The study is designed to have a safety run-in period (~6 patients) followed by Day 8.

A safety review meeting will occur when ≥6 enrolled participants have completed

Randomized Part

Day 15

Day 28

Endpoint(s) for secondary objective(s)

Helsinki, Finland; PD-1 inhibitor spartalizumab in Phase II study of the anti–TGF-β inhibitor NIS793. The primary objective of the randomized part is to evaluate the safety and efficacy of NIS793 with and without spartalizumab, combined with NG in first-line PDAC.

The primary objective of the randomized run-in is to evaluate the safety and tolerability of NIS793 in combination with NG in patients with first-line PDAC.

The primary objective of the randomized part is to evaluate the progression-free survival (PFS) in patients with locally advanced, inoperable PDAC.

The dose regimen for the randomized part of the study will be determined following the safety review.

Crossover between treatment arms is not permitted at any time during the study.

Participants will have safety evaluations for 150 days (Safety run-in and Arm 1), 90 days (Arm 2), and 30 days (Arm 3) after the last dose of NIS793, spartalizumab, and NG.

The dose regimen for the randomized part of the study will be determined following the safety review.

Participants who have enrolled in the randomized part of the study will be followed for a minimum of 18 months after the completion of their last dose of NIS793, spartalizumab, and NG.

The authors would like to thank the study principal investigators: Emiliano Calvo Aller, Thomas Aparicio, Nathan Bahary, and Claire Fabre.

NSCLC, non-small cell lung cancer; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; 2.5D, two-dimensional drug

References