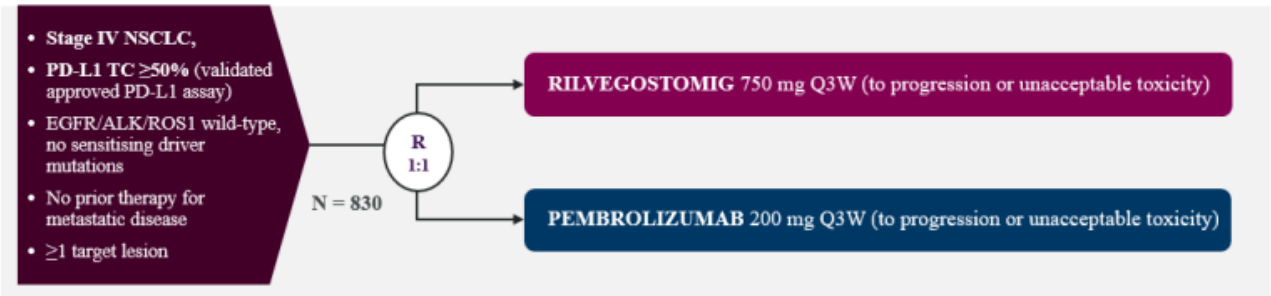
Artemide (D702GC00001)

A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab Monotherapy for the First-line Treatment of Patients with PD-L1-high Metastatic Non-small Cell Lung Cancer.

This is the trial summary as assessed on clinicaltrials.gov. You can check this on this direct link:

Study Details | NCT06868277 | A Global Phase III Study of Rilvegostomig or Pembrolizumab Monotherapy for First-Line Treatment of PD-L1-high Metastatic Non-small Cell Lung Cancer | ClinicalTrials.gov

Trial Design:



ALK = anaplastic lymphoma kinase; *EGFR* = epidermal growth factor receptor; N = number of participants; NSCLC = non-small cell lung cancer; PD-L1 = programmed cell death-ligand 1; Q3W = every 3 weeks; R = ratio; *ROS1* = c-ros oncogene 1; TC = tumor cell.

Inclusion criteria:

1. Histologically or cytologically documented NSCLC, including all histological subtypes
2. Stage IV mNSCLC
3. Absence of sensitizing EGFR mutations and ALK and ROS1 rearrangements
4. Absence of documented tumor genomic mutation results from tests conducted as part of standard local practice in any other actionable driver oncogenes for which there are locally approved targeted 1L therapies
5. WHO/ECOG performance status of 0 or 1
6. Minimum life expectancy of 12 weeks.
7. Tumor PD-L1 expression of TC ≥ 50%
8. At least one lesion not previously irradiated that qualifies as a RECIST 1.1 TL at baseline and can be accurately measured at baseline as ≥ 10 mm in the longest diameter (except lymph nodes, which must have short axis ≥ 15 mm) with CT or MRI and is suitable for accurate repeated measurements.

Exclusion criteria:

1. As judged by the investigator, any severe or uncontrolled systemic diseases, including, but not limited to, uncontrolled hypertension, and active bleeding diseases, ongoing or active known infection; ILD (of any grade), serious chronic

gastrointestinal conditions associated with diarrhea (eg, active inflammatory bowel disease), active non-infectious skin disease (including any grade rash, urticaria, dermatitis, ulceration, or psoriasis) requiring systemic treatment, psychiatric illness/social situations, substance abuse, or significant cardiac conditions which, in the investigator's opinion, makes it undesirable for the participant to participate in the study or that would jeopardize compliance with the protocol.

2. History of another primary malignancy except for malignancy treated with curative intent with no known active disease ≥ 2 years before the first dose of study intervention and of low potential risk for recurrence. Exceptions include adequately resected non-melanoma skin cancer and curatively treated in situ disease.
3. Presence of small cell and neuroendocrine histology components.
4. Brain metastases unless asymptomatic, stable, and not requiring steroids or anticonvulsants for at least 7 days prior to randomization. A minimum of 2 weeks must have elapsed between the end of local therapy (brain radiotherapy or surgery) and randomization. Participants must have recovered from the acute toxic effect of radiotherapy or surgery (eg, dizziness and signs of increased intracranial pressure) prior to randomization.
5. Persistent toxicities (CTCAE Grade ≥ 2) caused by previous anticancer therapy, excluding alopecia. Participants may be enrolled with the following chronic, stable Grade 2 toxicities (defined as no worsening to > Grade 2 for at least 3 months prior to the first dose of study intervention and managed with SoC treatment) which the investigator deems related to previous anticancer therapy:
   (a) Chemotherapy-induced neuropathy.
   (b) Fatigue.
   (c) Vitiligo.
   (d) Endocrine disorders, that are controlled with replacement hormone therapy.
6. Any concomitant medication known to be associated with Torsades de pointes.
7. Any prior systemic therapy received for advanced or mNSCLC.
   Note: Prior systemic therapy in the neoadjuvant or adjuvant setting and/or definitive radio- or chemoradiotherapy for early-stage resectable disease are allowed, provided that recurrence or progression has occurred > 12 months after the end of treatment.
8. Any prior exposure to an anti-TIGIT therapy or any other anticancer therapy targeting immune-regulatory receptors or mechanisms.
9. Any prior treatment with an anti-PD-1 or anti-PD-L1 agent.
10. Any concurrent chemotherapy, radiotherapy, immunotherapy, investigational, or biologic or hormonal therapy for cancer treatment other than those under investigation in this study. Concurrent use of hormonal therapy for non-cancer-related conditions (eg, insulin for diabetes, HRT, gonadotropin-releasing hormone analogs, and bisphosphonates) is acceptable.
11. Palliative radiotherapy with a limited field of radiation within 2 weeks or with a wide field of radiation or to more than 30% of the bone marrow within 4 weeks, prior to the first dose of study intervention.
    Note: Local treatment of isolated lesions for palliative intent is acceptable.