Phase I Study in HER2-Expressing Solid Tumors

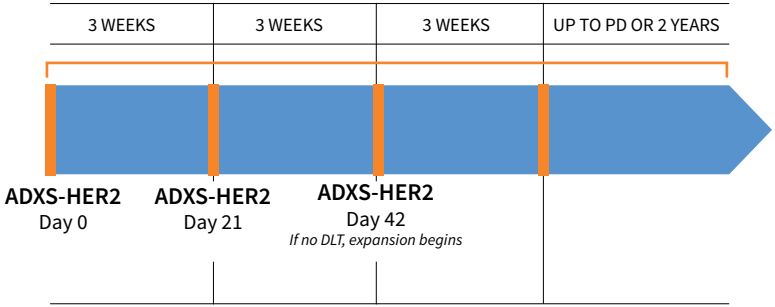
ADXS-HER2

ADVAXIS IMMUNOTHERAPIES™

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

For more information, contact Janet Flisak, Senior Director, Clinical Operations: flisak@advaxis.com Phone: 609-250-7505

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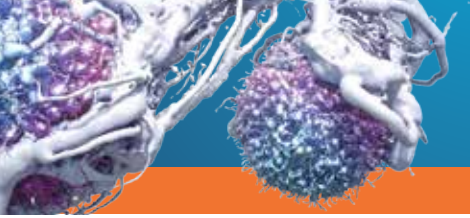

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TRIAL PHASE	Phase I
STUDY CENTERS	Multicenter
TRIAL BLINDING	Unblinded, open-label
NUMBER OF TRIAL PATIENTS	Approximately 100
ESTIMATED DURATION	Approximately 5 years
RANDOMIZATION RATIO	Nonrandomized
METHODOLOGY	Dose-finding, open-label study in patients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

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

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