ForPatients
*by Roche*

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

# A clinical trial to compare RO7247669 plus platinum-based chemotherapy with pembrolizumab plus platinum-based chemotherapy in people with untreated non-small cell lung cancer that has grown or spread

A Study of Tobemstomig Plus Platinum-Based Chemotherapy vs Pembrolizumab Plus Platinum-Based Chemotherapy in Participants With Previously Untreated Non-Small Cell Lung Cancer

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 11 Countries | NCT05775289 BO44178 |

*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 II, Randomized, Multicenter, Double-Blind, Controlled Study of Tobemstomig Plus Platinum-Based Chemotherapy Versus Pembrolizumab Plus Platinum-Based Chemotherapy in Patients With Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer

## *Trial Summary:*

The purpose of this study is to evaluate the efficacy, safety, and pharmacokinetics of tobemstomig (RO7247669) in combination with platinum-based chemotherapy compared with pembrolizumab plus platinum-based chemotherapy in participants with previously untreated, locally advanced, unresectable (Stage IIIB/IIIC) or metastatic (Stage IV) non-small-cell lung cancer (NSCLC) who are not eligible to receive curative surgery and/or definitive chemoradiotherapy.

**Hoffmann-La Roche**
Sponsor

**Phase 2**
Phase

**NCT05775289 BO44178**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## 1. Why is the BO44178 clinical trial needed?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. New treatments are needed that improve health outcomes for people living with NSCLCs that have grown (also called ‘locally advanced’) or spread to other parts of the body (also called ‘metastatic’) and who have not previously received treatment for NSCLC.

There are two main types of NSCLC – non-squamous and squamous, which are based on the type of cells found in the cancer.

Treatment for non-squamous NSCLCs depends on whether or not they contain certain genetic changes (mutations). The standard-of-care treatment for previously untreated advanced non-squamous NSCLC that does not contain certain mutations, and for previously untreated advanced squamous NSCLC, is cancer immunotherapy (such as pembrolizumab) with or without platinum-based chemotherapy (such as carboplatin and pemetrexed or paclitaxel).

Cancer immunotherapies can help your immune system stop or reverse tumour growth. RO7247669 is an experimental cancer immunotherapy being tested in this clinical trial in combination with platinum-based chemotherapy to see how well it works compared with the standard-of-care treatment in people with squamous or non-squamous NSCLC.

## 2. How does the BO44178 clinical trial work?

This clinical trial is recruiting people who have a type of lung cancer called NSCLC. People can take part if they have untreated NSCLC that has grown (‘locally advanced’) or has spread to other body parts (‘metastatic’).

The purpose of this clinical trial is to compare the effects, good or bad, of RO7247669 plus platinum-based chemotherapy against pembrolizumab plus platinum-based chemotherapy in people with NSCLC.

Participants who take part in this clinical trial will receive either:

- RO7247669 in combination with platinum-based chemotherapy (pemetrexed or paclitaxel, and carboplatin) OR
- Pembrolizumab in combination with platinum-based chemotherapy (pemetrexed or paclitaxel, and carboplatin)

Participants will be given the clinical trial treatment every 3 weeks (also called treatment ‘cycles’) for as long as treatment helps. Participants will be seen by the clinical trial doctor every 3 weeks until the end of their participation in the trial. These hospital visits will

include checks to see how the participant is responding to the treatment and any side effects they may be having.

If a participant stops treatment because their cancer gets worse, the clinical trial doctor will follow up with them by telephone calls or clinic visits every 3 months for as long as they agree to it.

Participants' total time in the clinical trial will depend on how well the trial treatment controls the cancer and could be up to approximately 4 and a half years. Participants are free to stop trial treatment and leave the clinical trial at any time.

**3. What are the main endpoints of the BO44178 clinical trial?**

The main clinical trial endpoints (the main results that are measured in the trial to see if the clinical trial treatment has worked) are:

1) the number of participants who have either no detectable cancer or who have cancer that has reduced in size (objective response rate)

2) the length of time between the start of the trial and participants cancer getting worse (progression-free survival)

The other clinical trial endpoints include the:

- length of time participants live (overall survival),
- participant-reported lung cancer symptoms and quality of life,
- number and seriousness of any side effects that occur while on the clinical trial treatment

**4. Who can take part in this clinical trial?**

People can take part in this trial if they are at least 18 years old and have been diagnosed with locally advanced or metastatic NSCLC that is not suitable for surgery or chemoradiotherapy and have not received previous treatment for NSCLC.

People may not be able to take part in this trial if they have certain types of NSCLC, or if they have certain medical conditions or have previously received certain treatments. Women cannot take part in this trial if they are pregnant or breastfeeding or are planning to become pregnant soon after the clinical trial.

**5. What treatment will participants be given in this clinical trial?**

Everyone who joins this clinical trial will be split into two groups randomly (by chance). Then, depending on the type of NSCLC that they have (either 'non-squamous' or 'squamous'), participants will be given:

**Group 1: RO7247669 in combination with platinum-based chemotherapy**

- People with **non-squamous NSCLC** will be given **RO7247669** in combination with **pemetrexed** and **carboplatin** every 3 weeks for four treatment cycles. Then **RO7247669** in combination with **pemetrexed** will be given every 3 weeks for as long as treatment helps. All treatments will be given as a drip (infusion) into a vein
- People with **squamous NSCLC** will be given **RO7247669** in combination with **paclitaxel** and **carboplatin** every 3 weeks for four treatment cycles. Then **RO7247669** will be given every 3 weeks for as long as treatment helps. All treatments will be given as an infusion into a vein

**Group 2: Pembrolizumab in combination with platinum-based chemotherapy**

- People with **non-squamous NSCLC** will be given **pembrolizumab** in combination with **pemetrexed** and **carboplatin** every 3 weeks for four treatment cycles. Then **pembrolizumab** in combination with **pemetrexed** will be given every 3 weeks for as long as treatment helps. All treatments will be given as an infusion into a vein
- People with **squamous NSCLC** will be given **pembrolizumab** in combination with **paclitaxel** and **carboplatin** every 3 weeks for four treatment cycles. Then **pembrolizumab** will be given every 3 weeks for as long as treatment helps. All treatments will be given as an infusion into a vein

Participants will have an equal chance of being placed in either group.

This is a double-blinded trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant's clinical trial doctor can find out which group the participant is in if their safety is at risk.

**6. Are there any risks or benefits in taking part in this clinical trial?**

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

**Risks associated with the clinical trial drugs**

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe and even life-threatening and can vary from person to person.

**RO7247669, pemetrexed, carboplatin, paclitaxel and pembrolizumab**

Potential participants will be told about the known side effects of RO7247669, pemetrexed, carboplatin, paclitaxel and pembrolizumab and, where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

RO7247669, pemetrexed, carboplatin, paclitaxel and pembrolizumab will be given as a drip into a vein (intravenous infusion). Participants will be told about any known side effects of intravenous infusion.

**Potential benefits associated with the clinical trial**

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

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For more information about this clinical trial, see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT05775289

## *Inclusion Criteria:*

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Histologically or cytologically documented locally advanced, unresectable (Stage IIIB/IIIC) or metastatic (Stage IV) NSCLC who are not eligible for curative surgery and/or definitive chemoradiotherapy
- No prior systemic treatment for metastatic NSCLC
- Known tumor PD-L1 status
- Confirmed availability of representative tumor specimens
- Measurable disease
- Life expectancy of at least 12 weeks
- Adequate hematologic and end-organ function
- Negative for HIV, hepatitis B (HBV), and hepatitis C (HCV)
- Adequate cardiovascular function

## *Exclusion Criteria:*

- NSCLC known to have a mutation in the EGFR gene or an ALK fusion oncogene
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Untreated or clinically unstable spinal cord confession
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once a month or more frequently)
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency, including, but not limited to, myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, antiphospholipid antibody syndrome, granulomatosis with polyangiitis, Sjögren syndrome, Guillain-Barré syndrome, or multiple sclerosis, with exceptions defined by the protocol
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on the screening chest computed tomography (CT) scan
- Active tuberculosis (TB) or untreated latent TB
- Current treatment with anti-viral therapy for HBV or HCV
- Significant cardiovascular disease within 3 months prior to randomization
- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- History of malignancy other than NSCLC within 5 years prior to randomization, with the exception of malignancies with a negligible risk of metastasis or death e.g., 5-year OS] rate > 90%), such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal breast carcinoma in situ, or Stage I uterine cancer
- Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia, or any active infection that could affect patient safety
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment
- Prior allogeneic stem cell or solid organ transplantation
- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during study treatment or within 5 months after the final dose of study treatment
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Any anti-cancer therapy, including hormonal therapy, within 21 days prior to initiation of study treatment

- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including, but not limited to, anti-cytotoxic T lymphocyte-associated protein 4, anti-T cell immunoreceptor with Ig and tyrosine-based inhibition motif domains, anti-PD-1 and anti-PD-L1 therapeutic antibodies, and anti-LAG3) agents
- Treatment with systemic immunostimulatory agents (including, but not limited to, interferon and interleukin-2) within 4 weeks or 5 drug-elimination half lives (whichever is longer) prior to initiation of study treatment
- Treatment with systemic immunosuppressive medication (including, but not limited to, corticosteroids, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor [TNF] agents) within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during study treatment
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies, fusion proteins, or platinum-containing compounds
- Known hypersensitivity to Chinese hamster ovary cell products or to any component of the tobemstomig or pembrolizumab formulation
- Known allergy or hypersensitivity or other contraindication to any component of the chemotherapy regimen the patient may receive during the study
- Pregnancy or breastfeeding