Preliminary Biomarker Analysis of Sitratavatinib in Combination with Nivolumab in NSCLC Patients Progressing on Prior Checkpoint Inhibitor

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CLINICAL BENEFIT

• No prior immunotherapies or combo therapies with similar mechanism of action
• No history of tumors positive for EGFR, ROS1, ALK mutations
• Gene expression (HTG EdgeSeq) and multi-plex immunofluorescence for selected cell populations
• Treatment with at least one prior therapy
• Investigate baseline biomarkers for correlation with clinical outcome parameters
• Safety, tolerability, pharmacokinetics
• PD-L1 IHC (28-8 assay (nivolumab); prior PD-L1 assay data)
• Non-squamous NSCLC, metastatic or unresectable, locally advanced

KEY ELIGIBILITY CRITERIA:
• Phase 2 study evaluating the tolerability and clinical activity of sitratavatinib in combination with nivolumab in patients with non-squamous NSCLC who have experienced progression of disease on or after treatment with CIT.
• Patients receive oral sitratavatinib once daily (QD) in combination with nivolumab 240/480 mg intravenously every 2/4 weeks, as continuous 28 day cycles.

MRTX-500 STUDY DESIGN

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STUDY OBJECTIVES

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METHODS

KEY ELIGIBILITY CRITERIA:
• Non-squamous NSCLC, metastatic or unresectable, locally advanced
• Treatment with at least one prior therapy
• CIT-experienced patients: Most recent treatment must have included a checkpoint inhibitor with the result of progression of disease on or after treatment.
• CIT-naive patients: Receipt of prior platinum-based doublet chemotherapy
• No active brain metastases
• No history of tumors positive for EGFR, ROS1, ALK mutations
• No prior immunotherapies or combo therapies with similar mechanism of action

BASELINE AND PHARMACODYNAMIC BIOMARKERS:
• PD-L1 IHC (2B-8 assay (nivolumab); prior PD-L1 assay data)
• Total mutation burden (TMB) – Guardant Omni plasma ctDNA assay
• Flow cytometry for key regulating immune cell populations including CD8+ effector cells, Tregs, myeloid cells, including MDSCs, and cytokines
• Gene expression (HTG EdgeSeq) and multi-plex immunofluorescence for selected cell populations in the tumor microenvironment

REFERENCES