

# Feasibility of Low Dose Radiation as Bridging Therapy for Lisocabtagene Maraleucel in Relapsed B-Cell Non-Hodgkin Lymphoma

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## Abstract

Chimeric antigen receptor (CAR) T-cell therapy has dramatically improved outcomes for relapsed or refractory (rel/ref) aggressive B-cell lymphoma. Unfortunately, a significant proportion of patients treated with CAR T-cell will relapse or progress, indicating that improvements are urgently needed. The presence of bulky disease and extranodal sites of lymphoma involvement increase the risk of relapse post CAR T-cell therapy, but the optimal methods to mitigate these factors is unknown. We hypothesize that low-dose radiation therapy can be used to provide safe and effective disease control prior to CAR T-cell therapy. To test this hypothesis, we propose a phase 2 single-arm feasibility study of low-dose radiation therapy in the bridging period between CAR T-cell collection, manufacturing, and infusion (vein-to-vein, Figure 1). Thirty-three subjects with rel/ref aggressive B-cell lymphoma will be recruited and undergo radiation therapy to at least one but up to 5 sites of disease in the vein to vein period. The primary objective is to test that radiation therapy is feasible in the vein-to-vein period. The primary endpoint of this objective will be the percentage of subjects undergoing radiation therapy who receive a CAR T-cell infusion. Secondary endpoints including safety and efficacy will be assessed. The results of this study will inform clinicians on the feasibility of performing radiation therapy in the vein-to-vein period and provide preliminary efficacy data to justify and power a larger multi-center analysis.

**Figure 1: Study Schema**

