SERIOUS ADVERSE EVENT NARRATIVE

Subject ID:	101-901
Subject Initials:	M.C.
Protocol:	NVX-1218.22
SAE Term:	Immune-Mediated Myocarditis / Cardiac Arrest
CTCAE Grade:	4 (Life-threatening)
Causality:	Related to NovaPlex-450 (probable)
Onset Date:	2024-08-14
Report Date:	2024-08-15 (15-day initial report submitted)
Status:	Ongoing (subject hospitalised)

Narrative

Subject 101-901 is a 58-year-old female with advanced NSCLC (Stage IV, non-squamous) randomised to NovaPlex-450 on 2024-06-01 (Cycle 1 Day 1).

On 2024-08-14 (Cycle 3 Day 14), subject presented to emergency department with acute chest pain, dyspnoea, and hypotension. ECG demonstrated ST elevation in multiple leads. High-sensitivity troponin I was markedly elevated at 8,450 ng/L (ULN: 52 ng/L). Echocardiography demonstrated global LV dysfunction with LVEF 25% (baseline: 62%).

Cardiac MRI confirmed immune-mediated myocarditis. Subject suffered witnessed cardiac arrest (VF) on 2024-08-15, successfully resuscitated with defibrillation. Transferred to cardiac ICU. NovaPlex-450 permanently discontinued.

Treatment: IV methylprednisolone 1g/day x 3 days, then oral prednisolone 1mg/kg/day with planned taper. Cardiology review ongoing. Subject remains hospitalised.

Regulatory Reporting

15-day report submitted:	2024-08-15 to FDA/EMA
Follow-up report due:	2024-09-14