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ASIA EDITION

China makes new inclusions in national reimbursement drug list

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Internally-developed anti-PD-1 antibody tislelizumab and BTK inhibitor BRUKINSA® (zanubrutinib) are included in the NRDL in a total of four approved indications

BeiGene, Ltd., a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, has announced that three of its innovative oncology medicines have been included in the updated National Reimbursement Drug List (NRDL) by the China National Healthcare Security Administration (NHSA), including its internally-developed anti-PD-1 antibody tislelizumab, its internally-developed BTK inhibitor BRUKINSA® (zanubrutinib), and XGEVA® (120-mg denosumab) from its strategic collaboration with Amgen.

The following conditionally approved indications have been included in the updated NRDL:

- Tislelizumab for the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies (approved in December 2019);
- Tislelizumab for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (approved in April 2020);
- BRUKINSA for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy (approved in June 2020);
- BRUKINSA for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least one prior therapy (approved in June 2020); and
- XGEVA for the treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity (Amgen obtained approval of XGEVA in China in May 2019).

As part of its broad development program, BeiGene expects to work with the NHSA for potential NRDL inclusion in future expanded indications for these medicines. The Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted and is reviewing a total of four supplemental new drug applications (sNDAs) or supplemental biologics applications (sBLAs) for tislelizumab and BRUKINSA, including:

- Tislelizumab for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy (accepted in April 2020);
- Tislelizumab for first-line treatment of patients with advanced non-squamous NSCLC in combination with

chemotherapy (accepted in June 2020);
- Tislelizumab for previously treated patients with unresectable hepatocellular carcinoma (HCC) (accepted in July 2020); and
- BRUKINSA for patients with relapsed/refractory (R/R) Waldenström's macroglobulinemia (WM) (accepted in October 2020, under priority review).

XGEVA has also received conditional approval in China for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors and in patients with multiple myeloma (MM), which was not eligible for 2020 NRDL considerations as it was approved after the cutoff date.