Phase 2 Adaptive Design Study (M14-239/Teliso-V)
Phase 2, Open-Label Safety and Efficacy Study of Telisotuzumab Vedotin (ABBV-399) in Subjects with Previously Treated c-Met+ Non-Small Cell Lung Cancer

Patient Population
Subjects with locally advanced or metastatic NSCLC c-Met+ as determined by an immunohistochemistry (IHC) assay performed by an AbbVie designated IHC laboratory, who have previously failed and/or are ineligible for first or second line standard of care treatments, including platinum-based chemotherapy doublet and/or an immune checkpoint inhibitor, or an Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor (TKI) (if harboring a therapy qualifying EGFR TK activating mutation).

Endpoints
Primary Efficacy Endpoint:
• Overall response rate assessed by an independent central review according to RECIST, version 1.1. ORR will be defined as the proportion of subjects with a confirmed complete response (CR) or confirmed partial response (PR) based on RECIST, version 1.1.

Secondary Efficacy Endpoints:
• Duration of response
• Disease control rate
• Duration of disease control
• Progression-free survival
• Overall survival

N = ≤ 310

Teliso-V Monotherapy Q2wk Dosing

Key Inclusion Criteria
• Subject must be ≥ 18 years of age.
• Subjects with histologically documented non-squamous cell NSCLC with known EGFR status (wild type or mutant; with documentation of status), or histologically documented squamous cell NSCLC
• Locally advanced or metastatic NSCLC
• Subject must have c-Met+ NSCLC as assessed by an AbbVie designated IHC laboratory. Subject must agree to submit archival or fresh tumor material for assessment of c-Met levels during the pre-screening period.
• If a subject meets eligibility criteria for c-Met protein expression level based on archival tissue material, subject must agree to submit fresh tumor material for assessment of c-Met protein expression level prior to first dose of telisotuzumab vedotin
• Subject who has progressed or is ineligible for treatment with platinum-based chemotherapy doublet, and/or an immune checkpoint inhibitor, or EGFR TKI (if harboring a therapy qualifying EGFR TK activating mutation).
• Subject has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1.

Key Exclusion Criteria
• Subject must have received no more than 2 lines of prior systemic therapy in the metastatic setting.
• Subject must not have adenocarcinoma histology.
• Subject must not have received anticancer therapy including chemotherapy, radiation therapy, immunotherapy, biologic, or any investigational therapy within a period of 28 days or herbal therapy or strong CYP3A4 inhibitors within 7 days prior to the first dose of telisotuzumab vedotin:
  - Palliative radiation therapy for bone, skin or subcutaneous metastases for 10 fractions or less is not subject to a washout period; see below for central nervous system metastases (CNS) metastases
  - For approved targeted small molecules, a washout period of 28 days or 5 half-lives (whichever is longer) is adequate (no washout period required for subjects currently on EGFR TKIs)
• Subject must not have known uncontrolled metastases to the CNS. Subjects with brain metastases are eligible after definitive therapy provided they are asymptomatic and off systemic steroids and anticonvulsants for at least 2 weeks prior to first dose of telisotuzumab vedotin
• Subject must not have known uncontrolled adverse events ≥ grade 2 from prior anticancer therapy, except for alopecia or anemia.
• Subject must not have had major surgery within 21 days prior to the first dose of telisotuzumab vedotin.

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

The anticipated trial start date is October 26, 2018.

Safety will be assessed by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE Version 4.03) and as defined by study protocol.

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