Antengene Announces XPOVIO® plus Bortezomib and Dexamethasone Included for Reimbursement by the PBS in Australia for the Treatment of Relapsed and/or Refractory Multiple Myeloma

- *XPOVIO® (selinexor) is **the first and only** selective inhibitor of nuclear export (SINE) inhibitor approved by the Therapeutic Goods Administration (TGA) of Australia for patients with relapsed and/or refractory multiple myeloma (R/R MM) and in triple class refractory R/R MM.*[1]
- *This inclusion by the Pharmaceutical Benefits Scheme (PBS) for the treatment of patients with R/R MM who have received at least one prior therapy is **the second inclusion of XPOVIO® by the PBS. Prior to this, XPOVIO® in combination with dexamethasone (Xd) was included by the PBS in September 2022.***
- *Results from the Phase III **BOSTON study** showed that the XVd regimen was effective in both young and older patients, frail and non-frail patients, as well as patients with renal impairment. **Importantly, the***

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XVd combination was particularly effective in patients with high-risk cytogenetics.[2-7]

Shanghai and Hong Kong, PRC, June 1, 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 **XPOVIO® (selinexor) in combination with bortezomib and dexamethasone (XVd) is now listed on the PBS for the treatment of adult patients with R/R MM who have received at least one prior therapy.**

MM accounts for about 10% of all blood malignancies and 1.6% of all cancers across Australia.[8] Around 2,400 people are newly diagnosed each year with MM, and around 20,000 patients are living with MM at a time. Sadly, **around 1,000 people will die from this form of blood cancer**

in any given year in Australia,[9] and newly listed XVd offers an additional treatment option for these patients.

In the Phase III BOSTON study, once-weekly XVd demonstrated a significantly greater overall response rate (ORR) compared with twice-weekly Vd, with over three in four patients responding to treatment, including patients with renal impairment as well as patients with both standard-risk and high-risk cytogenetics. **The primary endpoint was progression-free survival (PFS) in the intention-to-treat (ITT) population. The PFS was 13.93 months for once-weekly XVd vs 9.46 months for twice-weekly Vd (HR:0.70 [95%Cl, 0.53,0.93] *p*=0.0075).** The ORRs were 76.4% for XVd vs 62.3% for Vd (OR:1.96 (1.3,3.1) *p*=0.0012). XVd demonstrated a PFS of 21 months in patients aged ≥65 years vs 9.5 months for patients on Vd.[2-7]

Xd is the only PBS-listed treatment clinically proven to work in daratumumab-refractory patients.[1,10] XVd was also associated with a PFS of over 10 months in lenalidomide-refractory patients.[2,3,5-7] XPOVIO®'s

adverse event (AE) profile is predictable, reversible, transient, and manageable through dose adjustment and proactive support care.

Professor Hang Quach, Haematologist, St Vincent's Hospital Melbourne said, "I was privileged to be one of the investigators in the BOSTON study. Selinexor is the first-in-class exportin-1 (XPO1) inhibitor that is effective in the treatment of MM. The XVd regimen is amongst the most effective therapies for early-line relapse in the era of lenalidomide refractoriness.[2,3,5-7] On subset analyses, XVd is effective in both young and older patients, frail and non-frail patients, as well as patients with renal impairment.[2-7] Importantly, the XVd combination was particularly effective in patients with high-risk cytogenetics.[5] The lack of sufficient choices for patients with lenalidomide-refractory MM represents an area of urgent unmet clinical need in Australia and the availability of the XVd regimen as an option in this space will address this unmet need.[2-7]"

Mr Mark Henderson, CEO of Myeloma Australia said "There is a growing need for patients to have more treatment options for MM while this new

and unique treatment class provides us with a strategy to tackle the disease from a new angle.[1,8,9] It's important that patients have more options to treat their myeloma. Myeloma Australia have also been part of a co-designed patient support program with Antengene as part of the familiarisation program for patients receiving the XVd or Xd regimen. This involved our nurses providing expert care and ongoing support to patients with early access to selinexor."

Dr Dan Mellor, Antengene's Medical Director for ANZ said "this second PBS listing for selinexor marks another significant milestone for Antengene in Australia. As a company, we strive to put patients at the core of our decision making, so this is a proud day for the Australian Antengene team. Antengene is also proud to assist in increasing the number of treatments options for patients with relapsed or refractory multiple myeloma, an area of unmet clinical need. The listing of XVd provides subsidised access to an important new treatment option for haematologists and their patients who have had 1 prior line of therapy for their multiple myeloma. Importantly, selinexor is an XPO-1 inhibitor, a

novel target in multiple myeloma treatment with a new mechanism of action.[1,2-10] "

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 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:[1]

- 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

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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 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

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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.

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