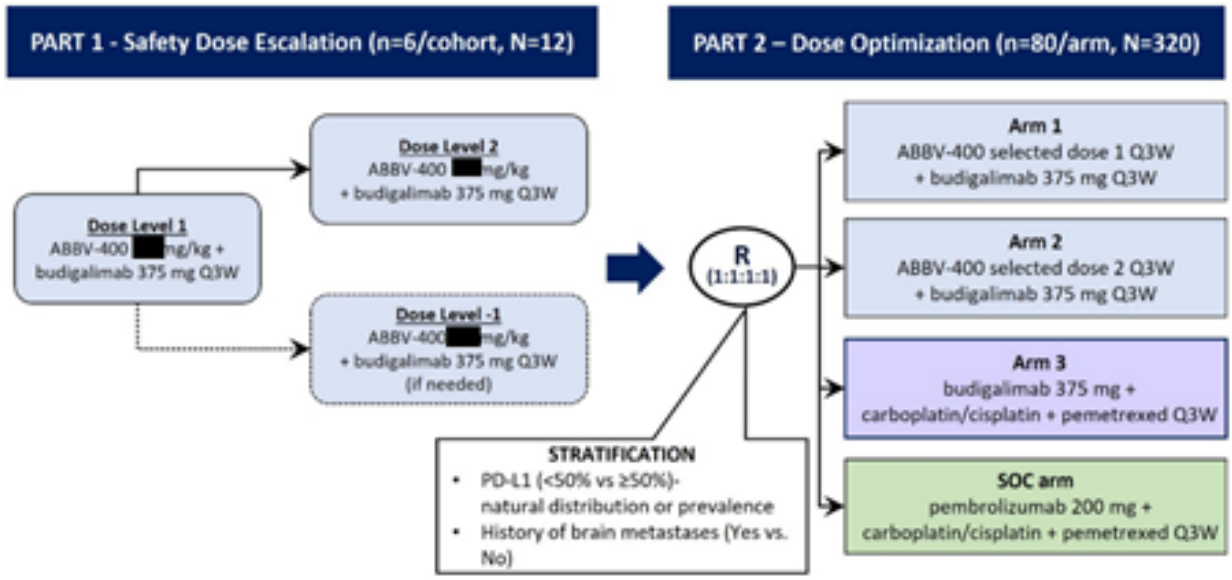
AndroMETa (M24-536 ABBVIE)

An Open-label Multi-Cohort Phase 1b/2 Study to Evaluate the Safety, Efficacy, and Optimal Dose of ABBV-400 in Combination with Budigalimab in Advanced or Metastatic Non-Squamous NSCLC with No Prior Treatment for Advanced Disease and No Actionable Genomic Alterations (AndroMETa-Lung-536)

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

Study Details | A Study to Evaluate the Adverse Events, Efficacy, and Optimal Dose of Intravenous (IV) Telisotuzumab Adizutecan in Combination With IV Budigalimab in Adult Participants With Advanced or Metastatic Non-Squamous NSCLC With No Prior Treatment for Advanced Disease, and No Actionable Genomic Alterations | ClinicalTrials.gov

Trial Design:



Inclusion criteria:

1. Subject must have histologically documented NSq NSCLC that is locally advanced or metastatic– Stage IIIB/C NSCLC (not candidates for surgical resection or definitive chemoradiation) or Stage IV NSCLC according to Version 8 of the International Association for the Study of Lung Cancer (IASLC) Staging Manual in Thoracic Oncology.

2. Subject must consent to provide tumor tissue.

    a. For 1L subjects in Part 1 and Part 2: Recently obtained or archival tissue sample from a metastatic tumor lesion or an unresectable primary lesion previously not irradiated, obtained preferably within 3 months, but not more than 12 months before enrollment. Subjects must not have received any intervening systemic anticancer therapy between the date the submitted tumor tissue was obtained and enrollment.

    • In the case that only tumor samples from previous resection are available, this can be submitted given that samples were obtained preferably within 3 months, but not more than 12 months before enrollment. Subjects must not have received any intervening systemic anticancer therapy between the date the submitted tumor tissue was obtained and enrollment.

3. Subject meets the following criteria:

Part 2 only:

• Subject has not received prior therapy with a PD-(L)1 or PD-L2 inhibitor, a cytotoxic T lymphocyte-associated protein 4 (CTLA-4) inhibitor, a T-cell immunoglobulin and mucin domain containing 3 (TIM 3) inhibitors, or any other immunotherapy agent (e.g., OX40, LAG-3 or TIGIT) for the treatment of cancer.

• Subject must have had no prior systemic therapy for locally advanced or metastatic NSCLC. Subject may have received prior adjuvant/neoadjuvant systemic chemotherapy and/or radiation provided that the subject has not progressed on or within 6 months of completing the regimen and it was completed 6 months or longer prior to the first dose of study drug

Exclusion Criteria:

1. For 1L subjects in Part 1 and 2: Subjects with EGFR or other genomic aberration (e.g., ALK, ROS1, KRAS G12C, BRAFV600E, NTRK1,2,3, RET1, HER-2, MET exon 14 skipping, etc.) for which a locally approved targeted therapy is available for first-line treatment.
2. Subject with known uncontrolled metastases to the CNS

3. Subject has received radiation to the lung that is > 30 Gray (Gy) within 6 months of the first dose of study treatment
4. Unresolved adverse events (AEs) ≥ Grade 1 from prior anticancer therapy, except for alopecia and anemia
5. Clinically significant condition(s) that in the Investigator's opinion, would adversely affect the subject's participation in the study
6. Subject has received anti-cancer therapy for antineoplastic intent including chemotherapy, radiation therapy, immunotherapy, or biologic therapy within 28 days or 5 half-lives of the drug (whichever is shorter) prior to the first dose of study drug
7. Subject has received radiation therapy within 14 days of the first dose of study treatment. Subjects must have recovered from all AEs related to radiation to Grade ≤ 1, not require corticosteroids, and not have had radiation pneumonitis.
8. Subject has systemically used known strong cytochrome P450 (CYP)3A inhibitors within 7 days before the first dose of study drug
9. Subject has current or prior use of corticosteroids within 14 days prior to the first dose of study drug(s)
10. Subject with known uncontrolled metastases to the CNS

For only 1L subjects in Parts 1 and 2:

- Subject with untreated asymptomatic brain metastases (i.e., no neurological symptoms, no requirements for corticosteroids, and no lesion > 1.5 cm) may participate but will require regular imaging of the brain as a site of disease.