ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Phase 1b Study of Atezolizumab in Combination With Erlotinib or Alectinib in Participants With Non-Small Cell Lung Cancer (NSCLC)

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT02013219 2013-004382-13 WP29158

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This open-label, multicenter study will assess the safety, tolerability, and pharmacokinetics of intravenous (IV) dosing of atezolizumab in combination with oral erlotinib or alectinib in participants with NSCLC. This study has two stages. In the erlotinib group, the combination treatment will be given to participants with epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI)-treatment-naive, advanced (nonresectable) NSCLC in a safety-evaluation stage and to participants with previously untreated EGFR mutation-positive, advanced NSCLC in an expansion stage (Stage 2). In the alectinib group, for both the safety-evaluation and expansion stages (Stages 1 and 2), the combination will be given to participants who are treatment-naive with anaplastic lymphoma kinase (ALK)-positive advanced NSCLC. In Stage 1, erlotinib will be given at a starting dose of 150 milligrams (mg) by mouth (PO) once daily (QD) and the starting dose of alectinib will be 600 mg twice daily (BID), for 28 consecutive days during Cycle 1 and on Days 1 through 21 of each cycle thereafter. The starting dose of atezolizumab will be 1200 mg, administered every 3 weeks (q3W) starting on Day 8 of Cycle 1. If the starting regimen for a combination treatment is not tolerated, alternative doses and/or schedules of erlotinib and atezolizumab or alectinib and atezolizumab may be tested to determine potential recommended Phase 2 dose (RP2D) for that combination treatment. In Stage 2, a potential RP2D and schedule for each combination treatment will be investigated in an expansion cohort. For both stages, continuation of treatment beyond Cycle 1 will be at the discretion of the treating investigator. Study treatment will be discontinued in participants who experience disease progression or unacceptable toxicity, are not compliant with the study protocol, or, in their opinion or in the opinion of the investigator, are not benefiting from study treatment. However, in the absence of unacceptable toxicity, participants with second-line or greater NSCLC who are still receiving atezolizumab at the time of radiographic disease progression may be permitted to continue study treatment.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**>=18 Years**	**No**