Abstract: PB2351

Title: TRIAL IN PROGRESS: A PHASE 2, MULTICENTRE STUDY OF BRENTUXIMAB VEDOTIN WITH CHEMOTHERAPY IN FRONTLINE TREATMENT OF CHINESE PATIENTS WITH CD30-POSITIVE PERIPHERAL T-CELL LYMPHOMAS

Abstract Type: Publication Only

Session Title: Myeloma and other monoclonal gammopathies - Clinical

Background:

Peripheral T-cell lymphoma (PTCL) is a heterogeneous, rare and aggressive group of mature T and NK cells neoplasms, representing 10% of newly diagnosed lymphoma in China. CD30 expression is a hallmark of diagnosis in systemic anaplastic large cell lymphoma (sALCL) and is well documented in some other most common PTCL subtypes. ECHELON-2 have shown significant improvement in progression-free survival (PFS) and overall survival (OS) with CD30-directed monoclonal antibody-drug conjugate, brentuximab vedotin (BV) in combination with cyclophosphamide, doxorubicin (hydroxydaunorubicin), prednisone (CHP) regimen in patients with treatment naïve CD30-positive PTCL, comparing with cyclophosphamide, doxorubicin (hydroxydaunorubicin), vincristine, prednisone (CHOP) regimen. In order to determine the efficacy and safety of BV combined with CHP regimen in Chinese population with untreated PTCL, a bridging study was planned to be conducted.

Aims:

To investigate the efficacy, safety, and PK of BV+CHP in the frontline treatment of Chinese patients with CD30+ PTCL.

Methods:

This phase 2, single-arm, open-label, multicenter study will include patients aged ≥18 years with newly diagnosed CD30+ PTCL and ECOG performance status ≤2. Following histological subtypes will be included - anaplastic lymphoma kinase (ALK)-positive sALCL with ≥2 International Prognostic Index score, ALK-negative sALCL, PTCL-not otherwise specified, angioimmunoblastic T-cell lymphoma, enteropathy-associated T-cell lymphoma, and hepatosplenic T-cell lymphoma. Patients will receive 1.8 mg/kg of BV intravenously for 30 mins on day 1 of 21-day cycle followed by IV administration of cyclophosphamide (750 mg/m^2), doxorubicin (50 mg/m^2) and daily oral dose of 100 mg of prednisone from day 1 to 5. The treatment will be continued until first occurrence of any one of these criteria: Progressive disease, unacceptable toxicity, or completion of the desired 6 to 8 cycles. The study will recruit approximately 52 patients including 36 patients with diagnosis of sALCL.

Overall response rate (ORR) following the completion of study treatment as assessed by independent review facility and adverse events will be the primary endpoints. The secondary endpoints will include complete response rate following the completion of study treatment, 1-year PFS and OS rate, time to response (TTR), duration of response, pharmacokinetic analyses and antidrug antibody status**.**

Results:

Summary/Conclusion: The results from this bridging study will determine if they are consistent with results from global population and may provide support for the use of BV in treatment of Chinese patients with CD30+ PTCL.

Study registration number: NCT05673785.

Keywords: ALK/ALCL, CD30, Adult, Peripheral T-cell lymphoma