ForPatients
by Roche

Cáncer de pulmón de células no pequeñas

ESTUDIO ALEATORIZADO, MULTICÉNTRICO, DE ETIQUETA ABIERTA Y CRUZADO PARA EVALUAR LA PREFERENCIA INFORMADA DE LOS PARTICIPANTES Y LOS PROFESIONALES DE LA SALUD CON RESPECTO A LA ADMINISTRACIÓN SUBCUTÁNEA DE ATEZOLIZUMAB EN COMPARACIÓN CON LA FORMULACIÓN INTRAVENOSA, EN PARTICIPANTES QUE PADECEN CÁNCER DE PULMÓN DE CÉLULAS NO PEQUEÑAS (IMscin002)

A Study to Evaluate Participant and Healthcare Professional Reported Preference for Subcutaneous Atezolizumab Compared With Intravenous Atezolizumab Formulation in Participants With Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completo	12 Countries	NCT05171777 MO43576 RENIS IS003795

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

A Randomized, Multicenter, Open-Label Cross-Over Study to Evaluate Participant and Healthcare Professional Reported Preference for Subcutaneous Atezolizumab Compared With Intravenous Atezolizumab Formulation in Participants With Non-Small Cell Lung Cancer

Trial Summary:

This is a Phase II, randomized, multi-center, multinational, open-label, cross-over study in adult participants with PD-L1-positive NSCLC. Two populations will be included: participants with resected Stage II, IIIA, and selected IIIB (T3-N2) NSCLC who have completed adjuvant platinum-based chemotherapy without evidence of disease relapse/ recurrence, and chemotherapy-naïve participants with Stage IV NSCLC. The study will evaluate participant- and healthcare professionals (HCP)-reported preference for atezolizumab subcutaneous (SC) compared with atezolizumab intravenous (IV).

Hoffmann-La Roche	Phase 2
Sponsor	Phase

ForPatients
by Roche

Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

Inclusion Criteria:

Inclusion Criteria for All Participants:

- ECOG performance status of 0 or 1

Inclusion Criteria for Participants with Early-stage NSCLC:

- Participants must have a complete resection of a histologically or cytologically confirmed Stage II, IIIA, and selected IIIB (T3-N2) NSCLC
- PD-L1 expression TC # 1% or TPS # 1%
- Participants must have completed adjuvant chemotherapy at least 4 weeks and up to 12 weeks prior to randomization and must be adequately recovered from chemotherapy. For participants in the adjuvant setting, neoadjuvant chemotherapy or chemoradiotherapy is acceptable provided that participants also received adjuvant chemotherapy as per protocol's requirement.

Inclusion Criteria for Participants with Stage IV NSCLC:

- Histologically or cytologically confirmed, Stage IV non-squamous or squamous NSCLC
- Life expectancy # 18 weeks in the opinion of the investigator
- PD-L1 expression TC # 50% or TPS # 50% or TC3 or IC3
- No prior systemic treatment for Stage IV non-squamous or squamous NSCLC
- Participants who have received prior neo-adjuvant, adjuvant chemotherapy, radiotherapy, or chemoradiotherapy with curative intent for non-metastatic disease must have experienced a treatment-free interval of at least 6 months from randomization since the last chemotherapy, radiotherapy, or chemoradiotherapy cycle.

Exclusion Criteria:

Exclusion Criteria for All Participants:

- History of malignancy within 5 years prior to initiation of study treatment, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Participants known to have a sensitizing mutation in the EGFR gene or an ALK fusion oncogene
- History of leptomeningeal disease
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency

- History of idiopathic pulmonary fibrosis, organizing pneumonia), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina

Exclusion Criteria for Participants with Stage IV NSCLC:

- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases