

## Antengene Announces XPOVIO® Included for Reimbursement by the PBS in Australia for the Treatment of Patients with 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.
- XPOVIO® is **the first** of a new class of SINE medicines to be made available to Australian patients with **penta-refractory R/R MM** on the Pharmaceutical Benefits Scheme (PBS).

Shanghai and Hong Kong, PRC, September 1, 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

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and/or best-in-class therapeutics in hematology and oncology, today announced that XPOVIO® (selinexor) in combination with dexamethasone (Xd) has been PBS Listed for the treatment of adult patients with R/R MM who have received at least four prior lines of therapy and whose disease is refractory to at least two proteasome inhibitors (PIs), at least two immunomodulatory agents (IMiDs), and an anti-CD38 monoclonal antibody (penta-refractory).

MM accounts for about 10% of all blood malignancies and 1.6% of all cancers in Australia<sup>1</sup>. Around 2,400 people are newly diagnosed each year with MM, and around 20,000 patients are living with MM in any given year. Unfortunately, around 1,000 people will die from this form of blood cancer in any given year<sup>2</sup> in Australia and therefore XPOVIO® is an important new oral treatment option with a unique mode of action.

"In Australia, one critical area of unmet need for patients with myeloma is the lack of effective therapies for patients who are triple-class refractory, that is refractory to a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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Selinexor is an oral drug with a completely novel mechanism of action, capable of inducing meaningful responses and prolong life in a clinically meaningful way", said **Professor Andrew Spencer**, **Haematologist, Alfred Hospital, Melbourne.** 

Ms. Hayley Beer, acting CEO of Myeloma Australia, said "Selinexor is an exciting new class of drug with a unique mode of action. This means that patients will now have access to type of treatment that their myeloma has never come up against before. We are also pleased to have been part of a co-designed patient support program with Antengene as part of the Xd patient familiarisation program where our nurses have provided expert information and support to those who have had early access to selinexor."

Dr. Tamara Etto, Antengene's Senior Medical Director for ANZ said,

"In this new era, where more and more Australian patients are

becoming refractory to IMiDs (lenalidomide, pomalidomide) as well as

proteosome Inhibitors (e.g., bortezomib, carfilzomib) and anti-CD38

monoclonal antibodies (e.g., daratumumab), it is important for patients

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to have access to newly proven treatment options with unique modes of action. It is great news that selinexor has been made available from today for Australian patients with penta-refractory myeloma – the first of this novel class of oral anti-myeloma medications reimbursed by the PBS."

"Having our product included by the PBS for the first time marks a significant milestone for Antengene and for MM patients in Australia. We are confident that as the first SINE inhibitor included by the PBS for the treatment of patients with R/R MM, selinexor will offer Australian physicians and patients a novel addition to their existing treatment options. Moving forward, we will strive to develop and commercialize more first-in-class and best-in-class transformational medicines for cancer and other life-threatening diseases," said **Dr. Jay Mei,**Antengene's Founder, Chairman and CEO.

Antengene is committed to bringing XPOVIO® to Australian patients with R/R MM in earlier stages of their treatment journey in combination with

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bortezomib and dexamethasone (XVd) as quickly as possible and look

forward to working with stakeholders to ensure access for patients.

**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

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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 of these global clinical 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 China for the following indication:

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• 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 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.

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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".

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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, 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

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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.

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