ADXS-HER2 MONOTHERAPY

Primary endpoint: Safety and recommended phase II dose (RP2D)

- N ≤18 (dose finding); N ≤80 (expansion phase in tumor-specific subgroups) (Total N ~100)
- HER2-positive solid tumor (>1+ positivity in 1% of cells by IHC)
- Disease progressed or intolerant to standard therapy
- ECOG performance status 0-1
- 3+3 phase I design with possible expansion phase in up to 4 different indications

Primary Endpoints:
Safety and RP2D

https://clinicaltrials.gov/ct2/show/NCT02386501
Phase I Study in HER2-Expressing Solid Tumors
ADXS-HER2

<table>
<thead>
<tr>
<th>TRIAL PHASE</th>
<th>Phase I</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY CENTERS</td>
<td>Multicenter</td>
</tr>
<tr>
<td>TRIAL BLINDING</td>
<td>Unblinded, open-label</td>
</tr>
<tr>
<td>NUMBER OF TRIAL PATIENTS</td>
<td>Approximately 100</td>
</tr>
<tr>
<td>ESTIMATED DURATION</td>
<td>Approximately 5 years</td>
</tr>
<tr>
<td>RANDOMIZATION RATIO</td>
<td>Nonrandomized</td>
</tr>
<tr>
<td>METHODOLOGY</td>
<td>Dose-finding, open-label study in patients with HER2-expressing solid tumors. Patients will receive doses of ADXS31-164 (ADXS-HER2) every 3 weeks during a 12-week treatment cycle</td>
</tr>
</tbody>
</table>

**OBJECTIVES**

- Primary: To evaluate safety and tolerability, and select an RP2D of ADXS-HER2 in patients with solid tumors that express HER2
- Secondary: To assess signs of clinical activity including tumor response and progression free survival by RECIST 1.1 and irRECIST criteria

**STATISTICAL CONSIDERATIONS**

- Descriptive statistics will be employed to evaluate the safety and tolerability of ADXS-HER2. Summary statistics for continuous variables will include mean, standard deviation, median, and range
- The safety analysis will be performed on the safety population, defined as all patients who receive at least 1 dose of study treatment
- The preliminary efficacy analysis will be performed on the efficacy population, defined as all patients who complete at least 1 cycle of ADXS-HER2 treatment