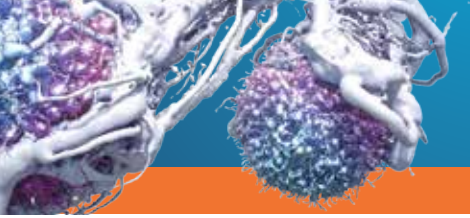


Phase I/II Dose Escalation and Safety Study Alone and Combined with Pembrolizumab

ADXS-PSA

ADVAXIS IMMUNOTHERAPIES™

- N = 21 (Part A); N = 30 (Part B) (Total N = 51)
- Pretreated metastatic castration-resistant prostate cancer (mCRPC)
- No more than 3 prior systemic treatment regimens with chemotherapy, hormonal, or immunotherapy or more than 1 prior chemotherapeutic regimen in the metastatic setting
- mTPI design (Part A) to determine recommended phase II dose (RP2D)
- Following the completion of enrollment and the safety evaluation of ADXS-PSA in Part A, Part B combination arm with pembrolizumab will commence
- Part B ADXS-PSA dose = Part A RP2D + pembrolizumab

PART A

ADXS-PSA Monotherapy

Dose escalation (3 dose levels)

Goal: To determine safety and RP2D

N = 21

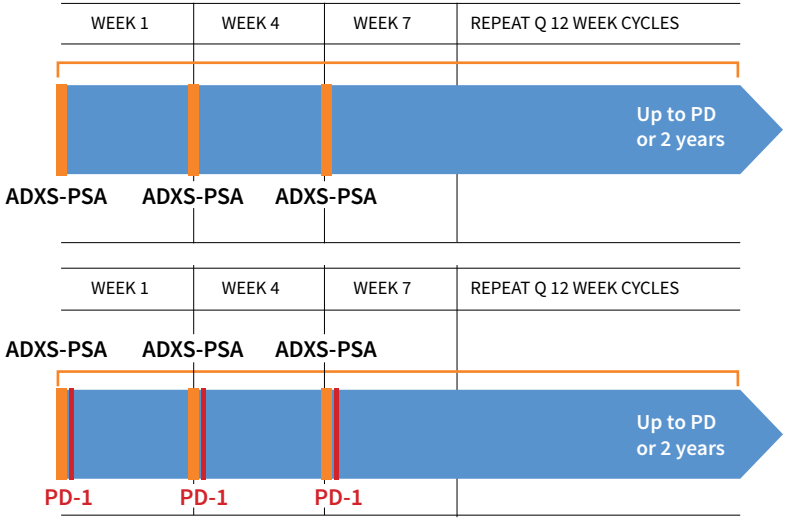
PART B

ADXS-PSA + Pembrolizumab (PD-1)

Dose determination and confirmation

Goal: To determine safety and RP2D of the combination

N = 30

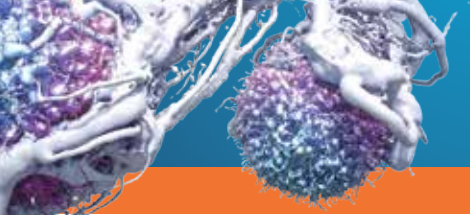


In collaboration with MERCK

https://clinicaltrials.gov/ct2/show/NCT02325557

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

 305 College Road East Princeton, NJ 08540 Phone: 609-452-9813 Fax: 609-452-9818



Phase I/II Dose Escalation and Safety Study Alone and Combined with Pembrolizumab

ADXS-PSA

ADVAXIS IMMUNOTHERAPIES™

TRIAL PHASE	Phase I/II
STUDY CENTERS	Multicenter, US only
TRIAL BLINDING	Open-label
NUMBER OF TRIAL PATIENTS	Approximately 51 patients with mCRPC
RANDOMIZATION RATIO	Nonrandomized
METHODOLOGY	• Part A: Dose-determining of ADXS-PSA monotherapy in patients with mCRPC • Part B: Dose-determining of ADXS-PSA in combination with pembrolizumab in patients with mCRPC. Dose-determination phase followed by an expansion cohort phase. The dose-determining phase of Part A monotherapy is intended to select an RP2D for the combination
OBJECTIVES	• Primary Part A: To evaluate safety and tolerability of ADXS-PSA monotherapy and select the RP2D in patients with mCRPC • Primary Part B: To evaluate safety and tolerability of ADXS-PSA in combination with pembrolizumab and to establish the RP2D for this combination in patients with mCRPC • Secondary: To evaluate antitumor activity and progression-free survival signal of ADXS-PSA monotherapy and ADXS-PSA + pembrolizumab combination therapy
STATISTICAL CONSIDERATIONS	• No inferential statistical analyses will be performed; however, the data will be summarized overall and by treatment dose. Discrete variables will be summarized with counts and percentages; continuous variables will be summarized with means, standard deviations, and ranges • Data will be summarized for safety by evaluating physical examinations, serum chemistry values, and hematology values

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