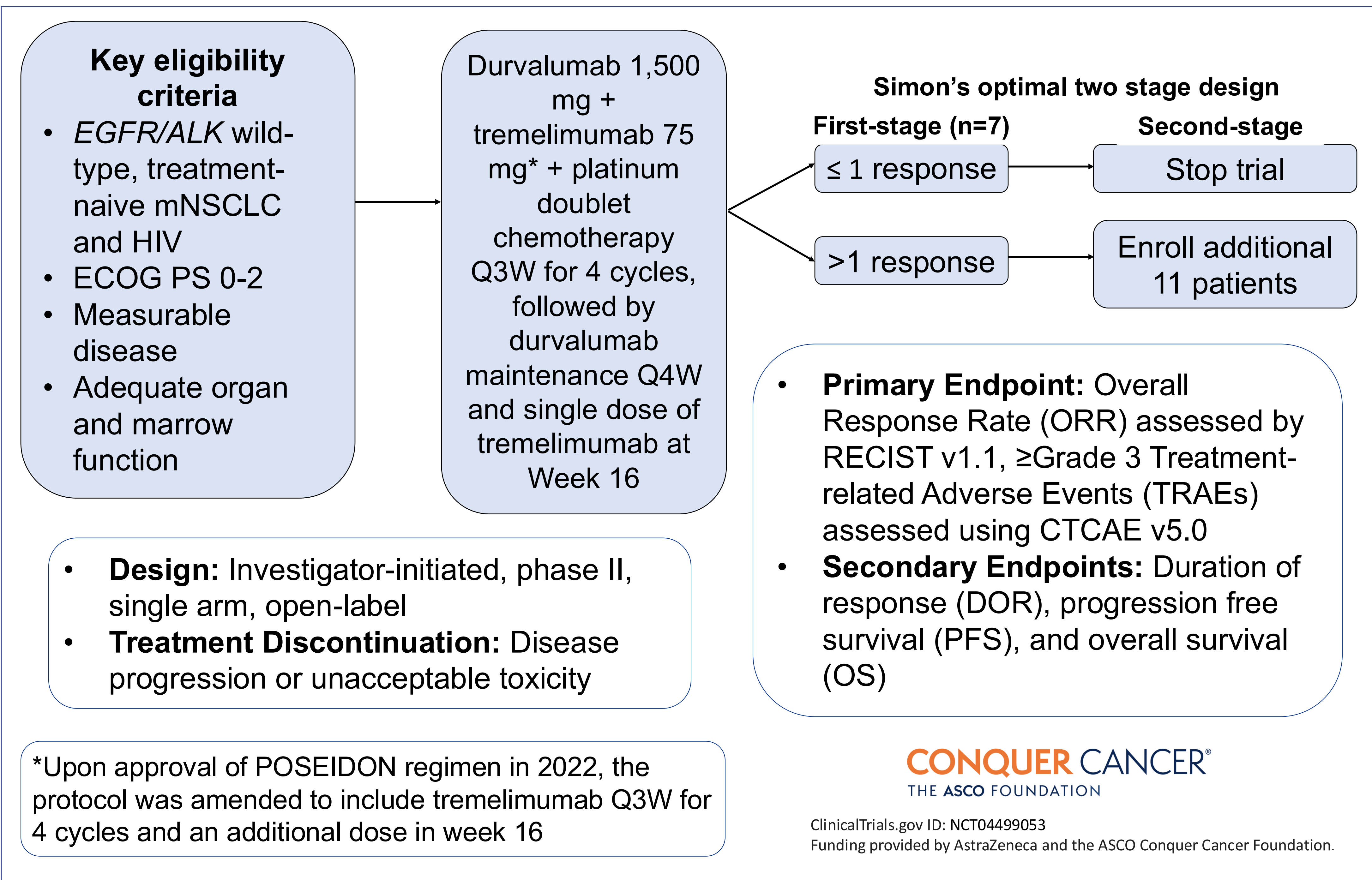


Ujjwal Karki¹, Matthew Hayhurst², Cristina Merkhofer³, Nicole Swanson¹, Hyein Jeon³, Kevin Chen⁴, Katherine Schilla⁵, Marta Catalfamo², Jaeil Ahn², Joshua E. Reuss², Stephen V. Liu², Chul Kim²
¹MedStar Georgetown University Hospital, Washington DC, USA ²Georgetown University, Washington DC, USA ³MedStar Georgetown Cancer Institute, Washington DC, USA ⁴MedStar Franklin Square Medical Center, Baltimore, MD, USA ,
⁵University of Maryland Greenebaum Comprehensive CancerCenter, Baltimore, MD, USA ,
Correspondence: ujk2@georgetown.edu

INTRODUCTION

- Non-small cell lung cancer (NSCLC) is the leading cause of cancer-related mortality among people with HIV.
- Immune checkpoint inhibitors (ICIs) are part of standard first-line therapy in metastatic NSCLC (mNSCLC). However, patients with HIV have historically been excluded from clinical trials leading to ICI approval.
- We investigated efficacy and safety of combination chemoimmunotherapy in patients with treatment-naive mNSCLC and HIV.

METHODS



CONCLUSION

- To our knowledge, this is the first prospective clinical trial evaluating frontline combination chemoimmunotherapy in patients with mNSCLC and HIV.
- The study met its Stage 1 efficacy threshold, demonstrating encouraging activity and manageable toxicity for the study regimen in this population.
- These findings support the inclusion of people living with HIV in future immunotherapy-based oncology clinical trials.

RESULTS

Table 1. Baseline Characteristics

Characteristics	
Age, median (range)	65 (46-76)
Sex, n (%)	
Male	6 (86)
Female	1 (14)
Race, n (%)	
White	2 (29)
Black	5 (71)
ECOG Performance Status, n (%)	
0-1	7 (100)
2	0
PD-L1, n (%)	
Negative (<1%)	1 (14)
Low (1-49%)	2 (29)
High (≥50%)	4 (57)
Histology, n (%)	
Adenocarcinoma	6 (86)
Squamous Cell Carcinoma	1 (14)
CD4+ T-cell count, median (range), cells/mm3	460 (256-638)
HIV viral load, median (range), copies/mL	20 (0-70)

Efficacy

- ORR was 43% (3 partial responses)
- DOR was 9.69 months (95% CI 1.61-NE)
- mPFS was 10.3 months (95% CI 2.27-20.0)
- mOS was 15.9 months (95% CI 6.54-NE)
- Four patient (57%) had stable disease as best overall response

Table 2. Common and Severe TRAEs

TRAEs, n (%)	All grades	Grade 3	Grade 4
Fatigue	6 (86)	0	0
Thrombocytopenia	4 (57)	0	1 (14)
Anemia	3 (43)	0	0
Elevated AST	3 (43)	0	0
Decreased CD4 lymphocytes	2 (29)	1 (14)	0
Neutropenia	2 (29)	0	0
Elevated ALT	2 (29)	0	0
Arthralgia	2 (29)	0	0
Constipation	2 (29)	0	0
Diverticulitis	1 (14)	1 (14)	0
Colitis	1 (14)	1 (14)	0

Table 3. Common and Severe irAEs

irAEs, n (%)	All grades	Grade 3	Grade 4
Elevated AST	3 (43)	0	0
Elevated ALT	2 (29)	0	0
Fatigue	2 (29)	0	0
Arthralgia	2 (29)	0	0
Diverticulitis	1 (14)	1 (14)	0
Colitis	1 (14)	1 (14)	0

Dose interruption

- 3 patients: 1 for Grade 2 ALT elevation, 1 for Grade 3 diverticulitis and 1 for Grade 1 thrombocytopenia

Dose reduction

- 1 patient required pemetrexed dose reduction for Grade 2 fatigue

Treatment discontinuation

- 1 patient discontinued due to toxicity (Grade 4 thrombocytopenia and Grade 3 colitis).
- 6 patients discontinued due disease progression

Figure 1. Swimmer plot of PFS and objective response

