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Geptanolimab in Chinese patients with relapsed or refractory primary mediastinal large B-cell lymphoma: Results from a multicenter, open-label, single-arm phase II trial

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Background

Primary mediastinal large B-cell lymphoma (PMBCL) is a rare aggressive B-cell non-Hodgkin lymphoma. Geptanolimab is a novel fully human anti-programmed cell death protein 1 (PD-1) mAb and exhibits favorable results in previous studies. This is a multi-center, open-label, single-arm phase II clinical trial aiming to evaluate the efficacy and safety of Geptanolimab in Chinese patients with relapsed or refractory PMBCL.

Methods

All patients enrolled received Geptanolimab 3mg/kg every 2 weeks until disease progression, death, unacceptable toxicity or withdraw from the study. The primary endpoint was objective response rate (ORR) per Lugano 2014. Adverse events (AEs) were graded by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) 5.0.

Results

From October 22nd, 2018 to October 27th, 2020, twenty-five patients with relapsed or refractory PMBCL were enrolled and treated. As of data cut-off on March 12th, 2021, patients received a median of 28 (2-56) cycles of treatment. At a median follow-up of 56 (3.86-112.14) weeks, overall response rate (ORR) was 64% (16/25, 95% confidence interval [CI]: 42.52%, 82.03%), including 6 patients (24%) with a complete response and 10 patients (40%) with a partial response. Median progression-free survival and duration of response have not reached yet. Treatment-related adverse events (TRAEs) of any grade occurred in 84% (21/25) patients. The most common grade 3-4 TRAEs were leucopenia (5/25, 20%), neutropenia (4/25, 16%) and lymphopenia (4/25, 16%).

Conclusions

Geptanolimab showed good anti-tumor activity with ORR of 64% and manageable safety profile in Chinese patients with relapsed or refractory PMBCL.

Clinical trial identification

NCT03639181.

Legal entity responsible for the study

Genor Biopharma Co., Ltd.

Funding

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Disclosure

All authors have declared no conflicts of interest.