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A Prospective Compartment-Matched Skin and Blood Resource for Defining Interferon Mechanism in Cutaneous T-Cell Lymphoma: Correlative Design and Accrual from an Ongoing Phase I/Ib Trial of Ropeginterferon alfa-2b (P1101)

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Abstract

Background

Interferon alfa has anchored mycosis fungoides (MF) and Sézary syndrome (SS) therapy for decades and remains guideline-recommended, yet no interferon carries a CTCL indication and recombinant IFN- α -2b is no longer marketed. Interferon is presumed to restore Th1 polarization and cytotoxic surveillance, but this has not been tested prospectively, and to our knowledge no prospective compartment-matched specimen set from interferon-treated CTCL exists.

Methods

An ongoing investigator-initiated phase I/Ib trial (NCT07047885) evaluates ropeginterferon alfa-2b in stage IA–IIIB CTCL using a Bayesian optimal interval design across 250, 350, and 500 mcg subcutaneously every 2 weeks (planned n=38). A prospective correlative schedule includes skin biopsies at baseline, week 7, and progression, with blood at week 1 (predose), 7, 15, 23, and 31. Global response (ISCL/EORTC/USCLC 2022) is assessed every 8 weeks. Planned analyses include spatial transcriptomics and AI-based quantification of

digitized pathology from serial lesional tissue, with T-cell immunophenotyping including $\gamma\delta$ subsets and plasma Th1/Th2 cytokine profiling.

Results

As of July 27, 2026, 10 patients had enrolled; 9 were response-evaluable; clinical outcomes are reported in a companion abstract. Eight of 10 (80%) consented to optional correlative biopsies, and all 8 provided paired baseline and week-7 specimens without attrition. At both timepoints, lesional tissue was banked as formalin-fixed and fresh-frozen material for spatial transcriptomic and digital pathology analyses. All 8 also had complete banked blood at the predose and four on-treatment timepoints with concurrent clinical flow cytometry.



Figure 1. Key Eligibility Criteria

Conclusion

Complete paired tissue and blood collection in every consenting patient establishes, to our

knowledge, the first prospective compartment-matched resource assembled during interferon therapy in CTCL. The specimens are collected; the planned assays remain unfunded. Funding would enable spatial transcriptomic and AI-

quantified digital pathology with paired immune profiling, testing whether clinical benefit is associated with Th1 restoration and recruitment of cytotoxic effectors into the lesional niche.

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