One-dose carboplatin followed by vaccine-enhanced adoptive cell therapy (ECI®) improves outcomes compared to four-dose carboplatin in dogs with osteosarcoma – 18-month update

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Speaker Disclosure

FINANCIAL DISCLOSURE

Dr. Jeffrey N Bryan is a member of the ELIAS Animal Health Scientific Advisory Board and conducts research/clinical trials sponsored by ELIAS Animal Health

UNLABELED/UNAPPROVED USES DISCLOSURE

Dr. Bryan will discuss results of a clinical trial for the following agents that are currently not approved for use in animals: carboplatin, doxorubicin

Combination Therapies in Oncology

- **USDA approval in March 2025**
  - Full autologous prescription product approval
  - Adjuvant treatment for canine osteosarcoma post-surgery[1]
  - Consistent, reliable manufacturing process
- Growing evidence indicates combined chemo-immunotherapy improves outcomes[2]
- Cytotoxic effect of chemotherapy may enhance immunological effects of ECI
- **Data presented here:**
  - 18-month survival analysis of prospectively enrolled study in dogs with appendicular osteosarcoma
  - Treated with **combination of chemotherapy and ECI**
  - Comparison to matched control group

[1] ECI® is USDA approved under Product Code No. 95A7.50 manufactured at USDA Licensed Est. No. 691

[2] https://www.cancer.gov/about-cancer/treatment/types (Accessed May 13, 2025)

ASCENT Combination Therapy Study

Methods

Study Design	Non-randomized, prospective, open-label study Target Enrollment: 30 dogs at 10+ sites Endpoints: Median survival time, % alive at 1-year and 18 months
Key Inclusion Criteria	Newly diagnosed appendicular osteosarcoma No prior treatment Surgically resectable cancer collected for ECI
Key Exclusion Criteria	Metastatic disease at diagnosis, including any detected via 3-view thoracic radiographs

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Methods

TIMELINE	DVM	ELIAS
Week 0	Surgery to collect cancer tissue	Vaccine preparation
Week 1	Administer chemotherapy	
Weeks 4-6	Administer vaccine series	
Week 8	Apheresis to collect MNCs	Ex vivo T cell expansion
Week 9	Infuse activated “killer” T cells	
Weeks 9-10	Administer IL-2 injection series	

- ECI protocol modified to integrate upfront chemotherapy ***7-10 days AFTER* cancer cell harvest**
- Recommended carboplatin dose 300 mg/m^2 (single-dose preferred)
- Initiate autologous cancer vaccines 21 days post-chemotherapy
- Remainder of ECI protocol unchanged

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Methods

Demographics of Enrolled Dogs

Study Sites:	13 private and 1 university oncology clinics		
Enrollment:	21 dogs (target for full study is 30)		
Tumor Location:	Radius (7)	Humerus (5)	Tibia (4)
	Ulna (2)	Femur(2)	Carpus (1)
Breed:	Labrador Retriever (7)		Mixed Breed (3)
	Doberman Pinscher (2)		Other (9)
Gender:	FS (5)	MN (10)	
	F (2)	M (4)	
Weight:	24-64 kg (average 35 kg)		
Age:	3-11 years (average 7.5 years)		

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Methods

Matched Control Dogs (n = 21)

- 21 dogs selected from a published dataset in NCI Canine Data Commons (COTC022)
- Minimum of 2 chemotherapy doses to approximate ECI treatment initiation in combination group
- Matching criterion in order of importance
  - Tumor location
  - Breed
  - Gender
  - Weight

ASCENT Combination Therapy Study

Methods

Chemotherapy and ECI® Dosing

- 19 of 21 dogs (90%) received carboplatin before ECI; 2 of 21 (10%) received doxorubicin
- 13 of 21 dogs (62%) in combination group received a single carboplatin dose before ECI
- 21 of 21 dogs (100%) completed ECI T cell infusion

Chemo doses	Combination Therapy (*n* = 21)	Matched Controls (*n* = 21)
One	13 (62%)	None
Two	4 (19%)	3 (14%)
Three	3 (14%)	2 (10%)
Four	1 (5%)	16 (76%)

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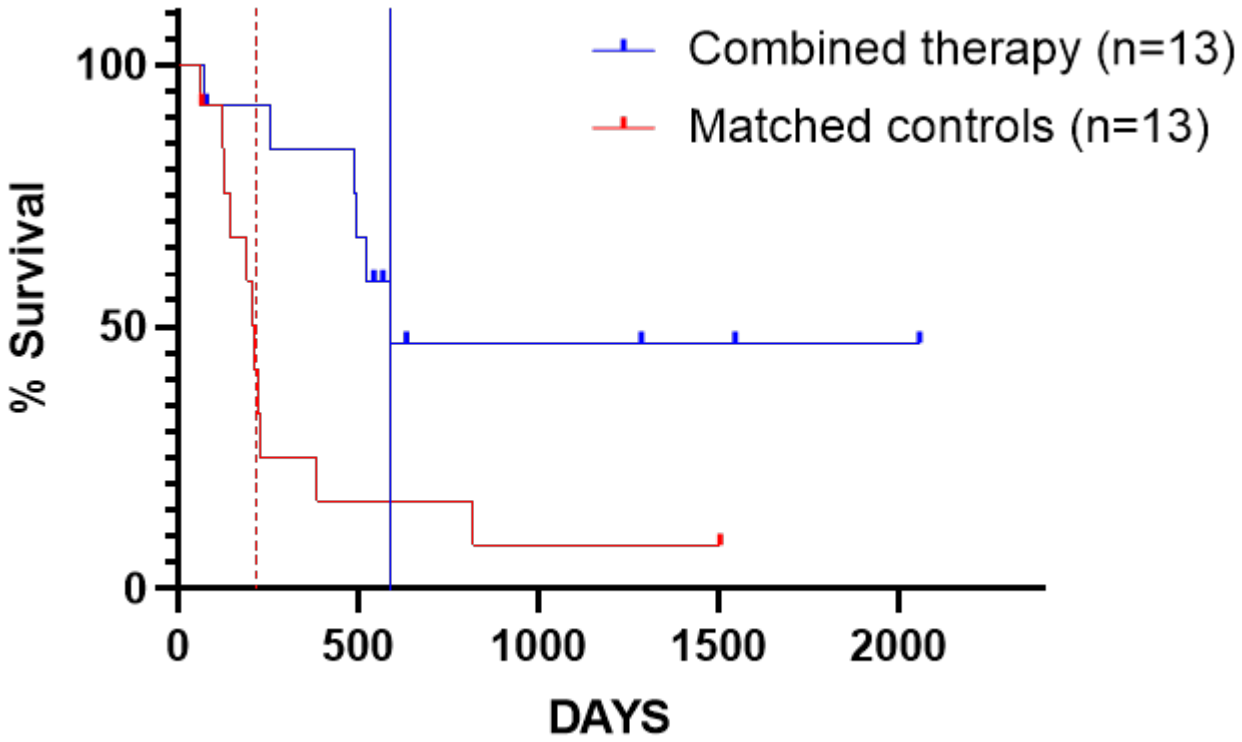
Overall Survival – Single Dose Cohort

Cohort	1-year survival	18-month survival	MST (days)
Combined therapy	83%	58%	586 (95% CI, range, 73 - 2057)
Matched controls	25%	17%	208 (95% CI, range, 61 - 1503)



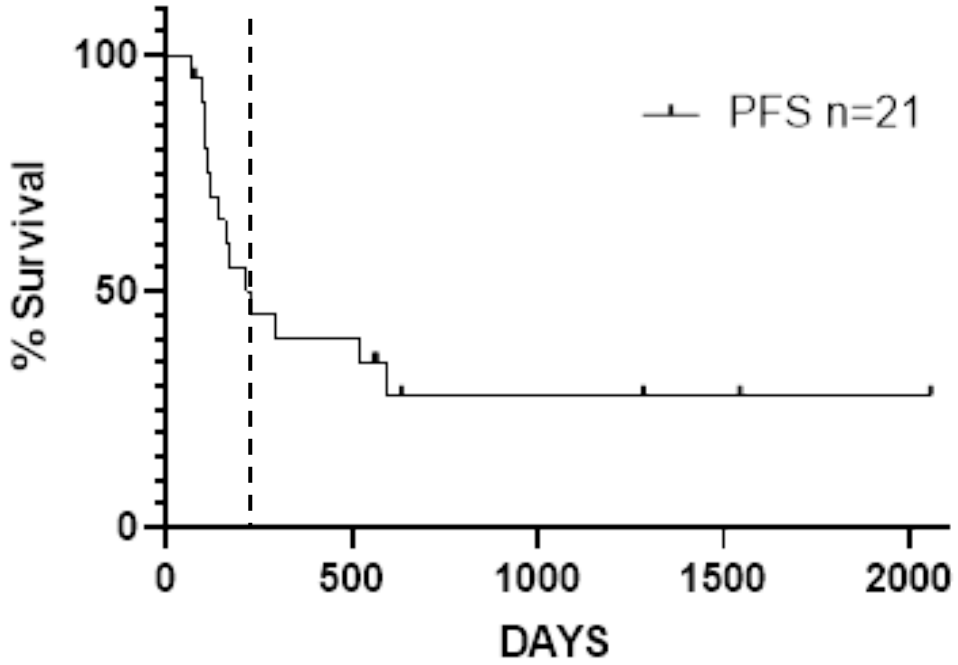
Statistics – 18 months		
	A/B	B/A
Hazard Ratio (logrank)		
p = 0.006 **		
Ratio (and its reciprocal)	0.2829	3.535
95% CI of ratio	0.1038 to 0.7709	1.297 to 9.632
Hazard Ratio (Mantel-Haenszel)		
Ratio (and its reciprocal)	0.2365	4.228
95% CI of ratio	0.0842 to 0.6643	1.505 to 11.87
Gehan-Breslow-Wilcoxon test		
p = 0.006 **		

** highly significant

ASCENT Combination Therapy Study

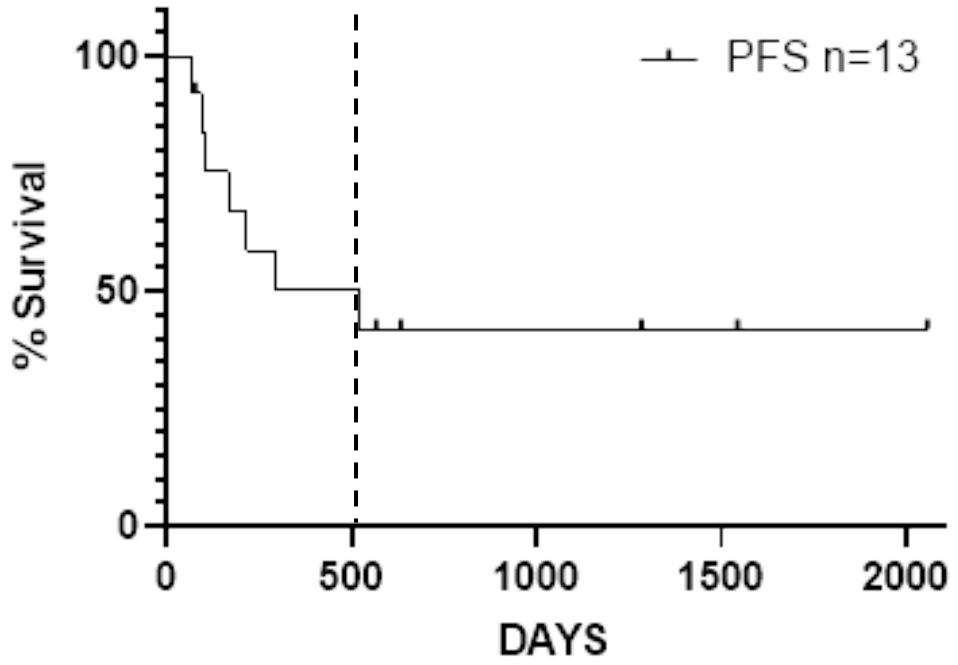
Progression-free Survival – Both Cohorts

All dogs (n=21) receiving *1 to 4 doses* of carboplatin prior to ECI immunotherapy



Median PFS = 232 days

Dogs (n=13) receiving *a single dose* of carboplatin prior to ECI immunotherapy



Median PFS = 519 days

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Post-DP Oncotherapy Administration

- 6 of 13 dogs showed no disease progression (DP) and received no additional oncotherapy
- 7 of 13 dogs showed DP (listed below)
  - 4 of 7 received multiple oncotherapies
  - 3 of 7 received no additional oncotherapy
- Post-DP survival time range was 1–448 days with 1 dog still alive

Dog ID	Overall survival (days)	Progression-free survival (days)	Last known status	Oncotherapy post-DP	Type	Post-DP survival (days)
04	253	107	Deceased	No	-	146
09	**494**	**297**	**Deceased**	**Yes**	**Radiotherapy, toceranib, losartan**	**197**
14	73	67	Deceased	No	-	6
18	519	519	Deceased	No	-	1
19	**489**	**167**	**Deceased**	**Yes**	**6X carboplatin, toceranib(?)[1]**	**322**
20	**586**	**214**	**Deceased**	**Yes**	**Toceranib/losartan, cellular polysaccharide peptides**	**372**
21	**542**	**94**	**Alive**	**Yes**	**6X carboplatin, losartan**	**448**

[1]Recommended by oncologist, pet owner chose to pursue administration via primary care DVM

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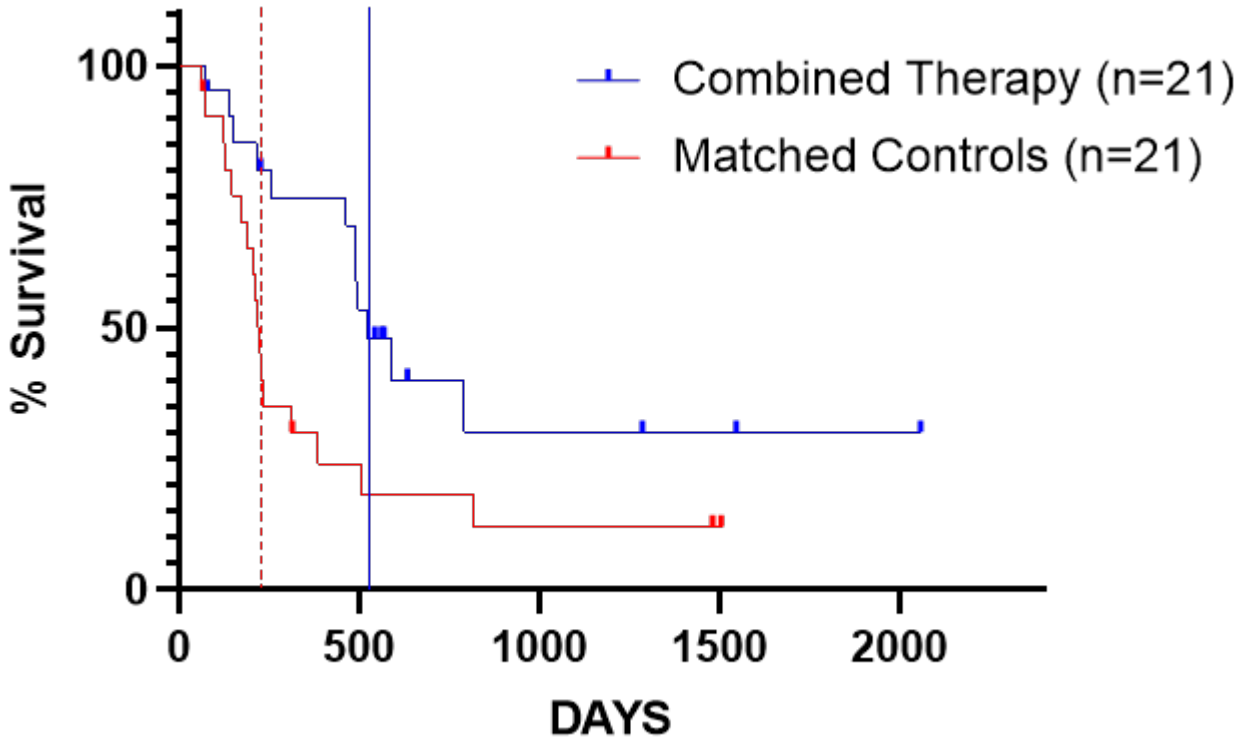
Survival – All dogs (1-4 doses chemo)

Cohort	1-year survival	18-month survival	MST (days)
Combined therapy (n=21)	70%	45%	519 (95% CI, range, 73-2057)
Matched controls (n=21)	26%	16%	220 (95% CI, range, 61-1503)



Statistics – 18 month		
	A/B	B/A
Hazard Ratio (logrank)		
p = 0.022 *		
Ratio (and its reciprocal)	0.438	2.283
95% CI of ratio	0.207 to 0.926	1.080 to 4.827
Hazard Ratio (Mantel-Haenszel)		
Ratio (and its reciprocal)	0.410	2.437
95% CI of ratio	0.192 to 0.879	1.137 to 5.220
Gehan-Breslow-Wilcoxon test		
p = 0.012 *		

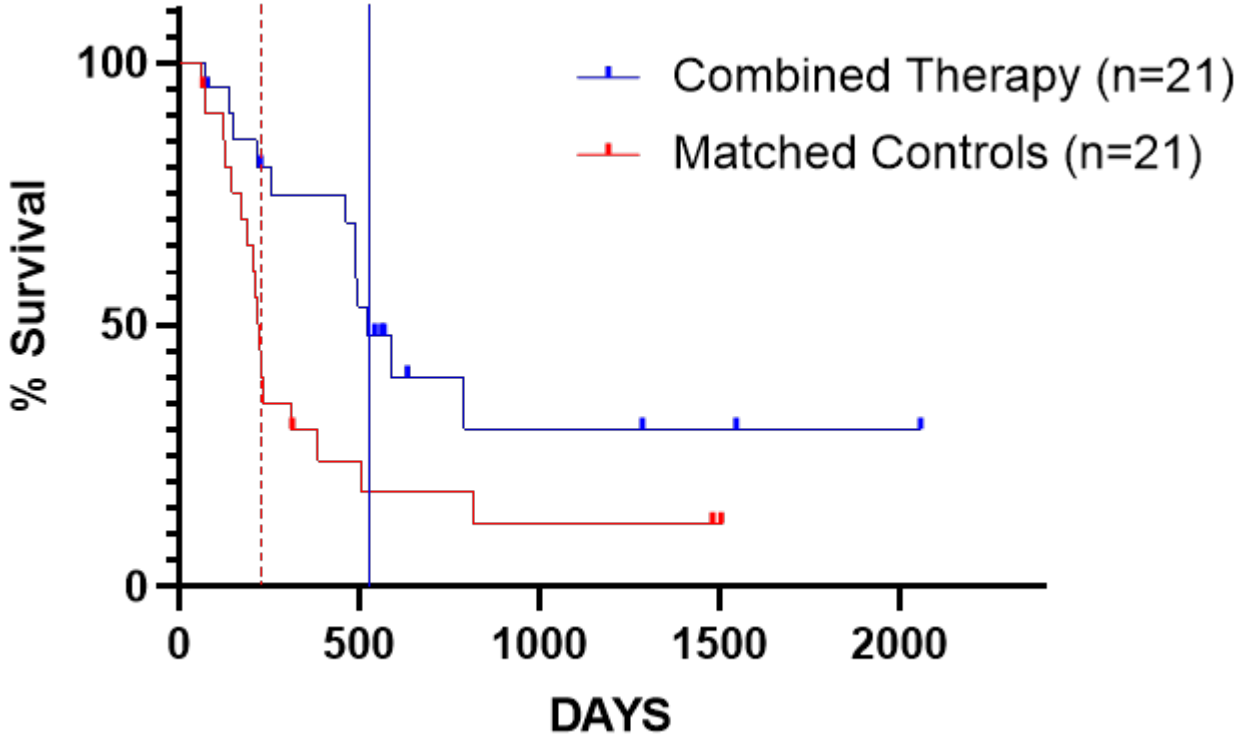
* significant

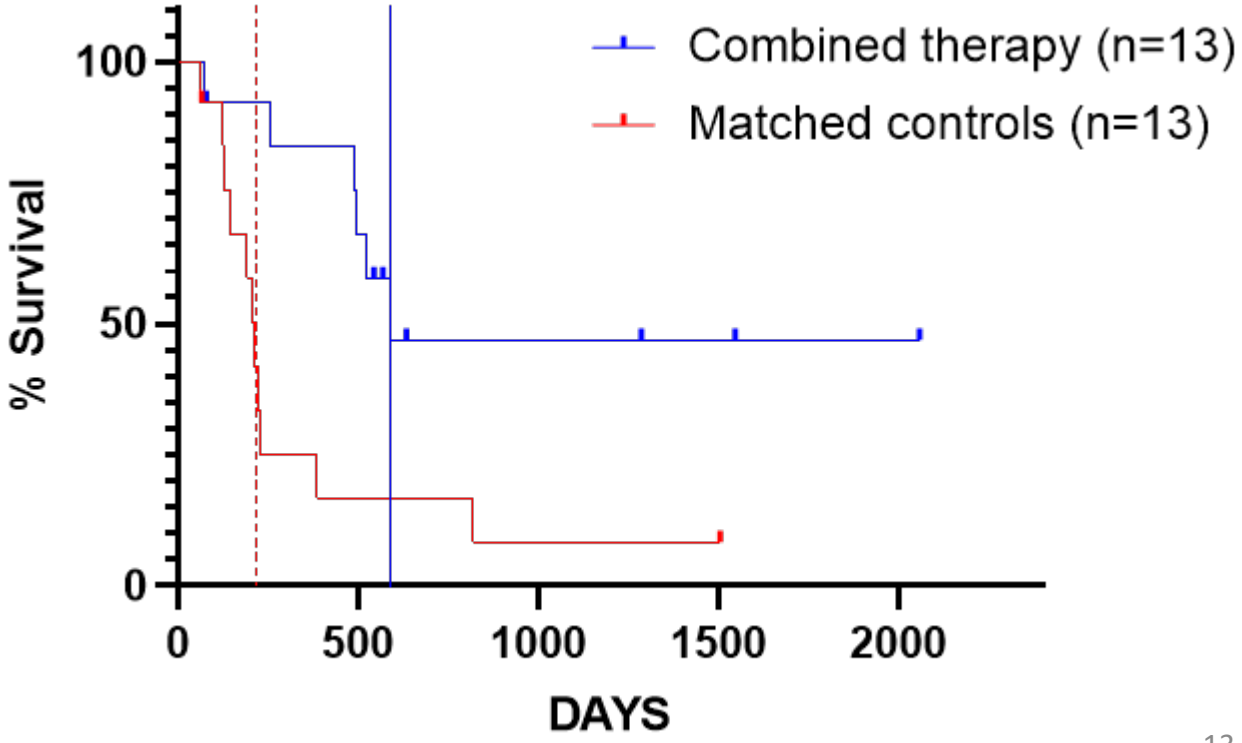
ASCENT Combination Therapy Study

Survival Comparison – All dogs vs. Single-dose

Cohort	1-year survival	18-month survival	MST (days)	*p value*
All dogs (*n*=21)	70%	45%	519 (95% CI, range, 73-2057)	*0.022**
Single-dose dogs (*n*=13)	83%	58%	586 (95% CI, range, 73-2057)	*0.006***

* significant
** highly significant





ECI Safety Profile

Statistically significant improvement in serious ARs

ASCENT Study (*n* = 21)

No serious adverse reactions reported
Findings consistent with ECI-OSA-04 randomized pivotal study results

ECI-OSA-04 BASE Study (*N* = 101)

Adverse Reaction	ECI (*n* = 49)	Carboplatin (*n* = 52)	OR (95% CI)*	Significance†
Any AR (≥1, any grade)	34 (69.4%)	35 (67.3%)	1.10; (0.48–2.55)	*p* = 0.83
Serious AR (≥1, grade 3-5)	**0 (0.0%)**	**13 (25.0%)**	**0.00 (0.00–0.51)**	***p* = 0.0001**

* Odds ratios (ORs) and exact 95% confidence intervals (CIs) derived from 2×2 contingency tables
† Two-tailed Fisher's exact test

ECI-OSA-04 Summary of Adverse Reactions[1]

Treatment Phase	Total Dogs Evaluated	Adverse Reaction	Any Grade AR	Serious ARs VCOG Grades 3-5
Autologous Vaccine	49	Lethargy/fatigue	8 (16.3%)	0
		Anorexia	6 (12.2%)	0
		Diarrhea	5 (10.2%)	0
		Personality/behavior	5 (10.2%)	0
		Nausea/ptyalism	3 (6.1%)	0
		Vomiting	3 (6.1%)	0
T cell Infusate	45	Lethargy/fatigue	8 (17.8%)	0
		Anorexia	7 (15.6%)	0
		Nausea/ptyalism	6 (13.3%)	0
		Fever	5 (11.1%)	0
		Diarrhea	3 (6.7%)	0

[1] ECI® product label (Safety Section)

ECI Product Label

No steroids … unless

ALL STEROIDS CONTRAINDICATED *except for managing* POTENTIALLY LIFE-THREATENING CRS

TABLE 3: Cytokine Release Syndrome: Clinical Description of Severity and Recommended Treatment[1]

	Severity			
	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
Clinical Signs	Fever (>39.5°C/103.5°F) with or without constitutional signs	Hospitalization for observation/supportive care without requirement for pressors or oxygen supplementation; hypotension responding to intravenous fluids	Hypotension managed with one pressor; hypoxia requiring non-invasive oxygen support (flow-by/ prongs/mask/ oxygen cage)	Life-threatening consequences; urgent intervention required; hypoxia requiring mechanical ventilation
Recommended Treatment	Monitor signs	IV fluids are indicated	**Dexamethasone (0.25 mg/kg, IV, once daily, as necessary)**	**Dexamethasone (0.25 mg/kg, IV, once daily, as necessary)**

[1] ECI® product label (Contraindications, Precautions)

ASCENT Combination Therapy Study

Conclusions

Chemotherapy before initiation of ECI indicates improved outcomes compared to matched controls receiving 4-dose carboplatin therapy

- **Statistically significant improvement in MST**
- **Well tolerated with no serious adverse reactions**
- **Single-dose carboplatin prior to ECI resulted in better outcomes than multiple doses**
- **18-month survival rate of 58% for single-dose combined therapy group continues to show improved outcomes compared with 17% for dogs receiving four-dose carboplatin**

Mirrors improved outcomes reported in human patients receiving combined therapies