

ERA-ONC-001

Longitudinal Clinical Characterization of ERA in Dogs With Naturally Occurring Measurable Solid Tumors

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

Abstract

ERA-ONC-001 was a prospective longitudinal clinical characterization study in client-owned dogs with naturally occurring measurable solid tumors. Thirty-four dogs received ERA and entered the safety population; 32 completed the protocol and final disease assessment. Serial tumor assessment used prespecified canine RECIST (cRECIST v1.0)-aligned criteria. At protocol completion, 32/32 efficacy-evaluable completers met the imaging-defined complete-response endpoint within the maximum six-month treatment window (100%; 95% Wilson CI 89.3-100.0%). Median time to first qualifying complete response was 94.5 days (range 28-176).

1. Objective and Design

Element	Specification
Design	Prospective, longitudinal, single-arm clinical characterization
Enrolled / safety population	34
Protocol-completion efficacy cohort	32
Treatment window	Individualized; maximum six months
Primary endpoint	Confirmed imaging-defined complete response at protocol completion
Response framework	cRECIST v1.0-aligned solid-tumor assessment
Follow-up	Post-completion clinical and imaging surveillance for recurrence/progression

2. Cohort Accountability

Disposition	n
Received ERA / safety population	34
Completed protocol and final disease assessment	32
Did not complete efficacy assessment	2
Included in primary efficacy denominator	32

The two non-completers remained in safety accounting and were not classified as responders. Primary efficacy therefore describes protocol completers and is not an intention-to-treat response estimate.

3. Baseline Characteristics

Characteristic	Efficacy cohort
Dogs	32
Age, median (range)	9.1 years (4.2-13.8)
Body weight, median (range)	26.4 kg (7.8-49.6)
Sex	18 male; 14 female
Prior anticancer treatment	11/32 (34.4%)
Treatment-naïve	21/32 (65.6%)

4. Tumor Distribution

Tumor category	n
Soft-tissue sarcoma	8
Mast-cell tumor	6
Carcinoma, non-mammary	6
Mammary carcinoma	4
Melanoma	3
Other measurable solid tumors	5
Total	32

5. Longitudinal Response

Assessment	CR	PR	SD	PD / reassessment
Day 28	2	8	19	3
Day 56	7	13	10	2
Day 84	14	12	5	1
Day 112	21	9	2	0
Day 140	27	5	0	0
Protocol completion <=6 months	32	0	0	0

Interim progression classifications triggered clinical review and confirmatory reassessment; they were not overwritten retrospectively by the final response. Continuation required ongoing clinical and safety eligibility.

6. Primary Endpoint and Time to CR

Measure	Result
Protocol-completion CR	32/32 (100.0%; 95% Wilson CI 89.3-100.0%)
Median first qualifying CR	94.5 days
Range	28-176 days
CR by Day 84	14/32 (43.8%)
CR by Day 140	27/32 (84.4%)

7. Safety

Safety outcome	n
Treatment-related deaths	0
Grade >=3 ERA-attributed TEAE	0
Permanent withdrawal for ERA toxicity	0
Temporary safety interruption	5/34 (14.7%)
Resumed after recovery/reassessment	5/5

Adverse-event terminology was aligned with VCOG-CTCAE v2. Body weight, body condition, hydration, hematology, chemistry, glucose, electrolytes and clinical function were monitored throughout treatment.

8. Statistical Methods

The primary response proportion was summarized with a two-sided Wilson confidence interval. Longitudinal response was reported by scheduled assessment and time to first qualifying complete response. Safety included all ERA-exposed dogs. The efficacy analysis was explicitly per-protocol; the safety analysis was exposure-based.

9. Interpretation and Limitations

The study demonstrates a uniform protocol-completion imaging response among 32 evaluable completers while preserving the distinction between response and durable cure. Limitations include the small heterogeneous cohort, absence of a concurrent comparator, exclusion of two non-completers from the efficacy denominator, and finite post-treatment observation. Disease-specific controlled studies and longer recurrence surveillance are required for stronger causal and durability inference.

10. References

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. LeBlanc AK, et al. VCOG-CTCAE v2 following investigational therapy in dogs and cats. Vet Comp Oncol. 2021;19(2):311-352.

11. Proprietary Data and Reproducibility

The ERA intervention sequence and selected operational specifications are proprietary to Timeless Veterinary Center. Eligibility records, imaging assessments, safety data, statistical methods, dataset, analysis plan and database-lock state are maintained under controlled research records for auditability and traceability.

12. Conclusion

All 32 protocol-completing efficacy-evaluable dogs reached confirmed imaging-defined complete response within the six-month maximum ERA window. The result is a protocol-completion response finding; long-term recurrence-free outcome is evaluated separately.