11910 MRTX-500: Phase II trial of sitravatinib (sitra) + nivolumab (nivo) in patients (pts) with non-squamous (NSQ) non-small cell lung cancer (NSCLC) progressing on or after prior checkpoint inhibitor (CPI) therapy

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Background: Therapy with CPI has improved OS across many tumor types, including in a subset of pts with NSCLC. Mechanisms of CPI resistance, however, have been described, including an immunosuppressive TME, which may include recruitment of immunosuppressive myeloid-derived suppressor cells (MDSCs), regulatory T cells (Tregs), and the presence of antigen presenting cells (APCs) in the TME. Sitrata, a selective and potent TKI targeting TANK-binding kinase 1 (TANKBP1) and VEGFR2, reduces the number of MDSCs and Tregs while increasing the ratio of M1/M2-polarized macrophages, and thus is hypothesized to overcome an immunosuppressive TME and augment anti-tumor immune response.

Methods: METHODS: MRTX-500 (NCT02954991) is a phase II study evaluating sitra (120 mg QD) + nivo (Q2W or Q4W) in pts with NSQ NSCLC who have progressed on or after treatment, with a CPI-based regimen (anti–PD1/PD-L1) and/or platinum doublet chemotherapy. The primary endpoint is ORR per RECIST 1.1. Secondary endpoints include OS, PFS, and safety. We report updated efficacy data for pts with NSCLC with PCB compared to historical controls and no new safety signals were observed in pts with NSQ NSCLC who have progressed on or after treatment, with a CPI-based regimen (anti–PD1/PD-L1) and/or platinum doublet chemotherapy. The primary endpoint is ORR per RECIST 1.1. Secondary endpoints include OS, PFS, and safety. We report updated efficacy data for pts with NSCLC with PCB compared to historical controls.

Results: As of 17 October 2020, 68 pts with PCB (57% female; median age, 66 years; ECOG PS 0/1/2, 27%/66%/7% were treated. Median follow-up was 28 months, median OS was 15 months (95% CI 9.3, 21.1) and 2-year OS rates were 56% and 32%, respectively. Median PFS was 6 months, and ORR was 16% (11/68), including 2 CRs. Median duration of response was 13 months. In all CPI-experienced pts evaluated, CRs. Median duration of response was 13 months. In all CPI-experienced pts evaluated.

Conclusions: Sitra + nivo demonstrated antitumor activity and encouraging OS compared to historical controls and no new safety signals were observed in pts with NSCLC who progressed on prior CPI. This combination is being evaluated in the phase III SAPPHIRE study.

Clinical trial identification: NCT02954991.

Disclosure: T.A. Leal: Financial Interests, Personal, Advisory Board: Beyond Spring Pharmaceuticals; Financial Interests, Personal, Advisory Board: AstraZeneca; Financial Interests, Personal, Advisory Board: Boehringer Ingelheim; Financial Interests, Personal, Advisory Board: Blueprint Medicines; Financial Interests, Personal, Advisory Board: Genentech; Financial Interests, Personal, Advisory Board: Novocure; Financial Interests, Personal, Advisory Board: Boehringer Ingelheim; Financial Interests, Personal, Advisory Board: Merck; Financial Interests, Personal, Advisory Board: Takeda; Financial Interests, Personal, Advisory Board: Blueprint Medicines; Financial Interests, Personal, Advisory Board: Boehringer Ingelheim; Financial Interests, Personal, Advisory Board: Merck; Financial Interests, Personal, Advisory Board: Takeda; Financial Interests, Personal, Advisory Board: Blueprint Medicines; Financial Interests, Personal, Advisory Board: Boehringer Ingelheim; Financial Interests, Personal, Advisory Board: Merck; 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