ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung Carcinoma

A Study Of Multiple Immunotherapy-Based Treatment Combinations In Participants With Metastatic Non-Small Cell Lung Cancer (Morpheus- Non-Small Cell Lung Cancer)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	8 Countries	NCT03337698 2017-001267-21 BO39610

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib/II, Open-Label, Multicenter, Randomized Umbrella Study Evaluating The Efficacy And Safety Of Multiple Immunotherapy-Based Treatment Combinations In Patients With Metastatic Non-Small Cell Lung Cancer (Morpheus-Lung)

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of immunotherapy-based treatment combinations in participants with metastatic non-small cell lung cancer (NSCLC). Two cohorts will be enrolled in parallel in this study: Cohort 1 will consist of participants with tumor PD-L1 expression who have received no prior systemic therapy for metastatic NSCLC, and Cohort 2 will consist of participants who experienced disease progression during or following treatment with a platinum-containing regimen and a PD-L1/PD-1 checkpoint inhibitor, given in combination as one line of therapy or as two separate lines of therapy, regardless of PD-L1 expression. In each cohort, eligible participants will initially be assigned to one of several treatment arms (Stage 1). Participants who experience disease progression, loss of clinical benefit, or unacceptable toxicity during Stage 1 may be eligible to continue treatment with a different treatment regimen (Stage 2).

Hoffmann-La Roche	**Phase 1/Phase 2**
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	**Age**	**Healthy Volunteers**

All	# 18 Years	No

Inclusion Criteria:

General Inclusion Criteria

- Eastern Cooperative Oncology Group (ECOG) performance Status of 0 or 1
- Life expectancy greater than or equal to 3 months
- Histologically or cytologically confirmed metastatic, non-squamous or squamous Non-Small Cell Lung Cancer (NSCLC)
- Measurable disease (at least one target lesion)
- Adequate hematologic and end-organ function
- Tumor accessible for biopsy
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating eggs as outlined for each specific treatment arm
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm, as outlined for each specific treatment arm

Inclusion Criteria for Cohort 1

- No prior systemic therapy for metastatic NSCLC
- High tumor PD-L1 expression, defined as Tumor Proportion Score (TPS) or TCs >= 50% or TC3

Inclusion Criteria for Cohort 2

- Disease progression during or following treatment for metastatic or locally advanced, inoperable NSCLC

Exclusion Criteria:

- Prior allogeneic stem cell or solid organ transplantation
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently)
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- History of leptomeningeal disease
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography scan
- History of malignancy other than NSCLC within 2 years prior to screening
- Active tuberculosis
- Severe infection within 4 weeks prior to initiation of study treatment