CAN-003 Analysis Phase 2 trial of CVac for the treatment of ovarian cancer patients in first or second remission

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Introductions



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PROGRESSION-FREE SURVIVAL IN OVARIAN CANCER PATIENTS IN SECOND REMISSION IS IMPROVED WITH MUCIN 1 AUTOLOGOUS DENDRITIC CELL THERAPY (CAN-003)

Heidi J. Gray, MD

Data presented at the 50th ASCO Annual Meeting May 31, 2014



CAN-003: Randomized open label, phase 2 trial

Purpose:

Determine the safety and efficacy
 of CVac vs Observational Standard of Care
 in patients with First or second remission

Primary Objectives:

- Safety
- Progression-free survival (PFS)

Secondary Objectives:

- Overall survival (OS)
- Immunologic response (humoral and cellular)



CAN-003 Study Design



CAN-003 Results: Demographics

Characteristic	CVAC	SOC	
	(N=29)	(N=27)	
Remission status			
Achieved after first-line therapy	19 (66%)	17 (63%)	
Achieved after second-line therapy	10 (34%)	10 (37%)	
Disease stage			
III	24 (83%)	20 (74%)	
IV	5 (17%)	7 (26%)	
Histology subtype			
Serous	25 (86%)	23 (85%)	
Endometrioid	1 (3%)	2 (7%)	
Mucinous	1 (3%)	1 (4%)	
Other (mixed, not specified)	2 (7%)	1 (4%)	
Cytoreduction/debulking surgery			
Optimal	27 (93%)	23 (85%)	
Suboptimal	2 (7%)	4 (15%)	
Age years			
median (range)	58 (34-75)	49 (43-70)	

IUMLU

CAN-003 Serious Adverse Events

Event	Outcome	Causality	Treatment group
1.Small bowel obstruction	Recovered with treatment	Unrelated	CVac
2. Abdominal pain, dehydration, nausea, vomiting	Recovered with treatment	Unrelated	SOC
3. Abdominal pain	Recovered	Unlikely Related	CVac
4. Respiratory failure	Fatal	Unrelated	SOC
5. Small bowel obstruction	Recovered	Unrelated	CVac
6. Febrile neutropenia	Recovered	Unrelated	CVac
7. Surgical removal iliac node (hospitalization for progression)	Recovered with treatment	Unrelated	CVac
8. Small bowel obstruction	Recovered	Unrelated	CVac
9. Disease progression / laparoscopy	Recovered with treatment	Unrelated	CVac



CAN-003 Progression-Free Survival (ITT, n=56)



(#events/#at risk)



CAN-003 Comparison of PFS

First Remission HR1.18



Second Remission HR0.32

RIMA BIOMED

CAN-003 Overall Survival

Second Remission HR0.17

RIMA BIOMED



First Remission HR0.63

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CAN-003 Conclusions

- Feasibility Multinational manufacture and distribution of CVac was possible
- Safe CVac was well tolerated with minimal toxicity
- Immunogenic Positive mucin 1-specific T cell response in CVac treated patients
- PFS signal in second remission
- Interim OS signal in second remission



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