**Single-Agent LV305 Induces Anti-tumor Immune And Clinical Responses In Patients With Advanced Or Metastatic Sarcoma And Other Cancers Expressing NY-ESO-1**

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### I. ABSTRACT

**Background:** NY-ESO-1 is a tumor-associated antigen whose function is unknown. It is expressed only in cancer and is thought to be an active agent that warrants further investigation.

**Methods:** Indication: lung cancers (breast cancer allowed in Part 1 dose escalation) expressing NY-ESO-1* s/p surgery/Radiation alone.

**Treatment/Study Measurements:**
- **Indication:** Lung cancers (breast cancer allowed in Part 1 dose escalation) expressing NY-ESO-1* s/p surgery/Radiation alone.
- **DC Targeting:** ZVex
- **Specificity:** • Dendritic Cell receptor, • Humoral antibodies

**Immune Response Measurements**
- **CAUTION:** ELISPOT >50 spots & >2-fold rise and/or ICS >2-fold over baseline were considered positive.

**Clinical Outcome:** Sarcomas:
- Median OS: 19 months
- 82% 1-year survival

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### II. RATIONALE / BACKGROUND

NY-ESO-1 is a weak immunogenic antigen that elicits low T cell responses in most patients. However, there are subsets of patients, particularly those with sarcoma, who have substantial immune responses to NY-ESO-1.

**LV305:** LV305 is the first product candidate from the ZVex platform that expresses NY-ESO-1. It induces DCs to generate high T cell immunity against NY-ESO-1 expressing tumors. The median OS has not been reached. The 1 year survival is 81%.

**Indication:** Sarcomas

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### III. LV305 TRIAL DESIGN AND RESULTS

- **Part 1:** Exclusion/Inclusion criteria and safety.
- **Part 2:** Dose escalation/Expansion.
- **Part 3:** Efficacy.
- **Safety:** Injection site reactions, fatigue, myalgia, arthralgia, nausea, vomiting, abdominal pain, rash, headache, alopecia.

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### IV. SUMMARY

LV305 is the first product candidate from the ZVex platform. It induces DCs to generate patient T cell responses against NY-ESO-1 following a single injection. The clinical trial results in patients with sarcoma and other cancers expressing NY-ESO-1 are promising, with a median OS of 19 months and an 82% 1-year survival.