Clinical Trial Referral Report

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Generated on June 06, 2026 at 09:14 PM

■■■■ Referring Clinician

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Trial Information

NCT ID:	NCT05533697
Title:	Phase 1/2 Study of mRNA-4359 Administered Alone and in Combination With Immune Checkpoint Blockade in Participants With Advanced Solid Tumors
Match Status:	**MATCH**

Trial Source Contacts

CEDARS

Dr. Omid Hamid — ohamid@theangelesclinic.org

Patient Summary

■ Demographics

Age:	70 years
Sex:	Male
Pregnancy:	not_applicable
Breastfeeding:	not_applicable
Childbearing:	not_applicable

■ Diagnosis

Cancer Type:	Metastatic Non-Small Cell Lung Cancer
Category:	Thoracic Malignancies
Histology:	Adenocarcinoma
Tumor Site:	Lung
Stage:	IV
Metastatic:	Yes
Metastases:	bone, lung, liver

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■ Biomarkers

EGFR:	positive
EGFR_MUTATION:	positive
EGFR_MUTATION_DETAIL:	exon 19 deletion
ALK:	negative
ROS1:	negative
KRAS:	negative
BRAF:	negative

■ Clinical Status

ECOG PS:	0
Prior Tx:	osimertinib

■ Laboratory Values

ANC:	2500 /µL
Platelets:	200000 /µL
Hemoglobin:	13 g/dL
WBC:	7000 /µL
Creatinine:	0.9 mg/dL
CrCl:	60 mL/min
Bilirubin:	0.8 mg/dL
Bilirubin/ULN:	0.7
AST:	25 U/L
ALT:	25 U/L
AST/ULN:	0.6
ALT/ULN:	0.6

■ Infection Status

HIV:	negative
Hepatitis C:	negative

Eligibility Evaluation Summary

Complete evidence of all inclusion and exclusion criteria reviewed:

TOTAL CRITERIA	MET (Eligible)	FAILED (Excluded)	MISSING DATA	MANUAL REVIEW	AUTO-PASS (Procedural)
25	10	0	0	11	4

DETERMINATION: ELIGIBLE — All 10 evaluated inclusion criteria were met. No exclusion criteria were triggered. 11 criteria require manual clinical review. 4 procedural requirements assumed to be met pending enrollment.

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✓ Inclusion Criteria Met

	Field	Criterion	Patient	Required	Type
✓	**diagnosis.cancer_type**	Disease targets: ['Advanced Solid Tumors', 'Neoplasm Metastasis', 'Recurrence']	Metastatic Non-Small	matches_any Advanced Soli	INC
✓	**demographics.age**		70	≥ 12	INC
✓	**diagnosis.cancer_type**	Participant has histologically confirmed locally advanced or metastatic cancer (...	Metastatic Non-Small	matches_any solid tumor,	INC
✓	**diagnosis.stage**	Participant has histologically confirmed locally advanced or metastatic cancer	IV	matches_any locally advan	INC
✓	**performance_status.ecog**	Participant has an Eastern Cooperative Oncology Group (ECOG) performance status ...	0	≤ 1	INC
✓	**diagnosis.metastatic_sites**	Participant has active central nervous system tumors or metastases.	bone, lung	not_contains brain, cns	EXC
✓	**current_treatments**	Participant has received treatment with prohibited medications (that is, concurr...		not_contains chemotherapy	EXC
✓	**prior_treatments**	Prior exposure to any investigational or approved agent designed to simultaneous...	osimertinib	not_contains IDO1 PD-L1 d	EXC
✓	**current_treatments**	Participant has required the use of additional immunosuppression (for example, i...		not_contains infliximab,	EXC
✓	**current_treatments**	Participant has any plan to receive a live attenuated vaccine during study treat...		not_contains live vaccine	EXC

■■ Criteria Requiring Manual Review

These criteria could not be automatically evaluated and require clinical judgment:

• All participants must have measurable disease as determined by RECIST v1.1.

Reason: Requires imaging review per RECIST v1.1 criteria

• Arm 1a participants must have received, and then progressed, relapsed, or been intolerant to, or ineligible for, at leas...

Reason: Complex arm-specific treatment history and conditional drive

• Dose Confirmation (Arm 1b): CPI refractory melanoma or NSCLC with disease progression after at least 1 line of standard ...

Reason: Complex arm-specific eligibility with temporal logic on prio

• For NSCLC participants with known EGFR, ALK, ROS1, or other actionable mutations for which there are approved targeted t...

Reason: Conditional biomarker-dependent treatment history logic

• Arm 2a/2c: Locally advanced or metastatic melanoma who have not yet received any prior systemic therapy for melanoma in ...

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Reason: Arm-specific treatment-naive requirement requiring arm assig

• Arm 2b: Newly diagnosed locally advanced or metastatic NSCLC with a PD-L1 TPS of ≥50% with no known EGFR or ALK positive...

Reason: Arm-specific combination of biomarker thresholds and treatme

• Arm 2d: Advanced/metastatic melanoma that is CPI refractory and having a centrally confirmed PD-L1 TPS of ≥1% on their S...

Reason: Arm-specific requirement requiring central PD-L1 testing

• Participant has adequate hematological and biological function.

Reason: Vague criterion without specific lab thresholds

• Participant has reversible toxicities from prior cancer therapy that have not recovered to Grade 1 or baseline. Any unre...

Reason: Requires clinical assessment of toxicity grades from prior t

• Participant has any unstable or clinically significant concurrent medical condition... that would, in the opinion of the...

Reason: Requires clinical judgment (investigator opinion)

... and 1 more

✓ Procedural Criteria (Auto-Pass)

These procedural requirements are assumed to be met pending enrollment:

✓ Males or females ≥18 years of age who have provided written informed consent prior to completing any...

✓ Participants must have a tumor lesion amenable to biopsy and must provide tumor biopsy sample at bas...

✓ Participant who is pregnant, breastfeeding, or is of childbearing potential... who are not willing t...

✓ Sexually active participants who refuse to use a condom during intercourse or participants who will ...

Clinical Notes

■ Patient Clinical Documentation

70 year old male with EGFR mutated exon 19 mutation metastatic adenocaricnoma of the lung, other mutations are negative, progressed on osimertinib. He has bone and lung and liver metastasis ECOG is 0
PT has normal laboratory function, EGFr over 60ml/min, liver function normal, CBC normal
no toxicity from Osimertinib
pt is HIV negative, hpe C negative

Total: 355 characters

✓ Procedural Criteria - Auto-Pass (4 items)

These procedural requirements are assumed to be met:

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✓	Males or females ≥18 years of age who have provided written informed consent prior to completing any study-specific procedure. For Arm 2d, participants ≥12 years are eligible with informed consent/assent.
✓	Participants must have a tumor lesion amenable to biopsy and must provide tumor biopsy sample at baseline (archival FFPE tissue collected within 90 days of informed consent is accepted as long as no intervening therapy is received).
✓	Participant who is pregnant, breastfeeding, or is of childbearing potential... who are not willing to employ a highly effective method of contraception during dosing and for 90 days after the last dose of mRNA-4359 or 4 months after the last dose of pembrolizumab or 5 months after the last dose of ipilimumab/nivolumab.
✓	Sexually active participants who refuse to use a condom during intercourse or participants who will not refrain from sperm donation while taking study treatment and for the specified period.

This report is generated by ClinixBoost Clinical Trial Matcher and is intended for informational purposes only. Final eligibility determination should be made by qualified clinical personnel in accordance with the full trial protocol.

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