# Phase 1 Study Evaluating VT1021 in Patients With Advanced Solid Tumors

**Presentation 456P**

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## Background

One of the major barriers to therapeutically treating tumors, as well as the ability of the immune system to effectively respond to tumors, is the immunosuppressive nature of the tumor microenvironment (TME). The immunosuppressive property of the TME is conveyed by several cell types, including MDSCs, M2 macrophages, and Tregs. Vigeo has chosen to address this critical unmet need by developing VT1021, a cyclic peptide derived from prosaposin that functions as a potent inducer of thrombospondin-1 (Tsp-1) expression in MDSCs that are recruited to the TME. By triggering the production of Tsp-1, VT1021 reprograms the TME from one that is immunosuppressive and tumor-promoting, to one that activates the adaptive immune system and is tumor-inhibiting. Tsp-1, induced by VT1021, reprograms the TME to: (i) induce apoptosis in tumor cells that express CD36 on their cell surface; (ii) convert macrophages from M2 to M1 polarization, promoting phagocytosis and blunting immunosuppression; (iii) block the CD47-mediated “do not eat me” signal; and, (iv) inhibit angiogenesis. Preclinical studies of VT1021 have shown robust anti-tumor activity in multiple animal models of ovarian, pancreatic and breast cancer. These observations led to the initiation of the first-in-human study of VT1021.

## Study Design

**Dose Escalation (N=~30)** → **RP2D determined** → **Dose Expansion (N=~75-100)**

This study is a first-in-human, Phase 1, open-label, multicenter, dose escalation (Part 1) study with dose expansion (Part 2) in advanced solid tumors.

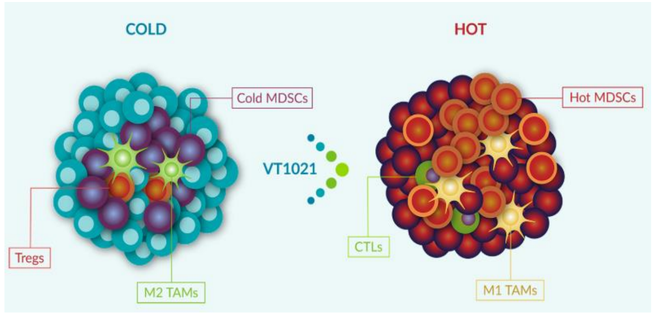
**Part 1 (Dose Escalation):** approximately 30 patients will be enrolled to determine the MTD and RP2D for expansion.

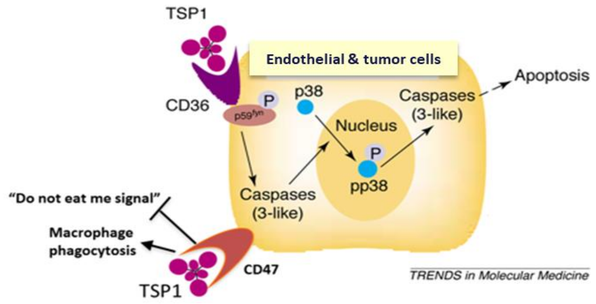
**Part 2 (Expansion):** approximately 75-100 patients with one of the following indications will be enrolled: Ovarian Cancer, Triple Negative Breast Cancer, Pancreatic Cancer, Glioblastoma, and a basket cohort with High CD36-expressing cancers.

## Contact

For more information on this trial, please contact Michael Cieslewicz at 617-945-0385, or email Michael.Cieslewicz@vigeotherapeutics.com.

## Novel TME Targeting




## Results

**Safety profile**

- 31 patients dosed to date: 22 completed cycle 1 (0.5mg/kg – 11.8 mg/kg, 2 patients ongoing in cycle 1, 7 discontinued before completing cycle 1
- 1 drug related SAE: Grade 3 infusion reaction, prior to pre-meds being required
- 5 drug-related AEs: 2 infusion reaction G2; 1 fatigue G2; 1 myalgia G2; 1 dizziness G1

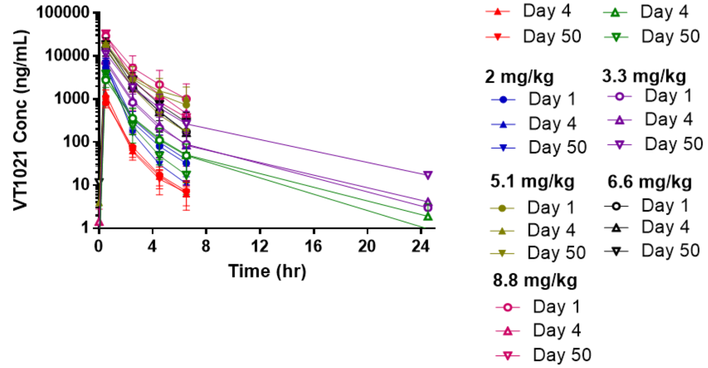
**Preliminary Efficacy**

Out of 22 patients that completed cycle one:

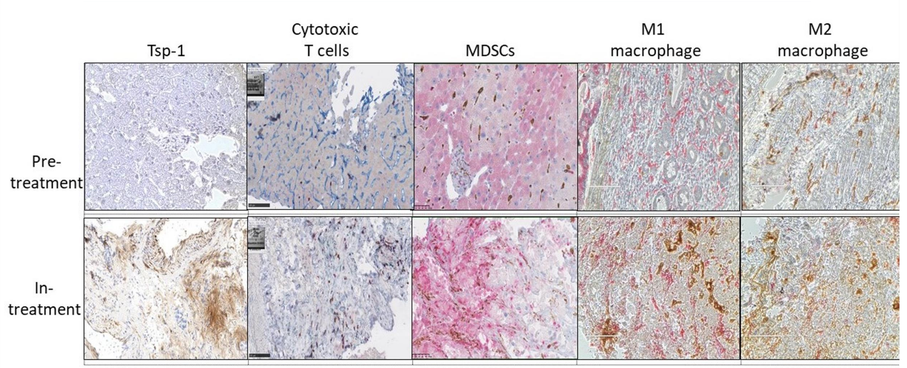
- Two patients with prolonged stable disease (over 6 months)
- One patient with unconfirmed partial response

**Currently dosing at 11.8 mg/kg (Cohort #8)**

## PK data (0.5mg/kg - 8.8mg/kg)




## Biomarker - IHC




## References

1. Kang *et al.* PNAS 2009; 106 (29); pp 12115-20
2. Catena *et al*. Cancer Discov. 2013; 5 (578-589)
3. Wang *et al*. Sci. Trans. Med. 2016; 8 (329-334)

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