**INTRODUCTION**

The highly immunogenic tLLO is rapidly taken up by antigen-presenting cells (APCs), stimulating both innate and adaptive tumor-specific immunity. They direct APCs to develop a vector targeting the specific tumor of interest to develop a vector targeting the specific tumor of interest.

**OBJECTIVES**

- **Primary objective(s)**
  - Determine the RP2D of ADXS31-164
  - Determine the safety and tolerability of ADXS31-164

- **Secondary objective**
  - Assess tumor response and DFS as a measure of antitumor activity of ADXS31-164 using RECIST v1.1 and irRECIST

**METHODS**

**STUDY DESIGN**

Three cycles of ADXS31-164 will be administered on day 1 of each cycle. Subsequent infusions will be administered every 3 weeks.

**STUDY TREATMENT**

- **Primary end points:**
  - Response per RECIST v1.1 and irRECIST
  - OS
  - DFS

**ENDPOINTS**

- **Secondary end points:**
  - Safety:
    - AEs will be graded as per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03

- **Safety:**
  - Toxicity will be assessed using the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

**DISCLOSURES**

Advaxis Disclosure: Advaxis, Inc. provided financial support for the study and participated in the preparation of the submission and its review and, as a result, may have a financial interest in the study described in this poster. The authors are fully responsible for all content and editorial decisions for this poster.

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**REFERENCES**


**TABLE 2. KEY PATIENT ELIGIBILITY CRITERIA**

<table>
<thead>
<tr>
<th>Key inclusion criteria</th>
<th>Key exclusion criteria</th>
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<tbody>
<tr>
<td>Adult patients (≥18 years)</td>
<td>HER2 positive by IHC or FISH test</td>
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<tr>
<td>Presence of histologic or clinically diagnosed locally advanced/metastatic HER2-positive tumors that have progressed or become resistant to standard therapy for which no standard therapy is available</td>
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<td>Adequate hematologic, hepatic, renal, and coagulatory functions</td>
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<td>ECOG PS ≤1</td>
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<td>No history of immunologic diseases</td>
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<td>No history of smoking</td>
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<td>No history of corticosteroids within the past 4 weeks</td>
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<tr>
<td>No history of immunosuppressive or immunotolerant conditions in the tumor microenvironment</td>
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</tbody>
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**ENDPOINTS**

- **AEs:** will be graded as per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.
- **Recurrence:**
  - Received prior adjuvant chemotherapy, surgical treatment, or radiation therapy within 12 weeks prior to the first study treatment has not been included.
- **Statistical methods:**
  - Descriptive statistics will be used to summarize and evaluate the safety and tolerability of ADXS31-164.