Cancer Research Consortium of West Michigan
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FAST FACTS

SWOG- S2302 PRAGMATICA – LUNG
"A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) plus Pembrolizumab (MK-3475; NSC 776864) versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer."

ELIGIBILITY CRITERIA

Disease Related Criteria

a. Participants must have histologically or cytologically confirmed non-small cell lung cancer (NSCLC) which is Stage IV or recurrent.

Prior/Concurrent Therapy Criteria

a. Participants must have received exactly **one** anti-PD-1 or anti-PD-L1 therapy for **advanced disease** (Stage IV or recurrent disease, or Stage I-III disease in certain circumstances outlined below). Anti-PD-1 or anti-PD-L1 therapy may have been given alone or in combination with other therapy.

For participants who received neoadjuvant, adjuvant, and/or consolidation anti-PD-1 or anti-PD-L1 therapy for Stage I-III disease:

- If they experienced disease progression within (<=) 365 days from initiation (Cycle 1 Day 1) of anti-PD-1 or anti-PD-L1 therapy, this counts as the single allowed anti-PD-1 or anti-PD-L1 therapy for advanced disease.
- If they experienced disease progression more than (>) 365 days from initiation (Cycle 1 Day 1) of anti-PD-1 or anti-PD-L1 therapy, this is not considered anti-PD-1 or anti-PD-L1 therapy for advanced disease. These participants must have received anti-PD-1 or anti-PD-L1 therapy for Stage IV or recurrent disease.

b. Participants must have experienced disease progression (in the opinion of the treating physician) more than (>) 84 days following initiation (Cycle 1 Day 1) of their most recent anti-PD-1 or anti-PD-L1 therapy.

c. Participants who received anti-PD-1 or anti-PD-L1 therapy for Stage IV or recurrent disease, must have had a best response of stable disease, partial response or complete response (in the opinion of the treating physician) On the anti-PD-1 or anti-PD-L1 therapy for stage IV or recurrent disease.

d. Participants must have received platinum-based chemotherapy and experienced disease progression (in the opinion of the treating physician) during or after this regimen.

e. Participants with a known sensitizing mutation for which an FDA-approved targeted therapy for NSCLC exists (e.g., EGFR, ALK, ROS1, BRAF, RET, NTRK, KRAS, HER2 and MET sensitizing mutations), must have previously received at least one of the appropriate targeted therapy(s). Prior targeted therapy for participants with targetable alterations is allowed if all other eligibility criteria are also met.

f. Participants must not be receiving or planning to receive another investigational therapy during study participation.

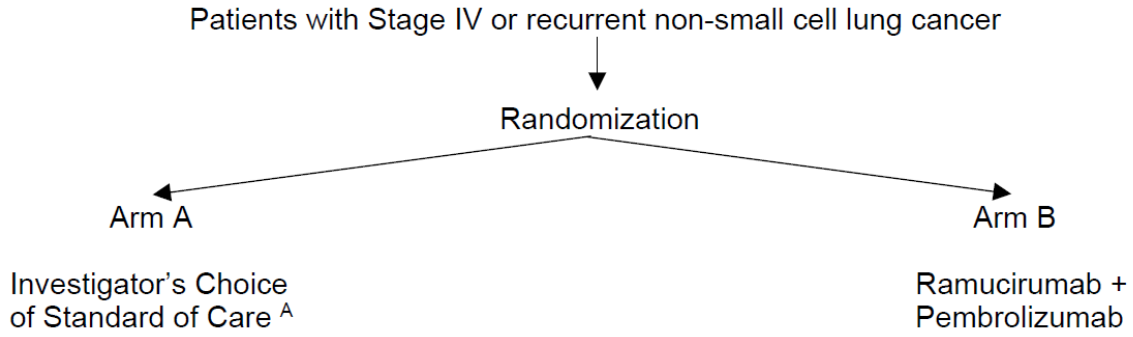
Clinical/Laboratory Criteria

a. Participants must be ≥ 18 years old.

b. Participants must be able to safely receive the investigational drug combination and the investigator's choice of standard of care regimens described in Section 7.2, per the current FDA-approved package insert(s), treating investigator's discretion, and institutional guidelines.

c. Participants must have Zubrod Performance Status of 0-2 (see Section 10.3

SCHEMA



A For guidance on Investigator's Choice of Standard of Care, see Section 7.2.