

## **XPOVIO® (selinexor) Approved for New Indication in DLBCL in China, Bringing a New Treatment Option to Patients in the Country**

- *Following its initial approval for the treatment of relapsed/refractory multiple myeloma (R/R MM), XPOVIO® has now received approval as a monotherapy for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) marking the second approved indication of XPOVIO® in China.*
- *Results from the registrational SEARCH study in China showed that the overall response rate (ORR) among the 60 Chinese patients treated with XPOVIO® met the study's prespecified primary endpoint.*
- *XPOVIO® is an oral drug with a novel mechanism of action. Antengene is currently developing multiple combination regimens of XPOVIO® for the treatment of various indications including myelofibrosis (MF), T-cell non-Hodgkin's lymphoma (T-NHL), and endometrial cancer.*



*- XPOVIO® has been approved for health insurance coverage in the mainland of China, Australia, Singapore and South Korea. Furthermore, Antengene has submitted new drug applications (NDAs) for XPOVIO® in other ASEAN markets including Thailand, Malaysia and Indonesia. Approvals in these markets are anticipated in the second half of 2024.*

Shanghai and Hong Kong, PRC, July 5, 2024 — 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 medicines for cancer, today announced that **the China National Medical Products Administration (NMPA) has approved a new indication of XPOVIO® (selinexor) as a monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL).**

## **A Novel Therapy Bringing Long-awaited Clinical Breakthrough to the Treatment of R/R DLBCL**

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DLBCL is one of the most common subtypes of non-Hodgkin lymphoma (NHL) in adults and is highly heterogeneous malignancy in both clinical manifestations and prognosis. The current standard treatment, immunotherapy, offers patients with DLBCL a five-year progression-free survival rate of 60%-65% and curative outcomes for 40%-50% of treated patients. However, 10%-15% of DLBCL patients do not respond to standard first-line treatment, and 20%-25% experience relapses after achieving initial responses, leading to a poor prognosis and enormous unmet clinical needs.

## **The Clinically Validated Efficacy and Convenience of Oral Administration of Selinexor Offer Benefits to a Broad Spectrum of Patients**

**The approval for the new indication was supported by data from the registrational SEARCH study in China.** Results from the study, which enrolled a total of 60 Chinese patients with DLBCL, showed that patients treated in the trial achieved a central radiological review assessed overall response rate (ORR) meeting the pre-specified primary endpoint. The SEARCH study demonstrated clear efficacy of orally-administered selinexor monotherapy in Chinese



patients, exhibiting significant response rates, durable responses, long survival.

**Prof. Jun Zhu, principal investigator of the SEARCH study from Peking University affiliated Beijing Cancer Hospital, said, “DLBCL is the most common subtype of NHL in adults and accounts for 40% of all NHL cases in China. The incidence of NHL has been steadily rising year over year, while patients with third- and later-lines relapsed or refractory disease lack effective and convenient therapies. As a nuclear export protein inhibitor with a novel mechanism of action (MOA), selinexor offers patients a new treatment option that is efficacious and easy to use, with oral availability that can reduce hospitalization and financial burden on patients by allowing them to receive treatment at home. Overall, the approval for this new indication of selinexor is indeed a great news for Chinese patients with R/R DLBCL.”**

**Approved in 40+ Markets Globally with Expanding Insurance Coverage Across APAC**

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With a novel mechanism of action, XPOVIO® is the world's first approved orally-available, selective XPO1 inhibitor. XPOVIO® has a global commercial presence with approvals in over 40 countries and regions. To date, XPOVIO® has already been included for health insurance coverage in the mainland of China, Australia, Singapore and South Korea. Antengene has also submitted the NDAs in additional ASEAN markets, including Thailand, Malaysia and Indonesia, where approvals are expected in the H2 of 2024.

### **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

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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 multiple clinical studies of XPOVIO® in the 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]).

## **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

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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, 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

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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, 2023, and the documents subsequently submitted to the Hong Kong Stock Exchange.

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