Purpose
- ADXS31-164c is a vaccine that is designed to cause the immune system to inhibit an important receptor that may aid in cancer progression known as HER2/neu. The purpose of this study is to determine if adding the vaccine ADXS31-164c into the treatment protocol for dogs with osteosarcoma will be safe and improve efficacy of current standard therapies for osteosarcoma in dogs.

Participation Requirements
- Untreated dogs diagnosed with osteosarcoma in one of her/his legs
- Dogs will need blood and urine collection, chest x-rays, and an abdominal ultrasound at UC Davis to determine eligibility.

Procedures
- Most of the exams, tests, and procedures your pet will have within the first 15 weeks of the trial are part of the usual approach for your dog’s treatment for osteosarcoma including blood collection, amputation of the affected limb and carboplatin chemotherapy given once every three weeks for 4 doses followed by monitoring using chest x-rays once every two months.
- Beyond that, dogs will receive/need:
  - Vaccine administration (3 doses)
  - Blood and urine samples collected throughout the trial
  - Tumor collection at the time of amputation
  - Body temperature and heart rhythm monitoring in the hospital for 8 hours following each vaccine administration
  - Rectal temperature monitoring at home 12 hours after the vaccine’s administration and reassessment the following day

Owner Responsibilities
- Having the limb amputated at UC Davis
- Covering costs of the initial examination, the screening diagnostic tests (blood and urine collection and analysis, chest x-rays, abdominal ultrasound, amputation), the four doses of carboplatin and the associated tests including bloodwork and chest x-rays, any costs associated with management of side effects from the Standard Therapy Phase of this study (amputation and carboplatin chemotherapy).
- Bringing your dog to all required study appointments
- Recording their rectal temperature 12 hours after your pet receives each vaccine
- Reporting any side effects

Benefits
- Following amputation and carboplatin, the study will cover the cost of follow-up examination, diagnostics, and all study costs associated with the ADXS31-164c Vaccine Phase of the trial.
- If your dog experiences adverse events related to the vaccine, a total of $500 will be allotted toward coverage of required care at UC Davis.
- Benefits of standard therapy include removal of the painful cancerous tumor in your dog’s bone and delay of spread of cancer by providing chemotherapy with carboplatin.

PRINCIPAL INVESTIGATOR
Dr. Jenn Willcox

CONTACT INFORMATION
oncologyclinicaltrials@ucdavis.edu
(530) 752 - 0125 • (530) 752 - 9759
www.vetmed.ucdavis.edu/clinicaltrials/