Study Design



A Randomized Open-label Phase 3 Trial of Dato-DXd Plus Pembrolizumab vs Pembrolizumab Alone in Treatment Naïve Subjects with Advanced or Metastatic Non-Small Cell Lung Cancer That Has High PDL-1 Expression (TPS≥50%) and Without Actionable Genomic Alterations (TROPION-LUNG08)

Screening

Key Eligibility
• Stage IIIB/C* or Stage IV NSCLC

- No known actionable genomic
- Measurable disease per RECIST v1.1
- ECOG PS 0 or 1
- High PDL-1 Expression (TPS ≥ 50%)
- No prior treatment with ADC targeting TOP1, TROP2-targeted therapy, anti-PD-1/LD-1/L-2 or another stimulatory or co-inhibitory T-cell receptor
- No previous therapy for advanced or metastatic NSCLC

Enrollment n= 740

Randomization 1:1 Stratification:

- Histology: squamous vs non-squamous Geographical Region (East Asia vs rest of world (ROW)
- Smoking status (former/current vs. never)

Dato-DXd (6 mg/kg)+200mg pembrolizumab (n=370)

200mg pembrolizumab (n=370)

Study continuation until disease progression, death, intolerable toxicity, withdrawal from study participation (by investigator or subject). Study will continue for a maximum of 35 cycles (pembrolizumab). There is no maximum treatment limit for Dato-Dxd.

Expected study duration: Enrollment 22 months, treatment and follow-up 31 months, total duration 53

Abbreviations

PFS = Progression Free Survival BICR = Blinded Independent Central Review OS = Overall Survival ORR = Overall Response Rate DOR = Duration of Response

TTR = Time to Response

DCR = Disease Control Rate
PRO = Patient-Reported Outcomes
TEAE = Treatment-Emergent Adverse Event
SAE = Serious Adverse Event

Primary

- PFS by BICR
- os

Secondary

- PFS by Investigator
- DoR
- **TTR**
- DCR
- **PROs**
- **TEAEs and Safety**
- **Immunogenicity**



