M15-534
A Phase 1 Dose-Escalation and Phase 2 Randomized, Open-Label Study of Nivolumab and Veliparib in Combination With Platinum Doublet Chemotherapy in Subjects With Metastatic or Advanced Non-Small Cell Lung Cancer (NSCLC)

Key Inclusion Criteria

- Participant must have cytologically or histologically confirmed Non-small Cell Lung Cancer (NSCLC)
- Participant must have metastatic or advanced NSCLC (Stage IIIB or IV) that is not amenable to surgical resection or radiation or chemoradiation with curative intent at time of study screening
- Participant must have at least one unidimensional measurable NSCLC lesion on a computed tomography (CT) scan as defined by Response Evaluation Criteria in Solid Tumors (RECIST) (version 1.1)
- Participant must have an Eastern Cooperative Oncology Group (ECOG) Performance Score of 0 to 1

Key Exclusion Criteria

- Participant has received prior cytotoxic chemotherapy (including chemotherapy in combination with radiotherapy) for NSCLC, except for adjuvant or neoadjuvant therapy accompanied by surgery with curative intent that was completed one year prior to Cycle 1 Day -2.
- Participant has received prior therapy with a Poly-(ADP-ribose)-Polymerase (PARP) inhibitor
- Participant has received prior treatment with any anti-programmed cell death protein-1 (anti-PD-1), or PD Ligand-1 (PD-L1) or PD Ligand-2 (PD-L2) agent or an antibody targeting other immunoregulatory receptors or mechanisms
- Participant has received radiation therapy to lung greater than 30 Gy within 6 months, or antineoplastic biologic therapy within 21 days, or major surgery within 21 days, or tyrosine kinase inhibitor therapy within 7 days, or palliative radiation within 7 days of the first dose of study medication
- Participant has untreated central nervous system (CNS) metastases

Outcome Measures

Primary
- Progression-free survival (PFS)
- Recommended Phase 2 dose (RPTD)

Secondary
- Duration of Overall Response (DOR)
- Objective Response Rate (ORR)
- Overall Survival (OS)

Veliparib is an investigational drug which has not been approved by regulatory health agencies. Efficacy and safety have not been established.


To learn more about our pipeline, please visit www.abbviescience.com/oncology

To learn more about these studies, please visit https://ClinicalTrials.gov or email abbbvieclinicaltrials@abbvie.com