government of the Hong Kong Special Administrative Region (HKSAR) has approved a New Drug Application (NDA) for XPOVIO® (selinexor), applicable in combination with dexamethasone (Xd), for the treatment of adult patients with** relapsed and/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), two immunomodulatory agents (IMiDs), an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

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**XPOVIO®** **is the world's first oral selective inhibitor of the nuclear export protein (XPO1), with regulatory approvals in 41 countries and regions** including the United States, Israel, the United Kingdom, the European Union (the 27 member countries including France and Italy), Canada, Norway, Iceland, Lichtenstein, South Korea, mainland of China, Taiwan China, Hong Kong China, Singapore, Australia and Northern Ireland. **To date, 6 XPOVIO® regimens received a total of 27 inclusions into 7 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)
- 5 regimens for the treatment of myeloma added to the guidelines for the Diagnosis and Management of First Relapsed Multiple Myeloma in China
- 4 regimens for the treatment of myeloma added to the guidelines for the Diagnosis and Management of Multiple Myeloma in China
- 4 regimens for the treatment of myeloma added to the China Anti-Cancer Association's Guidelines for the Holistic Integrative Management of Cancers (CACA)
- 2 regimens for the treatment of myeloma added to the guidelines of the European Society of Medical Oncology (ESMO)

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- 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 Hong Kong. Despite recent advances in the treatment of R/R MM, there remains an unmet need to extend survival for patients with this life-threatening disease and the approval of XPOVIO® presents Hong Kong patients with access to a novel therapy in their treatment of R/R MM. We will continue to build out Antengene's presence across APAC markets and strive to expand the indications of XPOVIO® in Hong Kong and the broader APAC region, in efforts to bring renewed hope to more cancer patients." said **Thomas Karalis, Antengene's Corporate Vice President, Head of Asia Pacific Region.**

"I am pleased that XPOVIO® has become the first and only XPO1 inhibitor approved for the treatment of R/R MM in Hong Kong," said **Dr. Jay Mei, Antengene's Founder, Chairman and CEO.** Dr. Mei continued, "the Company's Named Patient Program (NPP), a growing group of investigator-sponsored studies and ongoing advisory boards have helped us to ready the path for the successful adoption of XPOVIO® in Hong Kong. Moving forward, we will establish access to ASEAN markets that have a total population exceeding 600 million. To date, Antengene has successfully submitted NDAs in Macau China, Thailand, Malaysia and Indonesia."

**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. 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 China, with an estimated about 15,000 to 20,000 new MM patients and 10,300 deaths per year.[1]

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 of China for the treatment of relapsed/refractory hematologic malignancies and solid tumors (3 of these studies 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 of 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 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 Hong Kong 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 at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors (PIs), two immunomodulatory agents (IMiDs), an anti-CD38 monoclonal antibody (mAb), and who have demonstrated disease progression on the last 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 29 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 of China, Taiwan China, Hong Kong 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, please see the other risks and uncertainties described in the Company's Annual Report for the year ended December 31, 2022, and the documents subsequently submitted to the Hong Kong Stock Exchange.

## Reference

[1]. Statistics released by the International Myeloma Foundation at

https://www.myeloma.org/