(PB3906) BRENTUXIMAB VEDOTIN COMBINED WITH CHIDAMIDEIN AND MITOXANTRONE HYDROCHLORIDE LIPOSOME OR GOLIDOCITINIB IN RELAPSED/REFRACTORY CD30-POSITIVE CUTANEOUS T-CELL LYMPHOMA: A REAL-WORLD STUDY DESIGN

Topic: 20. Other aggressive lymphomas

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Background

Cutaneous T-cell lymphomas (CTCLs), characterized by recurrent and progressive course, are a group of rare and heterogenous diseases and associated with high symptoms burden. Mycosis fungoides and Sézary syndrome (MF/SS) are the most common subtypes, accounting for 70%. For advanced MF/SS patients, systemic therapies are often used including brentuximab vedotin (BV), liposomal doxorubicin, and HDAC inhibitors. Among these, BV, a CD30-directed ADC, combined with chidamide, an HDAC inhibitor, has been proven to have a synergistic effect and recommended in relapsed/refractory (R/R) settings. Additionally, BV in combination with mitoxantrone liposomal (MIT-LIP) or golidocitinib, a selective-JAK1 inhibitor, demonstrates favorable overall response rates (ORR). These findings indicate promising efficacy for the combination therapy containing BV and chidamidein with MIT-LIP or golidocitinib in R/R MF/SS patients.

Aims

This study aims to describe an ongoing real-world (RW) study evaluating the effectiveness and safety of combination therapy with BV and chidamidein, in combination with either MIT-LIP or golidocitinib for R/R CD30+ Chinese lymphoma patients.

Methods

This is a prospective, observational, multicenter, RW study conducted in China between May 2026 to November 2028. Patients aged 18-69 years, with a confirmed diagnosis of R/R CD30+ MF/SS at stages IIB-IVB and an Eastern Cooperative Oncology Group performance status of ≤2, were eligible. R/R patients are defined as those who received ≥3 prior courses of systemic anti-tumor therapy without response, or with progression/relapses. Those with stage IIB disease are required to have extensive/multicentric tumoral involvement and either failed prior local radiotherapy, relapsed after it, or tumors in locations unsuitable for radiotherapy. Patients have already started combination therapy for BV plus chidamidein, in combination with either MIT-LIP or golidocitinib before the enrollment and the treatment has not exceeded 28 days. The primary endpoint is ORR lasting ≥4 months (ORR4). The secondary endpoints are the ORR (including complete response [CR]), response rate for each component (skin, blood, lymph nodes, and viscera), disease control rate (DCR), time to response, time to progression, duration of response (DOR), time to next treatment, progression-free survival (PFS), overall survival (OS), disease-free survival (DFS), quality of life, and safety. The relationship between CD30 expression and efficacy is explored as well. All the efficacy analyses will be based on the full analysis set (FAS), defined as all enrolled patients with confirmed MF/SS who received at least one dose of the study drug. The safety assessments will utilize the safety analysis set including same population in the FAS. The ORR4, ORR, CR, and DCR are summarized as proportions with two-sided 95% confidence intervals (CIs), with no data imputation. Time-to-event endpoints, including DOR, PFS, and OS, are estimated using the Kaplan-Meier method, with the median and two-sided 95% CIs reported. Safety is assessed using descriptive statistics.

Summary/Conclusion

This study is designed to provide robust evidence for the combination therapy (BV plus chidamidein and MIT-LIP or golidocitinib) in RW settings, potentially offering a valuable therapeutic strategy in patients with R/R CD30+ CTCL. The study is recruiting, with preliminary results available in subsequent reports.