BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Antengene submits NDAs for XPOVIO (Selinexor) in multiple APAC markets

04 December 2020 | News

Aims to treat adult patients with "relapsed or refractory multiple myeloma (rrMM)" and "relapsed or refractory diffuse large B-cell lymphoma (rrDLBCL)" in Singapore, Australia, Hong Kong and South Korea

Antengene Corporation Limited, a leading innovative biopharmaceutical company dedicated to discovering, developing and commercializing global first-in-class and/or best-in class therapeutics in hematology and oncology, on 3 Dec 2020 announced it has submitted new drug applications ("**NDA(s)**") for XPOVIO® (selinexor, ATG-010) to the Health Sciences Authority of **Singapore** and to the **Australian** Therapeutic Goods Administration for three indications:

1. the treatment of adult patients with relapsed or refractory multiple myeloma ("**rrMM**") 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
2. In combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior line of therapy
3. For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma ("**rrDLBCL**"), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two lines of systemic therapy.

Australian Therapeutic Goods Administration has accepted the NDA of Antengene on December 2, 2020.

A new drug application (NDA) for XPOVIO® (selinexor) has also been submitted to the **Hong Kong** Department of Health for the treatment of adult patients with rrMM 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.

In **South Korea**, XPOVIO® (selinexor) has been granted orphan drug designation for the treatment of adult patients with rrMM 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 and for the treatment of adult patients with rrDLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two lines of systemic therapy.

XPOVIO® (selinexor, ATG-010) is a first-in-class and only-in-class oral selective inhibitor of nuclear export, developed by Antengene and Karyopharm Therapeutics Inc. In July 2019, the US Food and Drug Administration (FDA) approved XPOVIO® (selinexor) in combination with low-dose dexamethasone for the treatment of rrMM. After its initial approval of rrMM, FDA approved XPOVIO® (selinexor) as a single-agent for the treatment of rrDLBCL in June 2020.

In November 2020, at the Connective Tissue Oncology Society 2020 Annual Meeting (CTOS 2020), Antengene's partner, Karyopharm Therapeutics, presented positive results from the Phase 3 portion of the randomized, double blind, placebo controlled, cross-over SEAL study evaluating single agent, oral XPOVIO® (selinexor) versus matching placebo in patients with liposarcoma.

Karyopharm also recently announced that the ongoing phase 3 SIENDO study of XPOVIO® in patients with endometrial cancer passed planned interim futility analysis and that Data and Safety Monitoring Board (DSMB) recommended the study should proceed as planned without any modifications. Top-line SIENDO study results are expected in the second half of 2021.