

Antengene Announces Commercial Availability of XPOVIO[®] (Selinexor), for the Treatment of Relapsed/Refractory Multiple Myeloma, Prescribed for the First Time Across Mainland China

-Distribution channels in place to streamline/facilitate patient access. -XPOVIO[®] will be available in 600 hospitals and 105 DTPs (across China including Beijing, Shanghai, Guangdong, Jiangsu, Zhejiang, Henan, and Shandong).

Shanghai and Hong Kong, PRC, May 13, 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 and/or best-in-class therapeutics in hematology and oncology, announces that its first commercialized product, the oral XPO1 inhibitor XPOVIO[°] (selinexor) approved for the treatment of relapsed/refractory multiple myeloma (R/R MM), has officially entered multiple hospitals, online-hospitals, and direct-to-patient (DTP) pharmacies in mainland China and widely prescribed in the country for the first time at Shanghai Jiaotong University School of Medicine Ruijin Hospital, Shanghai Jiaotong University School of Medicine Renji Hospital, Tongji Hospital of Tongji University, Shanghai Sixth People's Hospital, Shanghai Jiaotong School of Medicine St. Luke's Hospital, and the PLA Naval Medical Center. By the end of May, selinexor will be expeditiously rolled out to approximately 600 hospitals and 105 DTPs in over 30 provinces, autonomous regions, and municipalities including Beijing, Shanghai, Guangdong, Jiangsu, Zhejiang, Henan, and Shandong, providing Chinese MM patients across the country with an easy to access to this new treatment option.

Expeditious Launch of Novel Targeted Therapy for Unmet Cancer Need

Multiple myeloma (MM) is the second most common hematologic malignancy in China, accounting for approximately 10% of all hematologic malignancy incidences. The number of new diagnoses of MM has been rising year after year, thus presenting



a rapidly growing medical need.^[1] Strikingly, more patients are diagnosed at younger ages.

The prior standard of care for MM has been based on treatment with a combination of therapies including dexamethasone, proteosome inhibitors, immunomodulatory agents and an anti-CD38 monoclonal antibody. Despite the availability of these therapies, MM remains a hard-to-treat cancer. Most patients with MM experience at least one relapse,^{[2][3]} with each relapse resulting in a shorter duration of response. In particular, those patients relapsed after third- or forth-line treatments have a poor prognosis and limited treatment options,^{[4][5]} with a median progression-free survival (PFS) of only 3-6 months and an overall survival (OS) of about 6 months.

In July 2019, the U.S. Food and Drug Administration (FDA) approved a new drug application (NDA) for XPOVIO[®], the world's first oral selective inhibitor of nuclear export protein-1 (XPO1) approved for combination use with low-dose dexamethasone for the treatment of patients with R/R MM who have received at least four prior therapies and whose disease is refractory to at least two proteosome inhibitors, at least two immunomodulatory agents and an anti-CD38 monoclonal antibody. Less than a year after that, the FDA granted approval for another indication for XPOVIO[®], as a monotherapy for the treatment of patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL). In December 2020, XPOVIO[®] obtained its third FDA-approved indication, for combination use with bortezomib and dexamethasone in treatment of adult patients with MM who previously received at least one prior therapy.

To address the urgent medical need of MM patients in China, Antengene raced against time and dedicated significant resources to bringing this novel drug to the country. On December 14, 2021, selinexor was approved through a priority review process by the China National Medical Products Administration (NMPA), for the treatment of adults with R/R MM who previously received treatment with at least three agents including a proteosome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Prof. Xiaojun Huang, at Peking University People's Hospital, commented, "R/R MM remains a major clinical challenge with limited treatment options for relapsed patients. I am glad that selinexor is available in China and can start benefiting Chinese patients right away. The introduction of this novel therapy represents a



clinical breakthrough bringing the country one step closer to advanced targeted therapies that are already available to patients in developed countries."

Prof. Jianxiang Wang, at the Hematology Institute of the Chinese Academy of Medical Sciences, noted, "I am pleased that selinexor has entered clinical application and now being prescribed to Chinese patients in need. This innovative drug has demonstrated an impressive clinical profile in the MARCH study, including favourable safety and tolerability, and clear efficacy with an overall response rate (ORR) of 29.3% and a median OS of 13.2 months.^[6] Moreover, this novel drug offers fast onset of actions and the convenience of once-weekly oral administration that simplifies the treatment regimen and spares patients from the ordeal of frequent injections."

Prof. Depei Wu, at the First Affiliated Hospital of Soochow University, said, "MM poses a growing threat to people's health in China. To effectively treat this condition, it requires early diagnosis, early treatment and timely adjusted treatment plans. I am thrilled that selinexor is now available to patients in China. I believe this new therapy will offer multiple myeloma patients significantly deeper responses, longer survival, and improved prognosis."

Prof. Jun Ma, at the Harbin Institute of Hematology&Oncology, added, "selinexor has a novel mechanism of action that delivers synergistic effects in combination with a number of readily available agents indicated for multiple myeloma. I am confident that we will be able to gain deeper insight from our clinical experience with selinexor-based combination therapies, thus bringing greater clinical benefit to patients."

Prof. Yu Hu, at the Union Hospital of Tongji Medical College, Huazhong

University of Science and Technology, remarked, "I am thrilled that selinexor can now be prescribed to patients in China. I believe this novel therapeutic offers a much-needed strategy that will bring renewed hope and improved health to many patients. I hope to see more novel medicines like selinexor, utilizing innovative mechanisms to bring new treatment options and potential curative care to patients, become available in China."

Integrated Distribution Channels, Coordinated Efforts to Fast Track Adoption



To make selinexor available to Chinese patients as swiftly as possible, Antengene has built world-class operations and commercial teams and established extensive strategic collaborations with Shanghai Pharmaceutical Lin-Gang Special Area Co., Ltd, the exclusive importer and national distributor of selinexor in China, and the provincial subsidiaries of Shanghai Pharmaceutical Co., Ltd, a Tier I distributor of selinexor in China, as well as a few other leaders in the across the product supply chain, such as DTP pharmacies under SPH Health Commerce Co., Ltd, the headquarters and provincial subsidiaries of SinoPharm Distribution Co., Ltd, China Resources Hunan Ruige Pharmaceutical Co., Ltd, Medbanks, LinkDoc, and Zhejiang INTYN Pharmacy Franchise Co., Ltd. Upon approval, Antengene promptly mobilized an internal team and external partners to secure supply chain readiness covering clearance. customs warehousing, quality assurance, distribution, and transportation. This coordinated effort paved the way for the rapid clinical application of selinexor across mainland China, hence benefiting many patients in need.

"Honoring our mission of Treating Patients Beyond Borders, we aim to leverage our global presence and extensive network of partners to commercialize practicechanging innovative therapies, and rapidly build out our distribution network to introduce high-quality innovative drugs to Chinese patients." said **Dr. Jay Mei, Antengene's Founder, Chairman and CEO**. "To have selinexor entering clinical practice and widely prescribed and utilized in mainland China vastly expands the drug's accessibility for patients. Committed to serving patients in need, our overseas teams are racing against time to secure the accessibility of this life-saving drug for patients in South Korea, Singapore and Australia, where selinexor was also granted approvals. Moving forward, we will continue to expand our distribution network to allow more patients to benefit from the important therapy."

Novel Mechanism with Broad Potential to be Combined with Other Therapies

Selinexor is the world's first orally-available, selective inhibitor of the nuclear export protein XPO1. Selinexor promotes the intra-nuclear accumulation and activation of tumor suppressor proteins and growth regulating proteins, down-regulating the levels of multiple oncogenic proteins, and activating the glucocorticoid receptors (GR) pathway, ultimately resulting in antitumor effects.



Utilizing this innovative mechanism of action, selinexor has demonstrated combinatory potential with multiple therapeutic agents including dexamethasone, proteasome inhibitors (PIs), immunomodulatory drugs (IMiDs), daratumumab, cyclophosphamide, adriamycin, and melphalan. To date, six selinexor-based regimens have received a total of 11 recommendations by numerous leading medical societies, including the National Cancer Care Network (NCCN) Guidelines, the Guidelines for the Diagnosis and Danagement of Multiple Myeloma in China, and the European Society of Medical Oncology (ESMO) Guidelines.

At present, Antengene is conducting a total of 10 clinical studies of selinexor in mainland China (3 are being jointly conducted by Antengene and Karyopharm Therapeutics Inc. [Nasdaq:KPTI]), including several late-stage clinical trials, for the treatment of a range of relapsed/refractory hematologic malignancies and advanced solid tumors such as relapsed/refractory multiple myeloma, relapsed/refractory diffused large B-cell lymphoma and indolent lymphoma, relapsed/refractory T and NK-cell lymphoma, and recurrent/metastatic cervical/endometrial/ovarian cancers.

Note: XPOVIO^{} is a prescription drug that should only be used under doctors' instructions. Should you need any advice on the use of this drug, please consult your local hospitals or pharmacies.*

About Antengene

Antengene Corporation Limited (**"Antengene"**, SEHK: 6996.HK) is a leading commercial-stage R&D-driven global biopharmaceutical company focused on innovative first-in-class/best-in-class therapeutic medicines for cancer and other life-threatening diseases. Driven by its vision of **"Treating Patients Beyond Borders"**, Antengene aims to provide the most advanced anti-cancer drugs to patients in the Asia Pacific Region and around the world. Since initiating operations in 2017, Antengene has obtained 23 investigational new drug (IND) approvals in the US and in Asia, submitted 6 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for selinexor/ATG-010/XPOVIO^{*} in China, South Korea, Singapore and Australia approved. Leveraging partnerships as well as in-house drug discovery, Antengene has built a broad and expanding pipeline of 15 clinical and pre-clinical assets. Antengene has global rights on 10 programs and Asia Pacific rights, including the Greater China region, on 5 programs.



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, 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.

References:

- [1]. http://pdf.dfcfw.com/pdf/H3_AP201805311150832442_1.PDF
- [2]. http://www.cqvip.com/qk/97751b/201301/44904542.html
- [3]. http://www.cqvip.com/qk/90720x/200512/20729438.html
- [4]. https://www.liangyihui.net/doc/68236
- [5]. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7342214/
- [6]. https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02305-4