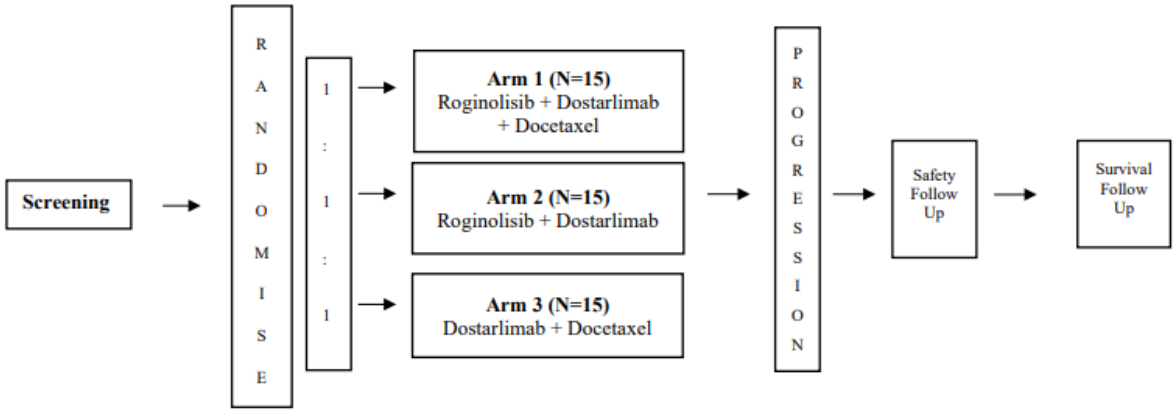
Pulmo-01 (IOA-244-202)

A Phase I/IIa Study of Roginolisib in combination with dostarlimab with or without docetaxel in patients with advanced non-squamous NSCLC who have progressed on standard of care immune checkpoint therapy and platinum doublet chemotherapy or standard immunotherapy without chemotherapy.

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

Study Details | A Study of Roginolisib (IOA-244) in Combination With Dostarlimab With or Without Docetaxel in Metastatic Non Small-cell Lung Cancer (NSCLC) Patients | ClinicalTrials.gov

Trial Design:



Treatment will be given on a 21-day cycle schedule

Inclusion criteria:

1. Histologically or cytologically confirmed stage IIIb/IV or recurrent non-squamous NSCLC.
2. Documented radiographic disease progression on or after prior anti-PD(L)1 therapy and platinum chemotherapy or after standard immunotherapy without chemotherapy in accordance with standard of care.
3. Have measurable disease per RECIST v1.1 as determined by the investigator. Tumour lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.

Exclusion criteria:

1. Histologically or cytologically confirmed squamous NSCLC.
2. Previously treated with dostarlimab or docetaxel.
3. History of a prior Grade 3 or 4 immune-related AE (irAE) or any grade ocular irAE from prior immunotherapy which did not respond to corticosteroid therapy or resolved with treatment interruptions and returned to at least Grade 1.

4. Known active CNS metastases and/or carcinomatous meningitis.
5. History of long QT syndrome or history or presence of an abnormal ECG that, in the Investigator's opinion, is clinically meaningful. Screening QTc interval > 450 milliseconds is excluded (corrected by Fridericia). In the event that a single QTc is > 450 milliseconds, the patient may enrol if the average QTc for the 3 ECGs is < 450 milliseconds.
6. Any history of interstitial lung disease or pneumonitis.
7. Clinically significant (i.e., active) cardiovascular disease.
8. History of allogenic stem cell transplantation or organ transplantation.
9. Cirrhosis or current unstable liver or biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, oesophageal/ gastric varices, persistent jaundice.
10. Active infection requiring systemic therapy.
11. Patients with active malignancy requiring concurrent intervention or previous malignancies (except non-melanoma skin cancers, and the following in situ cancers: bladder, gastric, colon, endometrial, cervical/dysplasia, melanoma or breast) unless a complete remission was achieved at least 2 years prior to study entry and no additional therapy is required during the study period.
12. Treatment with anticancer medications, investigational drugs, surgery and/or radiation within the following interval before the first administration of study drug:
    - <90 days for prior taxane
    - <14 days for chemotherapy, targeted small-molecule therapy, surgical resection of lesions or radiation therapy (prior palliative radiotherapy must have been completed at least 14 days prior to study drug administrations).
    - <14 days for a prior PD1 targeted agent.
    - <28 days for prior monoclonal antibody used for anticancer therapy with the exception of PD1 targeted agents.
13. Receiving an immune-suppressive based treatment for any reason (including chronic use of systemic corticosteroid at doses >10 mg/day prednisone equivalent) within 14 days prior to study treatment. Use of inhaled or topical steroids (including but not limited to creams or intra-articular injection) or brief corticosteroid use for radiographic procedures or systemic corticosteroids ≤ 10 mg is permitted.