Merck IIT: RRP Pembro and Lenvatinib

NCT04645602

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Yale University
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (42)

• Participants must have histologically or cytologically confirmed respiratory papillomas that involves the lungs. Subjects can have measurable or non-measurable* disease based on RECIST 1.1. Non-measurable disease based on RECIST 1.1 is defined as lesions with a short axis less than 10 mm.

• For those patients with non-measurable pulmonary disease, participants must have disease at other sites such as the larynx and trachea and must have undergone \> 3 surgical procedures over a 12-month period.

• Be required to provide tissue from a newly obtained biopsy of a lesion or an archived specimen. Newly-obtained is defined as a specimen obtained up to 6 weeks (42 days) prior to the first dose of study drug. Subjects for whom newly obtained samples cannot be provided (e.g. inaccessible or subject safety concern) may submit an archived specimen only upon agreement from the PI.

• Have confirmed human papillomavirus-associated lesions based on in-situ hybridization testing and/or polymerase chain reaction which may be performed on a newly obtained biopsy or archived sample.

• Age e18 years.

... and 37 more (see full listing online)

Exclusion (33)

• Has received prior systemic anti-cancer therapy including investigational agents within 4 weeks prior to study enrollment.

• Note: Participants must have recovered from all AEs due to previous therapies to dGrade 1 or baseline. Participants with dGrade 2 neuropathy may be eligible.

• Note: If participant received major surgery, they must have recovered adequately from the toxicity and/or complications from the intervention prior to starting study treatment. Withhold lenvatinib for at least 7 days prior to elective major surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. Endoscopic debridement of RRP lesions is NOT considered a major surgery.

• Has received prior radiotherapy within 2 weeks of start of study treatment. Participants must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis.

• Has had major surgery within 3 weeks prior to first dose of study interventions. Note: Adequate wound healing after major surgery must be assessed clinically, independent of time elapsed for eligibility.

... and 28 more (see full listing online)

Locations (1 total)

Yale University, New Haven, Connecticut, United States