TV 301 Phase III, Efficacy Data

Leslie Randall, MD, MAS
Virginia Commonwealth University
Richmond, VA

GOG FOUNDATION® *Transforming the standard of care™*

GOG PARTNERS

ENGOT-cx12/GOG-3057/innovaTV 301 Clinical Trial

Key Eligibility Criteria

- Recurrent cervical cancer
- Disease progression on or after chemotherapy
- ≤2 prior treatment lines
- Tumor at least 1 cm in size or lymph node at least 1.5 cm in size
- Good functional performance

Randomization

1:1

Treatment

Tisotumab Vedotin (n=253)

2.0 mg/kg IV Q3W

Standard Chemo (n=249)

- Topotecan
- Vinorelbine
- Gemcitabine
- Irinotecan
- Pemetrexed

Outcomes/Endpoints

Primary Outcome

- Overall survival time

Key Secondary Endpoints

- Progression free time
- Tumor response rate
- Safety/side effects

Demographics and Disease Characteristics

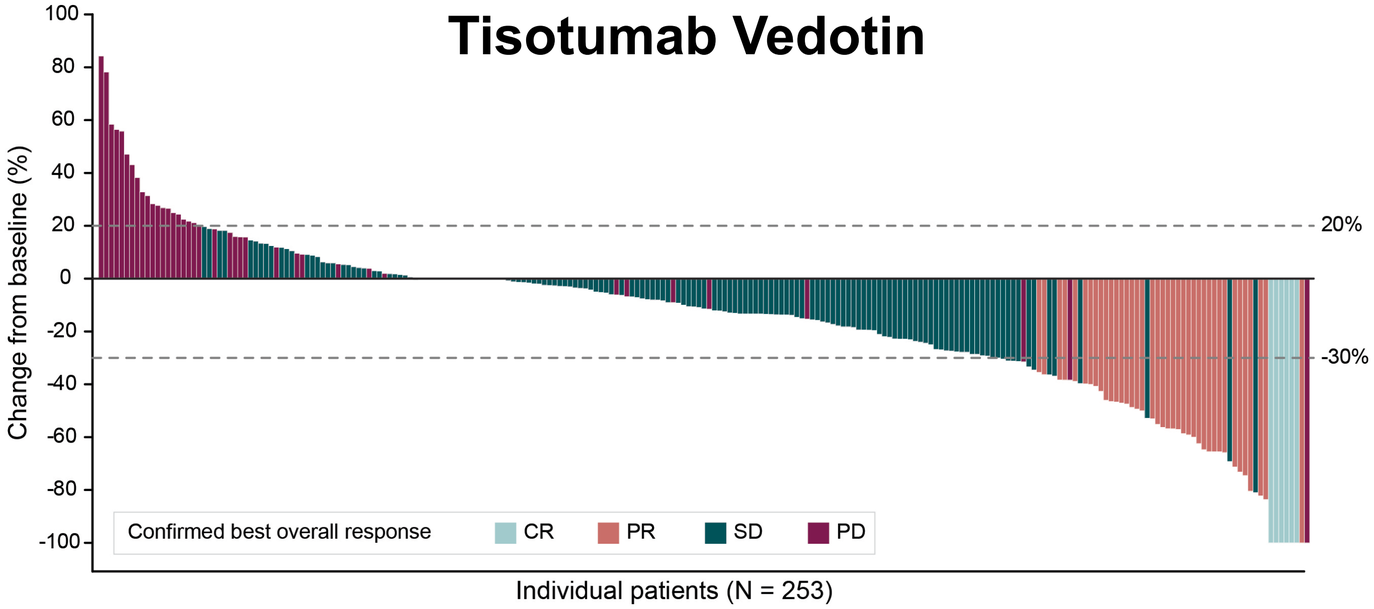
Age, ECOG performance status, and regions of enrollment were similar across both arms

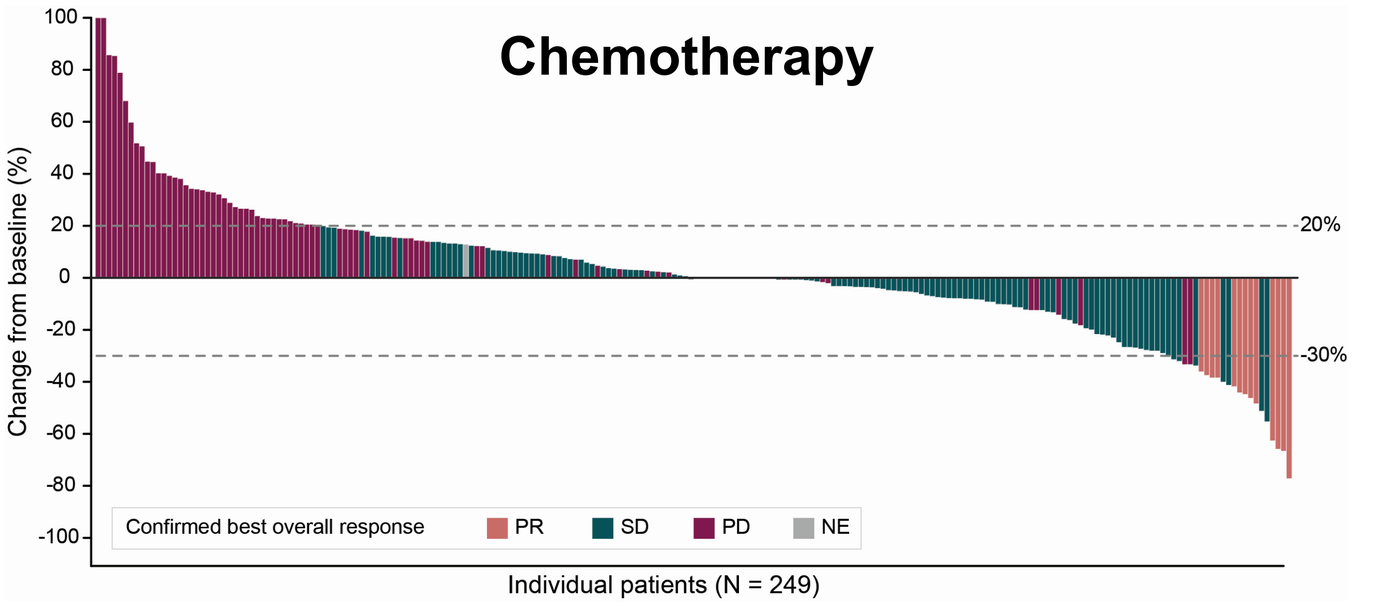
	Tisotumab Vedotin (N=253)	Chemotherapy (N=249)
Disease status at study entry, n (%)		
Pelvic recurrent only	27 (10.7)	24 (9.6)
Extra-pelvic metastatic	226 (89.3)	225 (90.4)
Histology, n (%)		
Squamous cell carcinoma	160 (63.2)	157 (63.1)
Adenocarcinoma	85 (33.6)	75 (30.1)
Adenosquamous carcinoma	8 (3.2)	17 (6.8)
Number of prior r/m systemic regimens, n (%)		
1	159 (62.8)	149 (59.8)
2	93 (36.8)	100 (40.2)
Unknown	1 (0.4)	0
Prior bevacizumab, n (%)	164 (64.8)	157 (63.1)
Prior anti-PD-(L)1 therapy, n (%)	71 (28.1)	67 (26.9)
Prior radiation therapy for cervical cancer, n (%)	205 (81.0)	203 (81.5)
Biopsy evaluable, n (%)	210 (83.0)	194 (77.9)
Positive membrane TF expression[a]	194 (92.4)	183 (94.3)

[a]TF expression is defined as TF membrane expression ≥1% with immunohistochemistry; percentages are calculated based on number of evaluable biopsies.

Antitumor Activity

	Tisotumab Vedotin (N=253)	Chemotherapy (N=249)
ORR, % (95% CI)	17.8 (13.3-23.1)	5.2 (2.8-8.8)
Odds ratio (95% CI) P value	4.0 (2.1-7.6) p<0.0001	
Best Overall Response, n (%)		
CR	6 (2.4)	0
PR	39 (15.4)	13 (5.2)
SD	147 (58.1)	132 (53.0)
PD	46 (18.2)	74 (29.7)
Not evaluable/Not available	15 (5.9)	30 (12.0)
DCR[a], % (95% CI)	75.9 (70.1-81.0)	58.2 (51.8-64.4)
Median DOR (95% CI)	5.3 (4.2-8.3)	5.7 (2.8-NR)





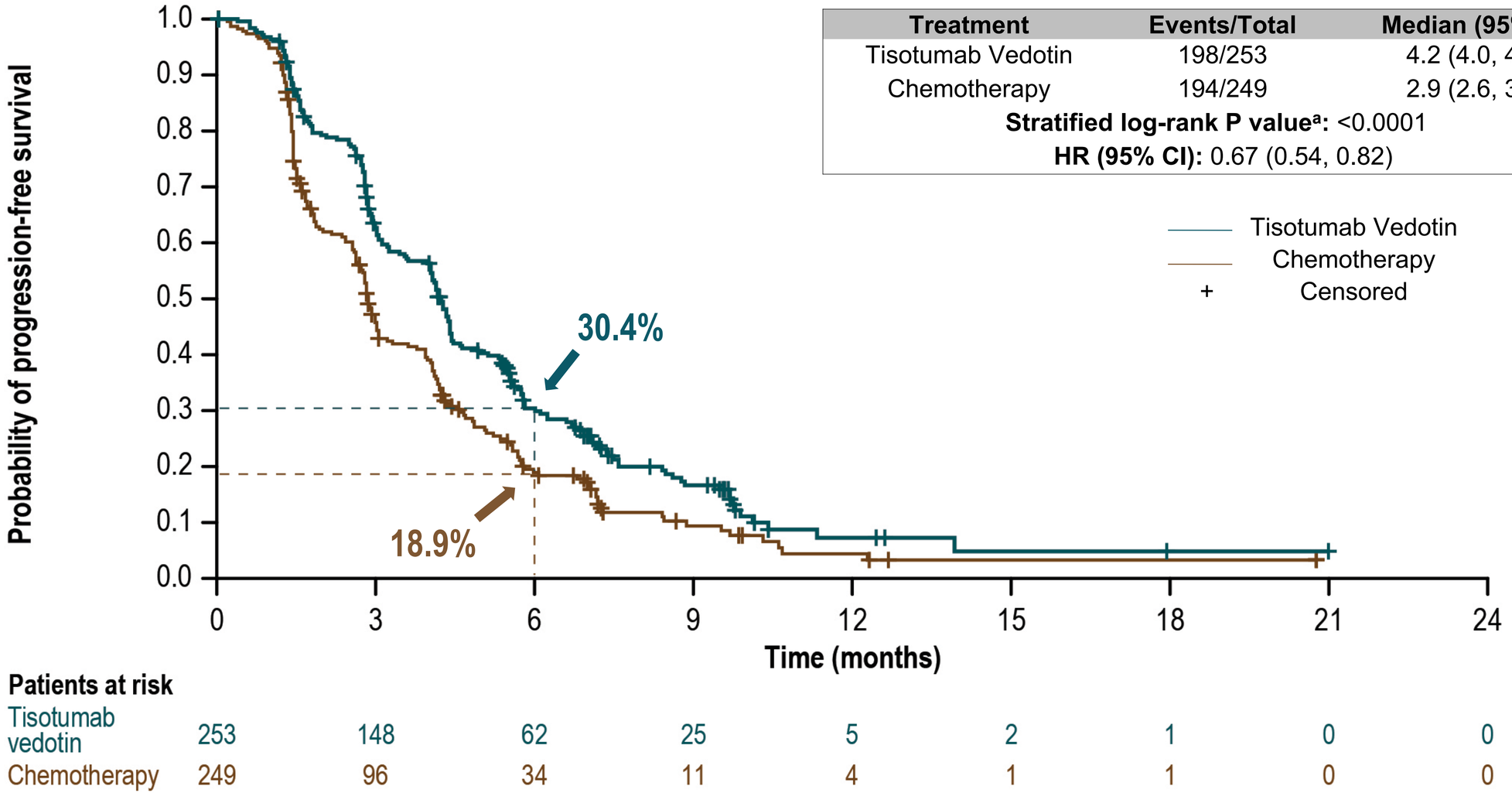
[a]DCR defined as CR+PR+SD; CR and PR were confirmed responses. The minimum criteria for SD duration was ≥5 weeks after the date of randomization.

Progression-Free Survival Per Investigator

Treatment	Events/Total	Median (95% CI)
Tisotumab Vedotin	198/253	4.2 (4.0, 4.4)
Chemotherapy	194/249	2.9 (2.6, 3.1)

Stratified log-rank P value[a]: <0.0001

HR (95% CI): 0.67 (0.54, 0.82)

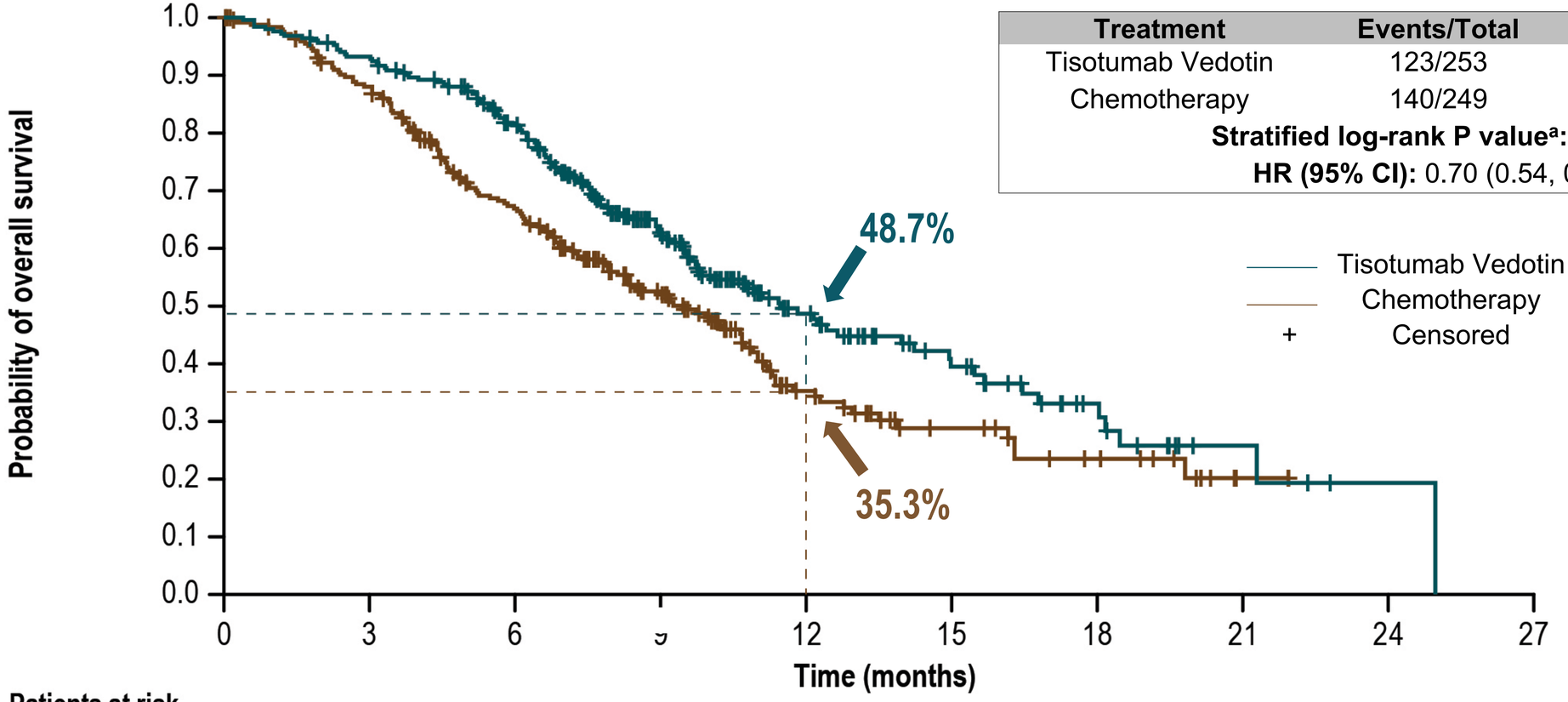


[a]The threshold for statistical significance is 0.0453 (2-sided), based on the actual number of PFS events at interim analysis.

Overall Survival (Primary Endpoint)

The study met overall survival statistical significance at the planned interim analysis

Treatment	Events/Total	Median (95% CI)
Tisotumab Vedotin	123/253	11.5 (9.8, 14.9)
Chemotherapy	140/249	9.5 (7.9, 10.7)
Stratified log-rank P value[a]: 0.0038		
HR (95% CI): 0.70 (0.54, 0.89)		



Patients at risk

Tisotumab vedotin	253	234	191	109	52	29	14	4	1	0
Chemotherapy	249	212	150	87	37	19	11	1	0	0

[a]The threshold for statistical significance is 0.0226 (2-sided), based on the actual number of OS events at interim analysis.