# (PB3862) SAFETY AND EFFICACY OF GOLIDOCITINIB IN COMBINATION WITH AZACITIDINE AND CHIDAMIDE FOR THE TREATMENT OF PERIPHERAL T-CELL LYMPHOMA: AN OPEN-LABEL, SINGLE-ARM STUDY

**Topic:** 20. Other aggressive lymphomas

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## Background

Peripheral T-cell lymphomas (PTCL) are aggressive non-Hodgkin lymphomas with poor outcomes. Traditional frontline therapy, such as anthracycline-based chemotherapy, offers limited clinical benefit, particularly in elderly patients or those with severe comorbidities. Golidocitinib, a selective oral JAK1 inhibitor, has shown reasonable antitumor activity with manageable safety in relapsed/refractory PTCL. Hypomethylating agents (azacitidine) and HDAC inhibitors (chidamide) also demonstrate clinical activity in practice. Preclinical studies indicated synergistic effects of the triplet combination, providing a rationale for a chemo-free approach in these frail patients.

## Aims

To evaluate the safety and efficacy of golidocitinib in combination with azacytidine and chidamide in patients with PTCL who are ineligible for standard chemotherapy or transplantation.

## Methods

Phase 1 employed a 3+3 dose-escalation design, exploring golidocitinib at two dose levels of 150 mg QOD or 150 mg QD to determine the RP2D. Phase 2 explored the safety and efficacy of golidocitinib RP2D in combination with chidamide 20mg twice a week and azacytidine 100mg D1-7 in PTCL. The primary endpoint was overall response rate (ORR) after at least 6 cycles according to 2024 Lugano criteria (NCT07081607).

## Results

Between Aug 1, 2025, and Feb 28, 2026, 11 patients, including 10 nodal T follicular helper cell lymphoma, angioimmunoblastic type (nTFHL-AI) and 1 PTCL-NOS, were enrolled in the study. Of the 11 patients, 9 patients were newly diagnosed and 2 in relapsed disease. The median age was 74 years (range, 68-84); 8 patients (72.7%) were male. 8 patients (72.7%) were in Lugano stage IV disease, 6 (54.5%) had ECOG performance status ≥2, and 9 (81.8%) with an international prognostic index (IPI) score ≥3. Among the 11 patients, 10 had the following comorbidities at baseline, considered ineligible for intensive treatment, including 7 with cardiovascular comorbidities (2 with arrhythmia and 5 with coronary heart disease), 2 with renal insufficiency, and 1 with cachexia. At data cutoff (Feb 28, 2026), with a median follow-up of 7.1 months, eight patients were evaluable for response assessment. Four patients achieved complete response (CR), with three partial response (PR) and one stable disease (SD), yielding an ORR of 87.5% (7/8) and a CR rate of 50% (4/8) after 3 cycles. Among the four patients who completed end-of-treatment assessment (6 cycles), two achieved CR (50%), and two had progressive disease (PD).
The most common grade ≥3 treatment-related adverse events were hematologic toxicities, consisting of 4 (36.4%) grade 3 leukopenia, 4 (36.4%) grade 3-4 thrombocytopenia, and 2 (18.2%) anemia. Grade 3 pulmonary infection and grade 3 gastrointestinal bleeding were separately observed in one patient (9.1%). Grade 1-2 cytomegalovirus infection occurred in six patients (54.5%) and resolved with antiviral therapy.

**Summary/Conclusion**

Golidocitinib combined with azacitidine and chidamide showed encouraging efficacy with manageable toxicity in frail PTCL patients. These preliminary results support further evaluation of this chemo-free regimen in this population.