Toca 511 infects cancer cells in both immunologically “hot” (T cells present) and “cold” (T cells low or absent) areas of the tumor microenvironment and primes an antitumor immune response (Figure 2).1,2 

Studying 10 to 20 patients with advanced malignancies (including colorectal cancer, pancreatic cancer, non-small cell lung cancer, and sarcoma) will be included into the study.

Key Entry Criteria

**Inclusion**
- 18 to 75 years of age
- Advanced malignancy that has progressed or recurred following standard therapy for advanced disease
- No curative options available
- Tumors accessible to biopsy and/or resection
- Tumor amenable to injection of Toca 511

**Exclusion**
- Active infection requiring antibiotic, antifungal, or antiviral therapy within 2 weeks
- Chemotherapy within 2 weeks; intravenous within 6 weeks
- Investigational treatment within 2 weeks; immunotherapy or antibody therapy within 28 days
- Condition that would prevent patient from swallowing Toca FC tablets or absorbing fluconazole

**STUDY OBJECTIVES**

- **Primary**
  - To evaluate immune activity following treatment with Toca 511 & Toca FC in patients with solid tumors
- **Secondary**
  - Safety and tolerability
  - Vector deposition in tumor specimens following Toca 511
  - Clinical activity of Toca 511 & Toca FC, alone or in combination with standard of care therapies

*Toca 511 is supported by a grant from the Food and Drug Administration Office of Orphan Products Development.

**METHODS**

**RESULTS**

As of the cut-off date for analysis (31 August 2018), 20 patients were enrolled into the study across 3 study sites: University of Miami, MD Anderson Cancer Center, and Sarah Cannon Research Institute. Demographic and baseline characteristics data are summarized in Table 1. Study drug exposure and patient disposition are summarized in Table 2.

**TREATMENT-EMERGENT ADVERSE EVENTS**

Toca 511 & Toca FC has been generally well tolerated (Table 3). Treatment-related adverse events leading to discontinuation of Toca 511 & Toca FC were reported in 1 patient (doctoral [Grade 2]), vomiting (Grade 1), and nausea (Grade 1). Although not related to treatment, an adverse event leading to discontinuation of Toca 511 & Toca FC was reported for 1 patient (facial palsy [Grade 3]). A Grade 5 adverse event has been reported for 1 patient (embolism); this event was not considered related to treatment.

**REFERENCES**


**IMMUNE MODULATION IN PERIPHERAL BLOOD**

Intratumoral Toca 511 injection produces in-depth immune activation and release of TIL-related cytokines, which can be measured in blood samples 1 week post-injection. Toca 511 and Toca FC are designed to deliver an optimized cytokine cocktail that will promote an antitumor immune response. The highest level of CD8 + T cells was measured 36.5+ months in a Phase 1 study. The incidence of grade 4 toxicities (consistent with what has been observed in preclinical models and clinical studies in patients with recurrent high grade gliomas.

**STUDY OBJECTIVES**

- **Primary**
  - To evaluate immune activity following treatment with Toca 511 & Toca FC in patients with solid tumors
- **Secondary**
  - Safety and tolerability
  - Vector deposition in tumor specimens following Toca 511
  - Clinical activity of Toca 511 & Toca FC, alone or in combination with standard of care therapies

*Toca 511 is supported by a grant from the Food and Drug Administration Office of Orphan Products Development.

**RESULTS**

As of the cut-off date for analysis (31 August 2018), 20 patients were enrolled into the study across 3 study sites: University of Miami, MD Anderson Cancer Center, and Sarah Cannon Research Institute. Demographic and baseline characteristics data are summarized in Table 1. Study drug exposure and patient disposition are summarized in Table 2.

**TREATMENT-EMERGENT ADVERSE EVENTS**

Toca 511 & Toca FC has been generally well tolerated (Table 3). Treatment-related adverse events leading to discontinuation of Toca 511 & Toca FC were reported in 1 patient (doctoral [Grade 2]), vomiting (Grade 1), and nausea (Grade 1). Although not related to treatment, an adverse event leading to discontinuation of Toca 511 & Toca FC was reported for 1 patient (facial palsy [Grade 3]). A Grade 5 adverse event has been reported for 1 patient (embolism); this event was not considered related to treatment.

**REFERENCES**


**IMMUNE MODULATION IN PERIPHERAL BLOOD**

Intratumoral Toca 511 injection produces in-depth immune activation and release of TIL-related cytokines, which can be measured in blood samples 1 week post-injection. Toca 511 and Toca FC are designed to deliver an optimized cytokine cocktail that will promote an antitumor immune response. The highest level of CD8 + T cells was measured 36.5+ months in a Phase 1 study. The incidence of grade 4 toxicities (consistent with what has been observed in preclinical models and clinical studies in patients with recurrent high grade gliomas.

**STUDY OBJECTIVES**

- **Primary**
  - To evaluate immune activity following treatment with Toca 511 & Toca FC in patients with solid tumors
- **Secondary**
  - Safety and tolerability
  - Vector deposition in tumor specimens following Toca 511
  - Clinical activity of Toca 511 & Toca FC, alone or in combination with standard of care therapies

*Toca 511 is supported by a grant from the Food and Drug Administration Office of Orphan Products Development.

**RESULTS**

As of the cut-off date for analysis (31 August 2018), 20 patients were enrolled into the study across 3 study sites: University of Miami, MD Anderson Cancer Center, and Sarah Cannon Research Institute. Demographic and baseline characteristics data are summarized in Table 1. Study drug exposure and patient disposition are summarized in Table 2.

**TREATMENT-EMERGENT ADVERSE EVENTS**

Toca 511 & Toca FC has been generally well tolerated (Table 3). Treatment-related adverse events leading to discontinuation of Toca 511 & Toca FC were reported in 1 patient (doctoral [Grade 2]), vomiting (Grade 1), and nausea (Grade 1). Although not related to treatment, an adverse event leading to discontinuation of Toca 511 & Toca FC was reported for 1 patient (facial palsy [Grade 3]). A Grade 5 adverse event has been reported for 1 patient (embolism); this event was not considered related to treatment.

**REFERENCES**