(PB3893) EFFICACY AND SAFETY OF BRENTUXIMAB VEDOTIN WITH CHIDAMIDE IN CD30-POSITIVE CUTANEOUS T-CELL LYMPHOMA: A MULTICENTER, OPEN-LABEL, SINGLE-COHORT STUDY PROTOCOL IN PROGRESS

Topic: 20. Other aggressive lymphomas

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Background

Cutaneous T-cell lymphoma (CTCL) is an incurable malignancy of skin-tropic malignant CD4+ T cells, with mycosis fungoides (MF; indolent cutaneous plaques/tumors) and Sézary syndrome (SS) as predominant subtypes. Phototherapy and topical drugs are recommended for early-stage diseases. However, patients with advanced-stage diseases experienced rapid progression, with poor responses to current systemic treatments. Brentuximab vedotin (BV), an antibody-drug conjugate targeting CD30, approved by China Food and Drug Administration (CFDA) for the treatment of CD30-positive CTCL in 2021. BV paved a way for the treatment of patients with CTCL with favourable clinical outcomes in advanced MF. Moreover, chidamide, a histone deacetylase inhibitor, has reported efficacy in T-cell lymphomas. However, prospective data on BV+chidamide combination therapy in patients with advanced or relapsed/refractory CD30-positive CTCL are limited.

Aims

This study aims to evaluate the efficacy and safety of BV+Chidamide combination therapy in patients with CD30-positive MF and SS.

Methods

This is a prospective, single-arm, open-label, multicenter clinical trial. Between May 2026 to November 2028, adult patients (aged:18–69 years) with CD30-positive CTCL (MF:stage IIA–IVB) or SS, received at least one prior systemic therapy, ECOG performance status ≤2, radiographically detectable lesions, men and women using highly effective contraception or women with negative pregnancy test will be enrolled. Patients previously treated with BV or chidamide will be excluded. Eligible patients will receive BV (1.8 mg/kg intravenously every 3 weeks) in combination with chidamide (20 mg orally twice-weekly on days 1, 4, 8, and 11) in 21-day cycles. Initiation of treatment will be done if the hematologic parameters are within range (absolute neutrophil:≥1.0×10^9/ L, platelet:≥50×10^9/ L, and hemoglobin:≥75 g/L). Initiation of treatment will be delayed if grade ≥3 non-hematologic toxicities occur. All patients will receive an initial 3 cycles of BV+Chidamide combination therapy and continue treatment for up to 8 cycles on achieving partial response (PR) or higher efficacy. Discontinuation of the treatment will be done in case of stable disease (SD) or lower efficacy after 3 cycles of treatment. Follow-up will be performed for adverse events (AEs). Survival follow-up will be conducted every three months. Primary endpoints (EPs) will include objective response rate lasting at least four months (ORR4). Secondary EPs include disease control rate (DCR), objective response rate (ORR), time to response (TTR), time to progression (TTP), duration of response (DoR), survival, quality of life and safety. Moreover, exploratory EPs will include relationship between CD30 expression and therapeutic efficacy. All primary and secondary efficacy EPs analyses will be based on the full analysis set (FAS) and 95% confidence-intervals will be calculated.

Summary/Conclusion

This study will address a critical need for real-world evidence to understand the efficacy and safety ofBV+Chidamide combination therapy in patients with CD30-positive MF and SS in China. By elucidating these factors, we aim to contribute substantial evidence to the field in ultimately guiding clinicians in making informed decisions tailored to the needs of Chinese patients with CD30-positive MF or SS.