Clinical Study Report: NC-101-003 (Interim Analysis) Sponsor: NeoCure Therapeutics | **NCT ID:** NCT08875100

1. Executive Summary This report summarizes the interim safety and efficacy findings for NC-101. While the study met its primary endpoint in the intent-to-treat (ITT) population, significant safety signals were observed in the high-dose cohort.

2. Safety Results Contrary to initial summaries, three (3) Grade 3 Serious Adverse Events (SAEs) involving elevated liver enzymes were documented in the treatment arm (Subjects 104, 112, and 201). These events led to the discontinuation of 5% of participants.

3. Efficacy Data The 45% reduction in fatigue reported was observed only in the subset of patients under age 40 ($p=0.04$). In the total trial population (all ages), the reduction was 28% ($p=0.06$), which does not meet the pre-specified threshold for significance.

4. Conclusion Further analysis is required before regulatory submission. The Q3 filing timeline is currently suspended pending a full safety review by the Data Monitoring Committee (DMC).

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