Efficacy, Safety and Cytokine Profiling with Addition of the Toll-Like Receptor (TLR) 7/8 Dual Agonist EIK1001 to Standard of Care First-Line (1L) Therapy: The Phase 2 TeLuRide-005 Trial in Stage 4 Non-Small Cell Lung Cancer (NSCLC)

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ABSTRACT#
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BACKGROUND

- Immune checkpoint inhibitors (ICIs) boost antitumor immune responses by relieving T-cell immunosuppression. ICIs combined with chemotherapy improve survival in advanced NSCLC; however, not all patients benefit.
- EIK1001, a TLR 7/8 dual agonist, activates dendritic cells through innate and adaptive pathways. This mechanism of action—associated with cytokine release and T-cell differentiation—is complementary to ICIs and has shown clinical activity as monotherapy. EIK1001 was well tolerated in phase 1 studies, with clinical responses seen in heavily pretreated participants. This provides rationale for adding EIK1001 to SOC chemotherapy (chemo) + ICI in Stage 4 NSCLC, a disease with unmet therapeutic needs.
- NSCLC Treatment Landscape: Anti-PD-1/PD-L1 + chemotherapy improves overall survival (OS), progression-free survival (PFS), and objective response rate (ORR) in patients with non-small cell lung cancer (NSCLC), non-squamous (NSQ) and squamous (SQ).
  - The addition of pembrolizumab to SOC chemotherapy (KEYNOTE 189 & KEYNOTE 407) is approved globally
  - The ORR by investigator-based assessment in KEYNOTE 189 and 407 was 43% (NSQ), and 55% (SQ), respectively.

STUDY DESIGN

TeLuRide-005 (NCT06246110) is an ongoing multicenter, open-label study of intravenous weekly (QW) EIK1001 combined with SOC Q3W pembrolizumab + chemotherapy (carboplatin plus pemetrexed or paclitaxel) in treatment-naïve patients with histologically confirmed Stage 4 NSCLC. After 8 cycles, EIK1001 administration is Q3W. The maximum treatment duration is 2 years (up to 35 cycles) for EIK1001 + pembrolizumab (with pemetrexed continued at the discretion of the Investigator for non-squamous patients).

Key Eligibility Criteria

INCLUSION
- Age ≥ 18 years
- Untreated stage IV NSQ or SQ NSCLC
- No driver mutations actionable as First-Line
- ECOG PS 0 or 1
- No symptomatic brain metastases

EXCLUSION
- Histologically confirmed small-cell elements

EIK1001 0.45 mg/m² + Pembrolizumab 200 mg (up to 35 cycles) + **Histology appropriate chemotherapy ***

Evaluate for Dose-limiting toxicities during Cycle 1 of 35 (Safety Run-In), 6 participants per histologic cohort

KEY ASSESSMENTS:
- Tumor Imaging (MRI or CT)
- EIK1001 PK
- Blood for cytokine sampling
- Blood for ctDNA

EIK1001 0.6 mg/m² + Pembrolizumab 200 mg (up to 35 cycles) + **Histology appropriate chemotherapy * n~25 pts per Cohort**

Primary Endpoints

Safety run-in phase:
- Dose-limiting toxicities
- Adverse events (AEs)

Expansion Phase:
- AEs
- Patients Discontinuing due to an AE

Secondary Endpoints:
- Objective response rate (ORR)
- Duration of response(DOR)

EIK1001 IV weekly x 8 cycles, then every 3 weeks + Pembrolizumab every 3 weeks, plus
* Cohort A Non-squamous: pemetrexed 500 mg/m² + carboplatin AUC 5 every 3 weeks x 4 Cycles + optional pemetrexed maintenance
* Cohort B Squamous: paclitaxel 200 mg/m² + carboplatin AUC 6 every 3 weeks x 4 Cycles

STUDY POPULATION & EXPOSURE

72 participants with previously untreated Stage 4 NSCLC received EIK1001 + standard-of-care pembrolizumab and histology-driven chemotherapy.

Baseline Characteristics

All Treated Participants	Total N=72
Age (years)	
Mean (sd)	68 (± 10)
Median (Range)	68 (23-83)
Gender	
(M/F)	72% / 28%
Histology	
NSQ	39 (54%)
SQ	33 (46%)
Smoking Status	
Previous	65%
Current	25%
Never	10%
PD-L1 TPS Status	
< 1%	18 (25%)
1% – 49%	29 (40%)
≥50%	25 (35%)

Disposition

Exposure & Disposition	Total N=72
EIK1001 0.45mg/m² QW	13 (18%)
EIK1001 0.60mg/m² QW	59 (82%)
Median Follow up, mo. (Range)	13.2 (2.8-25.3+)
Median Treatment Duration, mo. (Range)	5.7 (0.03-20.3+)
On Treatment at Data Cutoff	20 (28%)
Discontinued Treatment	52 (72%)

Reason for Treatment Discontinuation	N (%)
Progressive Disease	30 (42%)
Adverse Event	5 (7%)
Death	6 (8%)
Other*	11 (21%)

Safety, exposure, and disposition data cutoff: March 17, 2026.
Abbreviations: Mo: Months; QW: once weekly.
*: Other includes Lost to Follow Up, Physician Decision, Withdrawal by Subject.
+ : Treatment ongoing

RESULTS

Safety Results

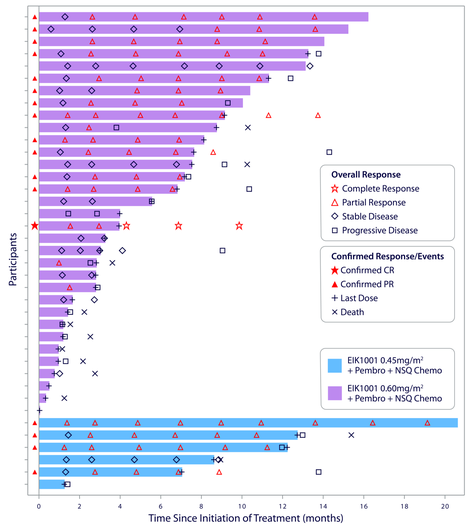
- Safety was evaluated in 72 treated participants across both dose levels. Most TEAEs were Grade 1–2. Grade ≥3 drug-related TEAEs occurred in 48.6% of participants, and TEAEs led to treatment discontinuation in 19.4%. No TEAEs leading to death were related to study treatments.
- No DLTs were observed during the safety run-in phase (N=13).

Overall Safety Summary	Total N=72
Any TEAE	72 (100%)
Grade ≥3 TEAE	57 (79.2%)
Grade ≥3 drug-related TEAE	35 (48.6%)
Serious adverse events (SAEs)	36 (50.0%)
TEAEs leading to death	9 (12.5%)
TEAEs leading to treatment discontinuation	14 (19.4%)
TEAEs leading to dose modification	17 (23.6%)

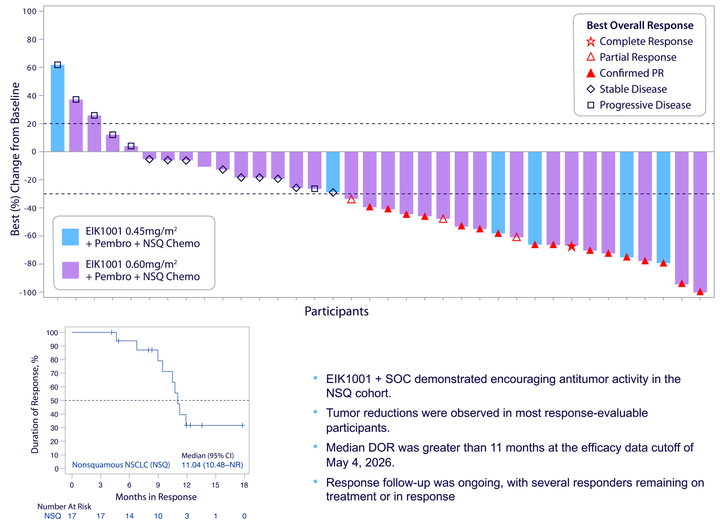
- High-grade treatment-related AEs were generally consistent with toxicities expected with pembrolizumab/platinum-based chemotherapy.

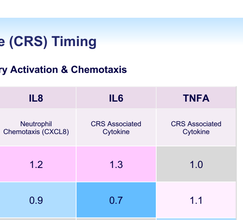
Grade ≥3 TRAE Occurring in At Least 2 Participants	NSQ N=39	SQ N=33	Total N=72
Neutropenia*	13 (33.3)	9 (27.3)	22 (30.6)
Anemia*	6 (15.4)	1 (3.0)	7 (9.7)
Thrombocytopenia*	6 (15.4)	1 (3.0)	7 (9.7)
Fatigue*	4 (10.3)	1 (3.0)	5 (6.9)
Colitis	1 (2.6)	2 (6.1)	3 (4.2)
Febrile neutropenia	2 (5.1)	None	2 (2.8)
Lymphopenia	1 (2.6)	1 (3.0)	2 (2.8)

*Consolidated terms
Drug-related: events determined by Investigator to be related to treatment regimen; TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event; SAE = serious adverse event; NSQ = non-squamous; SQ = squamous. Adverse events are shown for preferred terms occurring in ≥2 participants overall.



Non-Squamous NSCLC Cohorts





- EIK1001 + SOC demonstrated encouraging antitumor activity in the NSQ cohort.
- Tumor reductions were observed in most response-evaluable participants.
- Median DOR was greater than 11 months at the efficacy data cutoff of May 4, 2026.
- Response follow-up was ongoing, with several responders remaining on treatment or in response

Efficacy Results

- At the efficacy data cutoff (May 4, 2026), pooled efficacy was:

	Objective Response Rate (ORR), % (95%CI)	Disease Control Rate (DCR), % (95%CI)
Efficacy Evaluable Population	63.1% (50.2-74.7%)	90.8% (81.0-96.5%)

- Objective responses were observed across all PD-L1 TPS (Tumor Proportion Score) subgroups

Objective Response by PD-L1, TPS	N	ORR, % (95% CI)
Efficacy Evaluable	41/65	63.1% (50.2-74.7%)
PD-L1 TPS		
< 1%	9/15	60.0% (32.3-83.7%)
1% – 49%	16/27	59.3% (38.8-77.6%)
≥50%	16/23	69.6% (47.1-86.8%)

- Efficacy was observed in both histology cohorts, with numerically higher ORR and DCR in the SQ cohort (shorter follow up due to delayed enrollment).

Efficacy by Histology	NSQ (n=39)	SQ (n=33)
Median follow-up, mo. (range)	13.6 (7.9-25.3)	8.8 (2.8-21.4)
ORR, % (95% CI)	55.6% (38.1%-72.1%)	72.4% (52.8%-87.3%)
DCR, % (95% CI)	83.3% (67.2-93.6%)	100% (86.3-100%)

Abbreviations: DCR: Disease Control Rate (Complete Response + Partial Response + Stable Disease); Mo: Months; NSQ: Non-squamous NSCLC; ORR: Objective Response Rate; SQ: Squamous NSCLC

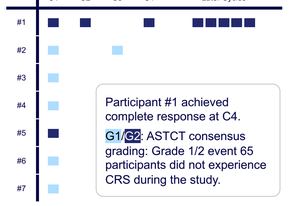
Cytokine Profiling and Cytokine Release Syndrome (CRS) Timing

	Innate / Regulatory Signaling			Inflammatory Activation & Chemotaxis			
Cytokine	IFNA	IL10	IFNG	IP10	IL8	IL6	TNFA
Function	Innate Immune Activation (Type I IFN)	Immune Regulatory Cytokine	Adaptive Immune (Type II IFN)	T-Cell Chemotaxis (CXCL10)	Neutrophil Chemotaxis (CXCL8)	CRS Associated Cytokine	CRS Associated Cytokine
C1D1 Max / C1D1 Pre-Dose	1.5	2.5	1.0	1.1	1.2	1.3	1.0
C4D1 Pre-Dose / C1D1 Pre-Dose	1.0	1.4	1.3	1.4	0.9	0.7	1.1
C4D1 Max / C4D1 Pre-Dose	1.3	3.9	1.0	1.1	1.0	1.0	0.9
# on C1D1 # on C4D1	N=65 N=45	N=62 N=36	N=62 N=36	N=60 N=35	N=62 N=36	N=62 N=36	N=62 N=36

- **C1D1**: EIK1001 induced acute cytokine activation, with strongest median induction observed for IL-10 and IFNα.
- **C4D1**: IP-10/CXCL10, IL-10, and IFNγ remained elevated compared with C1D1 baseline, consistent with sustained IFN-associated pharmacodynamic activity.
- **Repeat dosing**: IL-6, IL-8/CXCL8, and TNFα showed reduced or absent inducibility at C4D1, consistent with attenuation of acute CRS-associated cytokine induction.
- **CRS Timing and Severity**. All CRS Events were low grade and occurred before C4 in all but 1 participant.

Values are median fold-changes: Dark blue, light blue / gray / pink, magenta shading indicates reduced / neutral / or increased fold change.
Max: maximum cytokine value measured up to 24 hours post-dose.

Participants with CRS



Participant #1 achieved complete response at C4.
G1/G2: ASTCT consensus grading: Grade 1/2 event 65 participants did not experience CRS during the study.

CONCLUSIONS

First-line EIK1001 + SOC chemotherapy + pembrolizumab demonstrated encouraging efficacy in Stage 4 NSCLC, with evidence of durable effect in the NSQ cohort and high response rates in the SQ cohort.
- Safety profile was generally similar to SOC alone.
- CRS events were of low grade and occurred predominantly in Cycle 1.
- Cytokine data support the mechanism of action of EIK1001 as a TLR7/8 dual agonist both in terms of efficacy and declining CRS events over time.

Additional follow-up is needed to further characterize durability of response, particularly in the SQ cohort.

CURRENT STATUS

- This study opened on 02 July 2024 and is now closed to enrollment
- Clinicaltrials.gov identifier: NCT06246110

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