

## BNT327-06

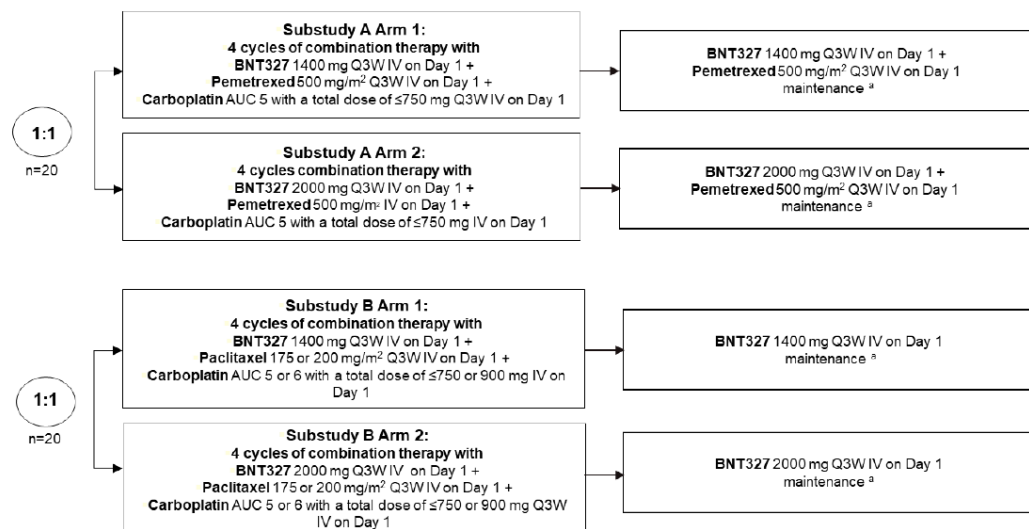
### A Phase II/III, multisite, randomized master protocol for a global trial of BNT327 in combination with chemotherapy and other investigational agents in first-line non-small cell lung cancer

This is the trial summary as assessed on [clinicaltrials.gov](https://clinicaltrials.gov). You can check this on this direct link:

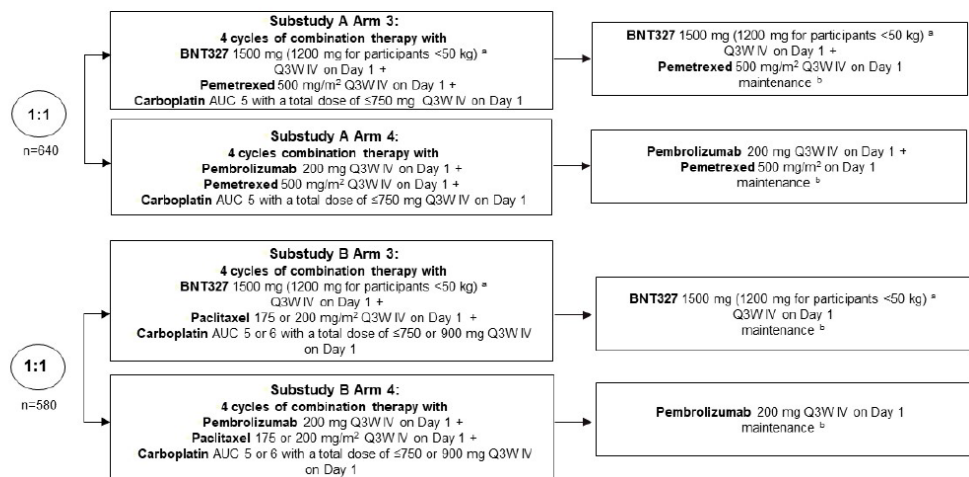
[Study Details | NCT06712316 | Safety, Efficacy, and Pharmacokinetics of BNT327 in Combination With Chemotherapy and Other Investigational Agents for Lung Cancer | ClinicalTrials.gov](#)

#### Trial design:

Phase II: Substudy A (non-squamous NSCLC) and Substudy B (squamous NSCLC)



Phase III: Substudy A (non-squamous NSCLC) and Substudy B (squamous NSCLC)



#### Key Inclusion Criteria:

- Have systemic treatment naive, histologically or cytologically confirmed diagnosis of Stage IIIB or IIIC (who are not amenable to curative surgery or radiotherapy) or Stage

IV NSCLC per the Union Internationale contre le Cancer/American Joint Committee on Cancer staging system, 9th edition.

- Have at least one measurable lesion as the targeted lesion based on RECIST v1.1. Lesions treated after prior local treatment (radiotherapy, ablation, interventional procedures, etc.) are generally not considered as target lesions. If the lesion with prior local treatment is the only targeted lesion, evidence-based radiology must be provided to demonstrate disease progression (the single bone metastasis or the single central nervous system metastasis should not be considered as a measurable lesion).
- Eastern Cooperative Oncology Group Performance Status of 0 or 1.
- Adequate organ function.

**Key Exclusion Criteria:**

- Have histologically or cytologically confirmed NSCLC with small-cell lung cancer histologic or neuroendocrine component.
- Have received any of the following therapies or drugs within the noted time intervals prior to study treatment:
- Previous chemotherapy (platinum-based) or PD(L)-1 for treating NSCLC in either neo-adjuvant/adjuvant or locally advanced/metastatic setting.
- Participants who received prior treatment with anti-VEGF monoclonal antibody, or PD(L)-1/VEGF bispecific antibody
- Have received systemic corticosteroids (at a dosage greater than 10 mg/day of prednisone or an equivalent dose of other corticosteroids) within 7 days prior to the initiation of study treatment. Note: local, intranasal, intraocular, intra-articular or inhaled corticosteroids, short-term use (<=7 days) of corticosteroids for prophylaxis (e.g., prevention of contrast agent allergy) or treatment of non-autoimmune conditions (e.g., delayed hypersensitivity reactions caused by exposure to allergens) are allowed.
- Have uncontrolled hypertension or poorly controlled diabetic conditions prior to study treatment.
- Have a serious or non-healing wound, or (incompletely healed) bone fracture. This includes history (within 6 months prior to study entry) or risk of abdominal fistula, tracheoesophageal fistula, gastrointestinal perforation, or intra-abdominal abscess or esophageal and gastric varices. In addition, the participant must have undergone correction (or spontaneous healing) of the perforation/fistula and/or the underlying process causing fistula/perforation.
- Participants with significant risk of hemorrhage (per investigator clinical judgment).
- Have superior vena cava syndrome or symptoms of spinal cord compression.

NOTE: Other protocol defined Inclusion/Exclusion criteria may apply.