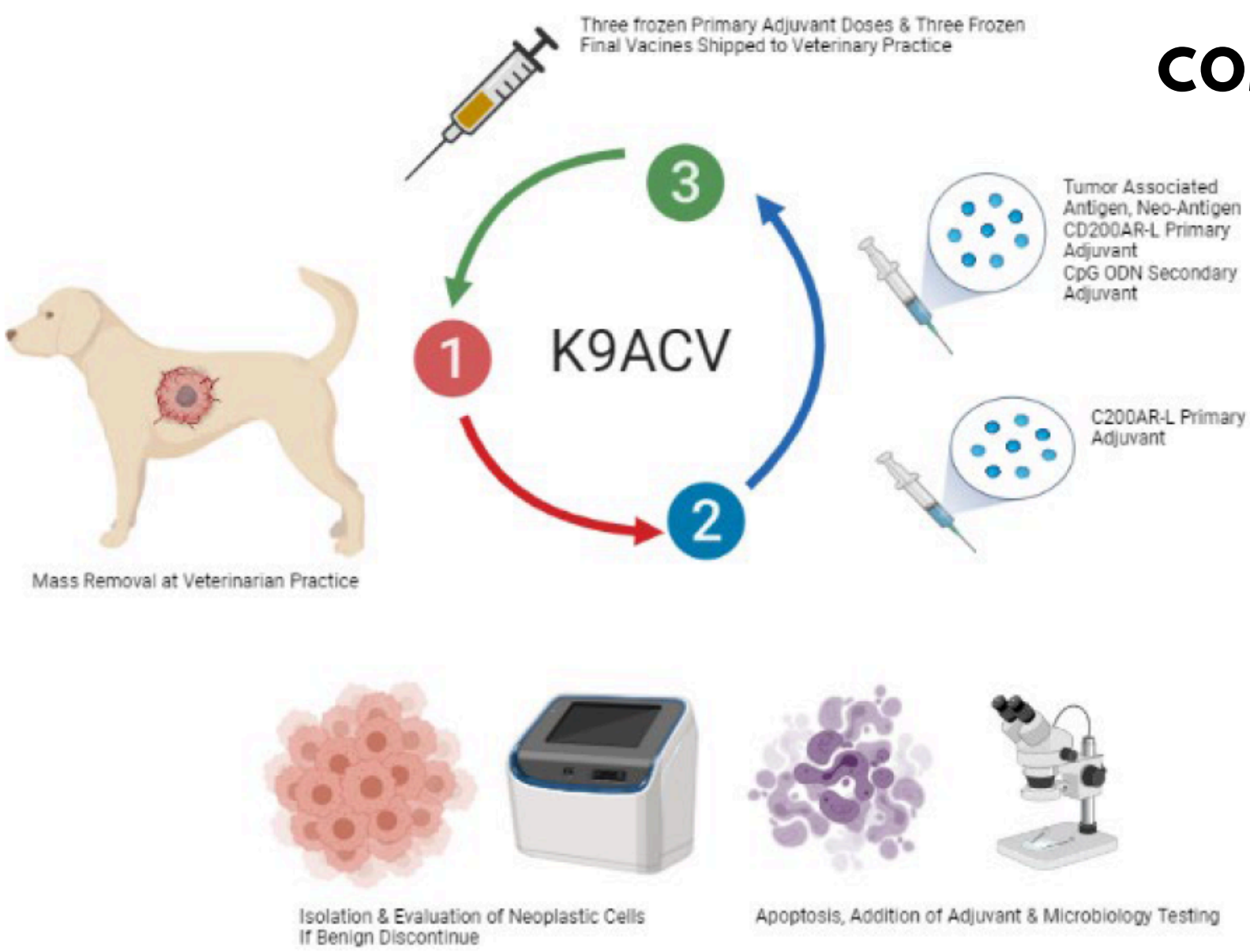


AUTOLOGOUS CANINE CANCER VACCINE WITH CHECKPOINT INHIBITOR FOR OSTEOSARCOMA

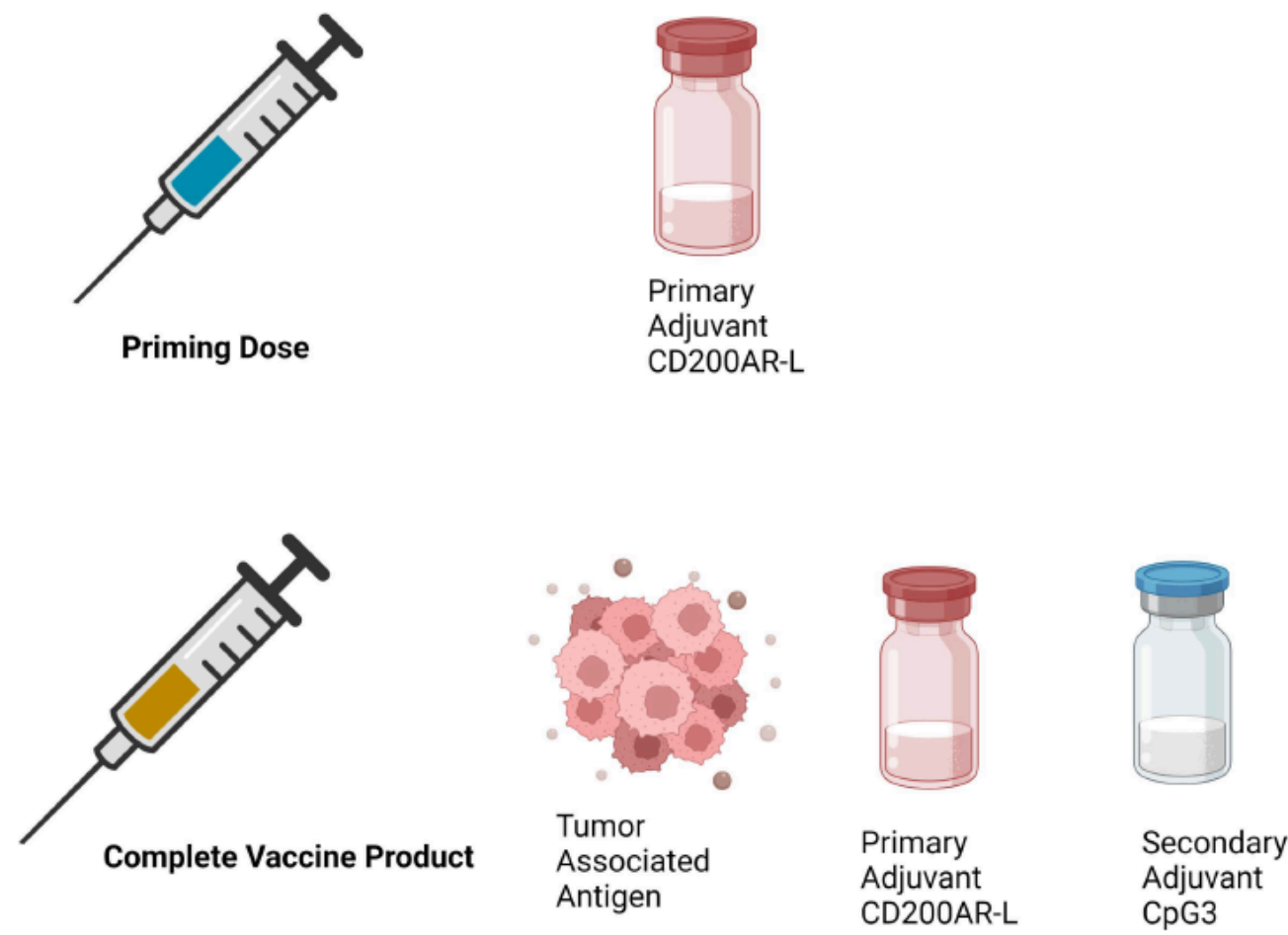
PRESENTER: ADRIENNE WRIGHT, MBA, PHD
 CLINICAL TRIAL TEAM: BRIAN FLESNER, DVM, MS, DACVIM (ONCOLOGY); MARISSA KROLL, BS; TIM FAN, PHD, DVM

BACKGROUND

Cancer is the leading cause of death in dogs, affecting as much as 60% of dogs over the age of 10. Standard of care options like surgery, chemotherapy, and radiation therapy provide clinical benefit, but lack long-term survival and can include harsh side effects. Immunotherapy is a therapeutic option using the patient’s immune system to kill tumor cells and is prevalent in human medicine. Since 2015, Ardent has been developing an immunotherapy option, an autologous canine cancer vaccine for resectable tumors. After resection by a veterinarian, the tumor material is overnighted to begin vaccine production. This personalized vaccine is prepared over 3 days from the excised tumor, UV-irradiated to induce immunogenic cell death, and mixed with a patent-pending canine-specific CpG ODN adjuvant to elicit a strong immune response. Osteosarcoma (OSA) was chosen for USDA licensure due to successful historical cases, and the fact that it is an aggressive cancer with a poor prognosis. Standard of care (amputation and carboplatin) yields a disease-free interval (DFI) of 6 months (n=157) for OSA [1].



COMBINATION TREATMENT SCHEMATIC



VACCINE

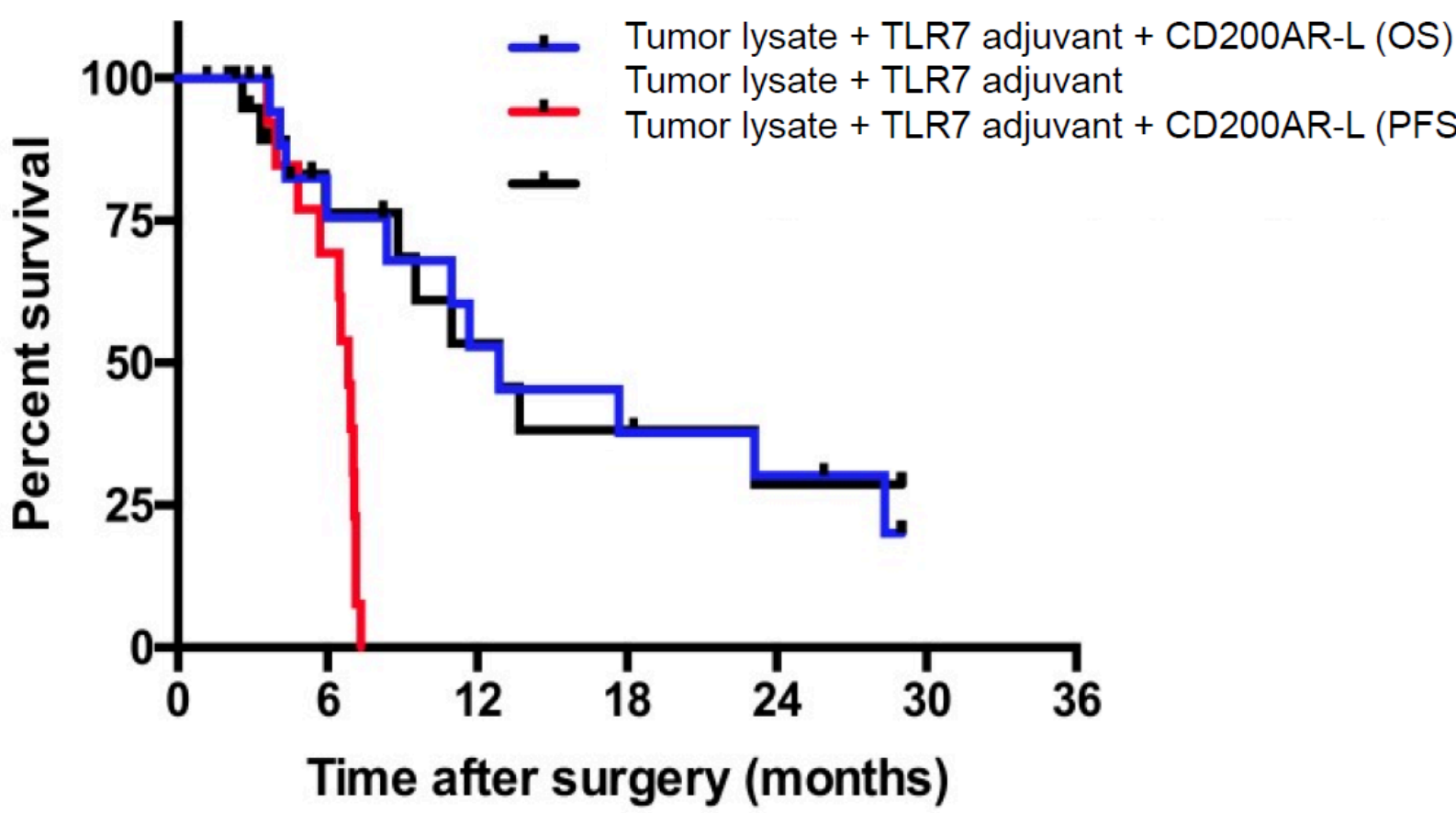
- Pilot data demonstrated that 17 of 20 (85%) of immunized dogs developed an augmented IgG response to the vaccine only [2].
- Internal records indicate that canine osteosarcoma treated with vaccine alone yields a mean survival time of 261 days (n=55).
- No serious adverse events; local reactions only.

REFERENCES

[1] LeBlanc, A.K., et al., Adjuvant Sirolimus Does Not Improve Outcome in Pet Dogs Receiving Standard-of-Care Therapy for Appendicular Osteosarcoma: A Prospective, Randomized Trial of 324 Dogs. Clin Cancer Res, 2021. 27(11): p. 3005-3016.
 [2] Yannelli, J.R., et al., Development of an autologous canine cancer vaccine system for resectable malignant tumors in dogs. Veterinary Immunology and Immunopathology, 2016. 182: p. 95-100.
 [3] Xiong, Z., et al., CD200 Checkpoint Reversal: A Novel Approach to Immunotherapy. Clin Cancer Res, 2020. 26(1): p. 232-241.

CD200AR-L

Addition of novel checkpoint inhibitor (CD200AR-L) elongated survival in dogs with high-grade glioma (MST 12.9 months vs 6.8 months without CD200AR-L [3].



CLINICAL TRIAL PRELIMINARY RESULTS



A non-inferiority clinical study, designed in accordance with USDA CVB VSM 100.121, began enrolling patients in April 2025.

60 dogs were enrolled at a 3:1 randomization (45 vaccine, 15 carboplatin). All dogs received amputation and either carboplatin (4 doses) or vaccine + CD200AR-L (3 doses). DFI monitored.

All dogs have received treatments and are in the check-up phase of the study. Data is promising, with improvements in quality of life noted from study sites.

Luna, the first dog who was treated, just celebrated 14 months cancer-free!