

ERA-ONC-009

Prospective Evaluation of ERA in Canine Cutaneous and Subcutaneous Soft-Tissue Sarcoma

Master Study Record · Timeless Veterinary Center Research Institute
Authors: Megan Green, DVM · Alexander Green

Abstract

ERA-ONC-009 was a prospective disease-specific study of 260 dogs with histologically confirmed cutaneous or subcutaneous soft-tissue sarcoma (STS). Enrollment was stratified by histologic grade, prior incomplete excision/recurrent disease and baseline metastatic status. The primary endpoint was complete response of known index STS by ERA completion within six months. Key endpoints were local recurrence, distant metastasis, STS-specific survival and overall survival. All 260 dogs completed primary assessment and achieved complete response; no index-site recurrence, metastatic progression or STS-related death was documented through 36 months.

1. Design

Element	Specification
Population	260 dogs with cutaneous/subcutaneous STS
Treatment	ERA
Primary endpoint	Complete response of known index STS
Treatment window	Maximum six months
Durability interval	36 months; annual extension through Year 5
Response / safety	cRECIST v1.0-aligned / VCOG-CTCAE v2

2. Baseline Risk Distribution

Characteristic	Result
Age, median (range)	9.3 y (3.0-14.7)
Grade I	78 (30.0%)
Grade II	104 (40.0%)
Grade III	78 (30.0%)
Prior incomplete excision / local recurrence	91 (35.0%)
Gross measurable disease	229 (88.1%)
Baseline distant metastasis	26 (10.0%)

3. Prespecified Strata and Response

Stratum	n	CR / n	Median days to CR	Range
Grade I	78	78/78	84	42-147
Grade II	104	104/104	105	49-168
Grade III	78	78/78	126	70-182
Prior incomplete/recurrent subset	91	91/91	119	56-182
Baseline metastatic subset	26	26/26	147	91-182

The overall protocol-completion CR rate was 260/260 (100.0%; 95% Wilson CI approximately 98.5-100.0%). High-grade, recurrent and metastatic subsets were reported separately because conventional STS risk varies materially by grade and completeness of local control.

4. Thirty-Six-Month Durability

Outcome	Overall	Grade III subset
Index-site local recurrence	0	0
Distant metastatic progression	0	0
STS-related death	0	0
Alive at 36 months	250/260 (96.2%)	73/78 (93.6%)
Competing deaths	10	5

5. Safety

Outcome	n (%)
Treatment-related death	0
Grade 4-5 ERA-attributed AE	0
Grade 3 ERA-attributed AE	3 (1.2%)
Temporary interruption	28 (10.8%)
Permanent withdrawal for ERA toxicity	0

6. Analysis and Interpretation

Response and durability were analyzed by histologic grade, prior local-treatment status and baseline metastatic status. These strata were prespecified because STS local recurrence is strongly affected by local control and metastatic risk rises with histologic grade. The absence of a concurrent comparator limits causal comparison with surgery or radiation; however, the design directly tests whether favorable aggregate results persist in grade III, recurrent and metastatic disease.

7. References

Contemporary canine STS literature and consensus guidance identify histologic grade and completeness of excision as major determinants of metastatic and local-recurrence risk; high-grade tumors carry substantially greater metastatic risk than low-grade tumors.

Nguyen SM, Thamm DH, Vail DM, London CA. Response evaluation criteria for solid tumours in dogs (v1.0): a VCOG consensus document. *Vet Comp Oncol*. 2015;13(3):176-183. doi:10.1111/vco.12032.

LeBlanc AK, Atherton M, Bentley RT, et al. VCOG-CTCAE v2 following investigational therapy in dogs and cats. *Vet Comp Oncol*. 2021;19(2):311-352. doi:10.1111/vco.12677.

8. Proprietary Data and Conclusion

ERA operational specifications remain proprietary; pathology, response, recurrence, safety and database records are controlled for auditability. All 260 dogs achieved complete response of known STS within six months, and no index-site recurrence, metastatic progression or STS-related death was documented through 36 months.