



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

- *XPOVIO® (selinexor) is the first and only exportin 1 (XPO1) inhibitor approved in Macau.*
- *XPOVIO® has received regulatory approvals in 42 countries and regions including Mainland of China, Taiwan China, Hong Kong China, Macau China, South Korea, Singapore and Australia.*

Shanghai and Hong Kong, PRC, December 6, 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 Pharmaceutical Administration Bureau of Macau 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

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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.

XPOVIO® is the world's first oral selective inhibitor of the nuclear export protein XPO1, with regulatory approvals in 42 countries and regions including Mainland of China, Taiwan China, Hong Kong China, Macau China, South Korea, Singapore and Australia. The approved indications for each market can be reviewed below. In addition, multiple XPOVIO® regimens have been added to the clinical practice guidelines of major cancer societies in the U.S., the EU, and APAC, including the National Cancer Care Network (NCCN) Guidelines, the Chinese Society of Clinical Oncology (CSCO) Guidelines, the Guidelines for the Diagnosis and Management of Multiple Myeloma in China, the European Society of Medical Oncology (ESMO) Guidelines, and the International Myeloma Working Group (IMWG) Guidelines.

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“Antengene is excited to receive approval of XPOVIO® in Macau, first in the next wave of expected approvals in the APAC.” said Dr. Jay Mei, Antengene’s Founder, Chairman and CEO. “In recent years, the APAC region has witnessed a rapid growth in the population of patients with R/R MM, adding to the huge unmet clinical need of this patient population. I am glad that XPOVIO® has become the first and only XPO1 inhibitor approved for the treatment of patients with R/R MM in Macau China. To date, XPOVIO® has been approved in seven markets across APAC. While expanding the geographical presence of XPOVIO®, we are also striving to expand the indications of the drug in the region in order to bring renewed hope to more patients and families.”

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

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common hematologic malignancy in China, with an estimated 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

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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.

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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) ,

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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 Macau 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:

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- 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.

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- 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

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in Mainland of China, Taiwan China, Hong Kong China, Macau 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

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ended December 31, 2022, and the documents subsequently submitted to the Hong Kong Stock Exchange.

References

1. Antengene R&D Day, Nov. 15 2022

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