

A Study of SER-155 to Treat Diarrhea in People on Immunotherapy

NCT06801067

Status	RECRUITING
Phase	Phase 1
Sponsor	Memorial Sloan Kettering Cancer Center
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (8)

- Age \geq 18 years
- Receipt of ICI (single-agent or combination) within the 180 days preceding screening.
- Concurrent treatment with cytotoxic chemotherapy or other tumor-directed agents is permitted.
- Grade 2 - 3 diarrhea (i.e., increase of at least 4 bowel movements a day above baseline during the screening window), deemed by the treating provider as likely related to ICI therapy, with or without concomitant symptoms of grade 1 - 2 colitis (e.g. abdominal pain, bloody or mucoid stools)

... and 3 more (see full listing online)

Exclusion (13)

- Active GI infection, including untreated viral, bacterial or fungal cause(s) of diarrhea.
- Received immunosuppressive therapies for suspected or confirmed irEC, including systemic corticosteroids (either oral or intravenous) and/or infliximab, vedolizumab or ustekinumab
- Grade 3 colitis symptoms, i.e. severe abdominal pain or peritoneal signs
- Admitted to the hospital for irEC
- Prednisone (or steroid equivalent) dose \geq 10 mg a day for a non-GI irAE at time of screening

... and 8 more (see full listing online)

Locations (7 total)

Memorial Sloan Kettering at Basking Ridge (Limited Protocol Activities), Basking Ridge, New Jersey, United States

Memorial Sloan Kettering Monmouth (All Protocol Activities), Middletown, New Jersey, United States

Memorial Sloan Kettering Bergen (All Protocol Activities), Montvale, New Jersey, United States

... and 4 more locations