BO44178 (Roche)

A Study of RO7247669 Plus Platinum-Based Chemotherapy vs Pembrolizumab Plus Platinum-Based Chemotherapy in Participants With Previously Untreated Non-Small Cell Lung Cancer

This is the trial summary as assessed on clinicaltrials.gov on 27/04//2023.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT05775289.

Trial Design:

ARM	INTERVENTION
Experimental: Arm A: **RO7247669 + Platinum-Based Chemotherapy** Participants with non-squamous (NSQ) NSCLC will receive induction treatment with blinded RO7247669 in combination with pemetrexed and carboplatin, all on Day 1 every 3 weeks (Q3W) for four 21-day cycles, followed by Q3W maintenance therapy with blinded RO7247669 together with pemetrexed until disease progression or treatment discontinuation. Participants with squamous (SQ) NSCLC will receive blinded RO7247669 in combination with paclitaxel and carboplatin, all on Day 1 Q3W for four 21 day cycles, followed by blinded RO7247669 (on Day 1) Q3W until disease progression or treatment discontinuation.	Drug: RO7247669 Participants will receive intravenous (IV) RO7247669 for four 21-day cycles Drug: Paclitaxel Participants will receive IV paclitaxel Q3W for four 21-day cycles Drug: Pemetrexed Participants will receive IV pemetrexed Q3W until disease progression or unacceptable toxicity Drug: Carboplatin Participants will receive IV carboplatin Q3W for four 21-day cycles
Active comparator: Arm B: **Pembrolizumab + Platinum-Based Chemotherapy** Participants with NSQ NSCLC will receive induction treatment with blinded pembrolizumab in combination with pemetrexed and carboplatin, all on Day 1 Q3W for four 21-day cycles, followed by a maintenance therapy with blinded pembrolizumab together with pemetrexed Q3W until disease progression or treatment discontinuation. Participants with SQ NSCLC will receive blinded pembrolizumab in combination with paclitaxel and carboplatin, all on Day 1 Q3W for four 21-day cycles, followed by blinded pembrolizumab (on Day 1) Q3W until disease progression or treatment discontinuation.	Drug: Pembrolizumab Participants will receive IV pembrolizumab four 21-day cycles Drug: Paclitaxel Participants will receive IV paclitaxel Q3W for four 21-day cycles Drug: Pemetrexed Participants will receive IV pemetrexed Q3W until disease progression or unacceptable toxicity Drug: Carboplatin Participants will receive IV carboplatin Q3W for four 21-day cycles

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, Wegener granulomatosis, 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 RO7247669 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