ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A clinical trial to compare atezolizumab plus tiragolumab with durvalumab in people with Stage III non-small cell lung cancer that cannot be removed by surgery (unresectable) and whose cancer has not gotten worse after chemoradiotherapy (SKYSCRAPER-03)

A Study of Atezolizumab and Tiragolumab Compared With Durvalumab in Participants With Locally Advanced, Unresectable Stage III Non-Small Cell Lung Cancer (NSCLC)

Trial Status	Trial Runs In	Trial Identifier
Completed	26 Countries	NCT04513925 2019-004773-29 GO41854

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 III, Open-Label, Randomized Study of Atezolizumab and Tiragolumab Compared With Durvalumab in Patients With Locally Advanced, Unresectable Stage III Non-Small Cell Lung Cancer Who Have Not Progressed After Concurrent Platinum-Based Chemoradiation

Trial Summary:

The purpose of this study is to evaluate the efficacy and safety of atezolizumab in combination with tiragolumab compared with durvalumab in participants with locally advanced, unresectable Stage III non-small cell lung cancer (NSCLC) who have received at least two cycles of concurrent platinum-based chemoradiotherapy (CRT) and have not had radiographic disease progression.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04513925 2019-004773-29 GO41854
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the SKYSCRAPER-03 clinical trial work?
This clinical trial is recruiting people who have a particular type of lung cancer called non-small cell lung cancer or NSCLC. In order to take part, patients must have NSCLC that is locally advanced (in the lung and lymph nodes in the middle of the chest), inoperable (cannot be removed by surgery) and have received at least two cycles of chemoradiotherapy without their disease worsening.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus tiragolumab versus durvalumab alone in patients with NSCLC. In this clinical trial, you will get either atezolizumab plus tiragolumab or durvalumab alone.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must be diagnosed with locally advanced, inoperable NSCLC and have received at least 2 cycles of chemoradiation without your cancer becoming worse. You must not have had any history of prior NSCLC or have tumours with a mutation in the epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) gene.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and given either:

- tiragolumab plus atezolizumab, given as an infusion into the vein every 28 days for no more than 13 times (approximately 1 year)

- OR durvalumab, given as an infusion into the vein once every 2 weeks for no more than 26 times or every 4 weeks for no more than 13 times (approximately 1 year), depending on the dose you are given

You will have an equal chance of being placed in either group and will be told which group you are in.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment atezolizumab plus tiragolumab OR durvalumab for approximately 1 year. You are free to stop this treatment at any time. While receiving treatment, you will be seen regularly by the clinical trial staff every 2 weeks until you complete treatment, and then approximately every 3 months after that for up to 1 year. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After you stop receiving treatment, you will still be contacted regularly by the clinical trial staff at least every 3 months.

What happens if I am unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04513925

Trial-identifier: NCT04513925

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Histologically or cytologically documented NSCLC with locally advanced, unresectable Stage III NSCLC of either squamous or non-squamous histology
- Whole-body Positron Emission Tomography-Computed Tomography (PET-CT) scan, performed prior and within 42 days of the first dose of concurrent chemoradiotherapy (cCRT)
- At least two prior cycles of platinum-based chemotherapy administered concurrently with radiotherapy (RT), which must be completed within 1 to 42 days prior to randomization in the study (one cycle of cCRT is defined as 21 or 28 days)
- The radiotherapy (RT) component in the cCRT must have been at a total dose of radiation of 60 (±10 percent [%]) gray (Gy) (54 Gy to 66 Gy) administered by intensity modulated RT (preferred) or 3D-conforming technique
- No progression during or following concurrent platinum-based CRT
- A known PD-L1 result
- Life expectancy >/= 12 weeks
- Adequate hematologic and end-organ function
- Female participants must be willing to avoid pregnancy for 90 days after the final dose of tiragolumab and 5 months after the final dose of atezolizumab, or for 3 months after the final dose of durvalumab
- Male participants must remain abstinent or use a condom during the treatment period and for 90 days after the final dose of tiragolumab

- Male participants must not donate sperm during the treatment period and for 90 days after the final dose of tiragolumab

Exclusion Criteria:

- Any history of prior NSCLC and/or any history of prior treatment for NSCLC (participants must be newly diagnosed with unresectable Stage III disease)
- NSCLC known to have a mutation in the epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) fusion oncogene
- Any evidence of Stage IV disease
- Treatment with sequential CRT for locally advanced NSCLC
- Participants with locally advanced NSCLC who have progressed during or after the definitive cCRT prior to randomization
- Any Grade >2 unresolved toxicity from previous CRT
- Grade >= 2 pneumonitis from prior CRT
- 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
- History of malignancy other than NSCLC within 5 years prior to screening with the exception of malignancies with a negligible risk of metastasis or death
- Prior allogeneic stem cell or solid organ transplantation
- Active Epstein-Barr virus (EBV) infection or known or suspected chronic active EBV infection at screening
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-cytotoxic T lymphocyte-associated protein 4, anti-T-cell immunoreceptor with Ig and ITIM domains (anti-TIGIT), anti-PD-1 and anti-PD-L1
- Any prior Grade >/= 3 immune-mediated adverse event or any unresolved Grade > 1 immune-mediated adverse event while receiving any previous immunotherapy agent other than immune checkpoint blockade agents
- Treatment with systemic immunosuppressive medication
- Women who are pregnant, or breastfeeding