**A PHASE I/II STUDY OF THE ONCOLYTIC PEPTIDE LTX-315 COMBINED WITH CHECKPOINT INHIBITION GENERATES DE NOVO T-CELL RESPONSES AND CLINICAL BENEFIT IN PATIENTS WITH ADVANCED SOLID TUMORS.**


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**Background**

LTX-315 is a first-in-class oncolytic peptide with unique properties that can be delivered to the tumor site, mimicking the physiologic release of essential chemokines with direct recruitment of immune cells, and specifically promotes infiltration of CD8+ TILs in the majority of patients (315 injection).

**Study Design**

Pharmacokinetics with LTX-315 with single and multiple injections (days 1, 8 & 15) and combination therapy (N=26). Combination therapy in injected and non-injected tumors (i.e. abscopal response).

**TREATMENT**

**Arm A + B**

- Induction (6 w)
- Maintenance (46 w)

**LTX-315 injection**

- Treatment in injected tumors (up to 50 mg/mL) was started with 20 µm (long distance)

**DOSING SCHEDULE**

- **X = biopsy (3 core)**
- **X = resection or biopsy (3 core)**
- **= LTX-315 injection**

**Response in Injected Lesions**

**Primary Endpoints**

- Safety and tolerability, including AEs and SAEs
- Inclusion Criteria
- Measurable and/or assessable tumors (11)
- **Primary Adverse Events**: CD8+PD-L1+
- **Secondary Tumor Response**: CD8+PD-L1-
- **Tumor Pairings**: Adv. Vascular/defective tumor types
- **Inclusion/Exclusion Criteria**: Exclusion Criteria
- **Inclusion Criteria**
- Patients with measurable and/or assessable tumors (11)
- **Exclusion Criteria**
- Patients with prior treatment with immune checkpoint inhibitors (ICIs) within 4 months
- No significant changes in tumor size
- **Dosing Schedule**
- **June 6, 2016**
- **June 8, 2016**
- **June 9, 2016**

**References**

1. Huang, B. et al. (2018)
2. Cui, H. et al. (2018)

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