For Patients with Steroid-Refractory Pneumonitis

EAQ172 Available Through ECOG-ACRIN Cancer Research Group
Optimizing Immunosuppression for Steroid-Refractory Anti-PD-1/PD-L1 Pneumonitis

**Patient Population**
See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years; ECOG PS 0-3; English-speaking; ability to understand and willingness to sign an informed consent (patients with a LAR/caregiver/family member available are also eligible)
- Must be willing and able to undergo arterial blood gas assessment as per the treating investigator
- Women must not be pregnant or breastfeeding
- May have any solid tumor/hematologic malignancy; may have received any number of lines of prior systemic therapy
- Must have received treatment with an anti-PD-1/PD-L1 agent either alone/in combination with another anti-cancer agent, as their most recent therapy prior to the development of pneumonitis; may have received anti-PD-1/PD-L1 therapy as standard of care/part of a clinical trial; must not be receiving anti-PD-1/PD-L1 in combination with the anti-cancer agents per protocol
- Must have steroid-refractory pneumonitis defined per protocol
- Must have had pathogen-negative infectious diagnostic evaluation within 21 days of randomization (must include items per protocol)
- No clinical evidence of cardiac dysfunction as an alternative diagnosis to steroid-refractory pneumonitis
- Must not be receiving concurrent radiation therapy to the chest
- Must not be deemed to have radiation pneumonitis (patients with a history are eligible per protocol)
- No pre-existing interstitial lung disease/pneumonitis requiring corticosteroid therapy from any other cause
- No absolute contraindication to IVIG/infliximab (see protocol); no contraindication for CT scan (performed 14 days prior to randomization)
- Must have negative tuberculosis assessment within 21 days of randomization and either negative or low clinical suspicion (see protocol for details)

**Treatment Plan**
See Section 5.0 for Complete Treatment Details

**Arm A:**
- Infliximab 5 mg/kg IV on day 1 followed by a 4-6 week corticosteroid taper, starting from a dose of prednisone 1-2 mg/kg (or methylprednisolone) either orally or IV in divided doses, as determined by the treating investigator
  - Corticosteroid taper to commence from Day 1 of the first infliximab dose
- Second dose of infliximab may be delivered 14 days after the first dose as per the treating investigator
  - If this occurs, corticosteroid taper to restart day 14
  - Infliximab may be received per locally obtainable formulation
- Patient should be under assessment for latent or active tuberculosis per institutional guidelines

**Arm B:**
- IVIG 2g/kg divided as per institutional guidelines as an IV infusion, followed by a 4-6 week corticosteroid taper, starting from a dose of prednisone 1-2 mg/kg (or methylprednisolone) either orally or IV in divided doses, determined by the treating investigator
  - Corticosteroid taper to commence from Day 1 of the first IVIG dose

**Notes:**
- Dosing is based on actual body weight
- Treatment may be delivered either as outpatient or inpatient, at the discretion of the treating investigator
- Patients will keep a pill calendar (corticosteroids) per protocol
- All patients will undergo a chest CT during study screening, and days 1, 14, and 28

**Patient Enrollment**
All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**
ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!