TPS8658 Poster Session

TeliMET NSCLC-04: A phase 2, open-label, randomized, global study of 2 telisotuzumab vedotin regimens in patients with previously treated c-Met protein–overexpressing, locally advanced/metastatic non-squamous *EGFR* wildtype non-small cell lung cancer.

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Background: c-Met protein (also known as MET protein) overexpression is observed in ~25% of patients with non-squamous *EGFR* wildtype (WT) non-small cell lung cancer (NSCLC) and is associated with poor prognosis. Telisotuzumab vedotin (Teliso-V) is a c-Met–directed antibody-drug conjugate consisting of the monoclonal antibody telisotuzumab and the cytotoxic payload monomethyl auristatin E. The primary analysis of the phase 2 LUMINOSTY trial (NCT03539536) demonstrated that Teliso-V at 1.9 mg/kg once every 2 weeks (Q2W) was associated with durable responses in patients with previously treated c-Met protein–overexpressing (OE) advanced/metastatic (a/m) non-squamous *EGFR* WT NSCLC, and adverse events (AEs) were generally manageable. The overall response rate was 28.6% among all patients with c-Met protein overexpression and 34.6% among those with c-Met high protein overexpression (Camidge et al. *JCO* 2024;42:3000-11). **Methods:** This global, multicenter, open-label, randomized phase 2 study (NCT06568939) evaluates the safety and efficacy of Teliso-V monotherapy at 1.6 mg/kg Q2W and 1.9 mg/kg Q2W in patients with previously treated c-Met protein OE, a/m non-squamous *EGFR* WT NSCLC. Eligible patients are ≥18 years old with c-Met protein OE (≥25% tumor cells at 3+ intensity by immunohistochemistry assay [investigational use only assay for MET (SP44) (Roche)]), a/m non-squamous *EGFR* WT NSCLC. Patients must have measurable disease according to RECIST v1.1, ECOG PS 0–1, and documented disease progression on ≥1 prior lines of therapy (≤1 line of prior chemotherapy) in the a/m setting. Approximately 100 patients will be randomized 1:1 to receive Teliso-V monotherapy at either 1.6 mg/kg or 1.9 mg/kg Q2W until disease progression or other protocol-specified discontinuation criteria are met. The primary safety endpoints are treatment-emergent AEs (TEAEs; any grade and grade ≥2), interstitial lung disease (any grade and grade ≥2), peripheral neuropathy (any grade and grade ≥2), ocular surface disorders (any grade and grade ≥2), TEAEs leading to discontinuation, and grade 5 TEAEs. The primary efficacy endpoint is objective response based on RECIST v1.1 by blinded independent central review (BICR). Secondary endpoints are pharmacokinetics, patient-reported outcomes, duration of response by BICR, progression-free survival by BICR, and overall survival. Clinical trial information: NCT06568939. Research Sponsor: AbbVie, Inc.; n/a.