

CAN-003 Analysis

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

Supplemental information to management presentation on
October 2, 2013



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CAN-003 Study Design

Treatment	<ul style="list-style-type: none">• CVac group – 10 doses (60 million cells ea.) in 56 weeks• Control – observation only (standard of care)
Patients	<ul style="list-style-type: none">• 63 patients enrolled• first 7 non randomized (to establish manufacturing comparability)• 56 patients randomized 1:1• 43 in 1st remission / 20 in 2nd remission
Design	<ul style="list-style-type: none">• enrolled w/in 12 weeks of complete remission after 1st or 2nd line• CVac dosing started within 10 weeks of enrollment• 2 year observation period• Progression determined by GCIC criteria (CA-125) & RECIST
Endpoints	<ul style="list-style-type: none">• Primary – Safety and Progression-free survival• Secondary - Overall survival and Immune monitoring
Analysis	<ul style="list-style-type: none">• Safety population: all 63 patients• ITT efficacy population: 56 randomized patients

CAN-003 Data Analysis Summary

Safety	<ul style="list-style-type: none">• CVac was well tolerated and non-toxic
Immune Monitoring	<ul style="list-style-type: none">• CVac induced a mucin 1 specific T cell response• No antibody response generated by CVac
Progression Free Survival	<ul style="list-style-type: none">• No statistically significant differences observed• Divergent trends observed between first and second remission groups
Overall Survival	<ul style="list-style-type: none">• 8 deceased out of 58 evaluable patients• observation ongoing

CAN-003 Statistical Considerations

- This trial was not powered to detect a statistically significant difference in PFS
- This sample size considered adequate on clinical grounds to evaluate rates of tumor progression, trends in immunological outcomes, disease markers, and other clinical outcomes for the purpose of planning future trials.
- The Intent-to-Treat (ITT) population includes all subjects randomized to treatment with CVac or SOC, excluding the 7 subjects assigned to CVac at the start of the study.

Serious Adverse Events (SAE)

(as of Sept 9 2013)

- Total of 10 SAEs in three years
- SAEs by causality (9 Not Related, 1 Unlikely Related)
 - “Unlikely related” event was small bowel obstruction
- SAEs by country (7 Australia / 3 USA)
- SAEs by category (9 hospitalizations / 1 death)
 - Death was **unrelated** to study agent and resulted from reported events of respiratory failure and subdural hematoma
- SAEs by outcome (8 recovered, 1 ongoing, 1 fatal)

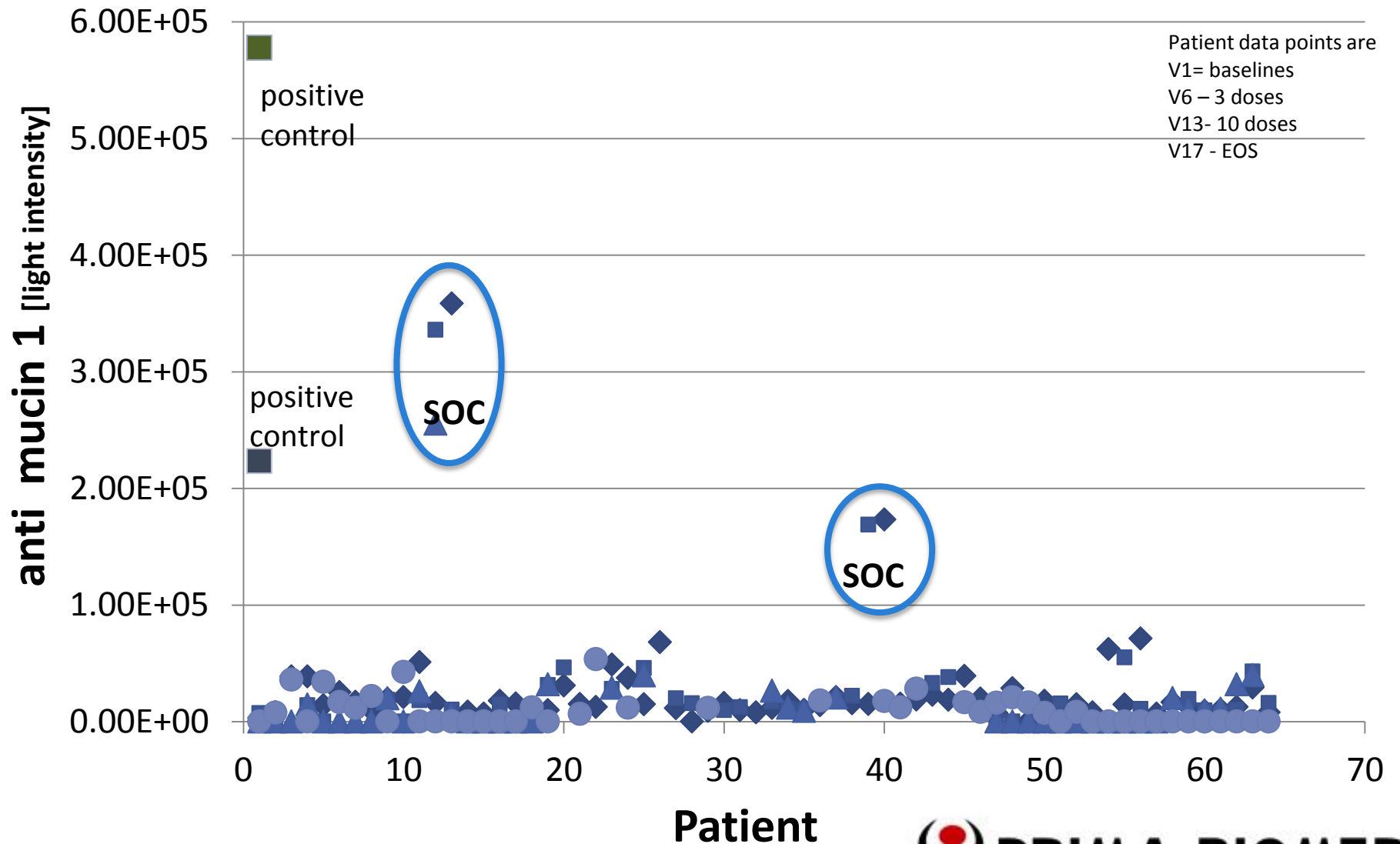
All Adverse Event (AE) Data

- Events deemed as **definitely related** included:
 - symptoms at injection site (localized pain, erythema, redness, swelling, burning)
 - events of fatigue, lethargy, and dizziness were also reported as related to study agent
- Majority of events were **mild (grade 1)** and resolved same day
- All severe events resolved except for 1 event of bunion
- Severe events were mostly **unrelated**.
 - except for 1 event of widespread itch which was deemed as probably related
 - 1 event of headache which was deemed as possibly related

→ CVac was well tolerated and non-toxic

Immune Monitoring - anti Mucin 1

➔ No antibody response generated by treatment with CVac



T cell Immune Monitoring Summary

(Table of CVac patients' best immune responses)

	CD4 IL-2	CD4 IL-4	CD4 IFN γ	CD4 TNF α	CD4 IL-17
CR1	*	*	*		
CR2	**	**	*		
CR1 + CR2					
	CD8 IL-2	CD8 IL-4	CD8 IFN γ	CD8 TNF α	CD8 IL-17
CR1	*	**		**	
CR2		*		*	**
CR1 + CR2		*	*		*

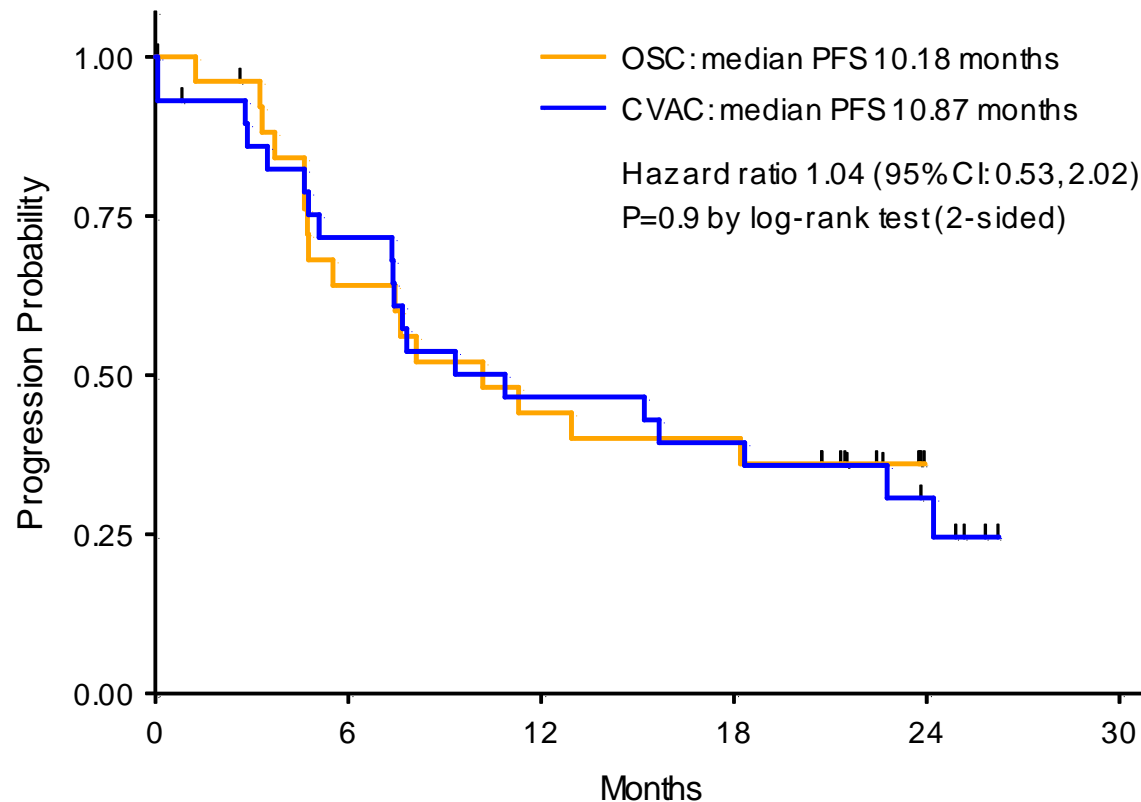
* P < 0.1

** P < 0.05

→ CVac induced a mucin 1 specific T cell response

Kaplan-Meier Estimates of Progression-Free Survival (ITT)

⇒ **Data of all 56 patients combined showed no difference in PFS**

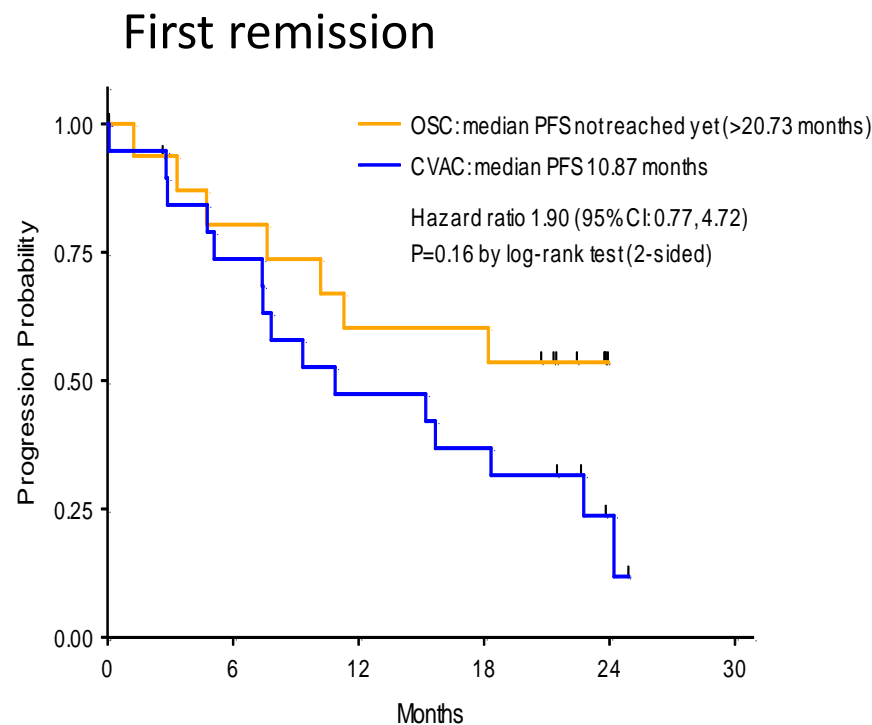


OSC	9/27	5/16	1/11	1/10	0/0
CVAC	8/29	7/20	2/13	2/11	1/5

(#events/#at risk)

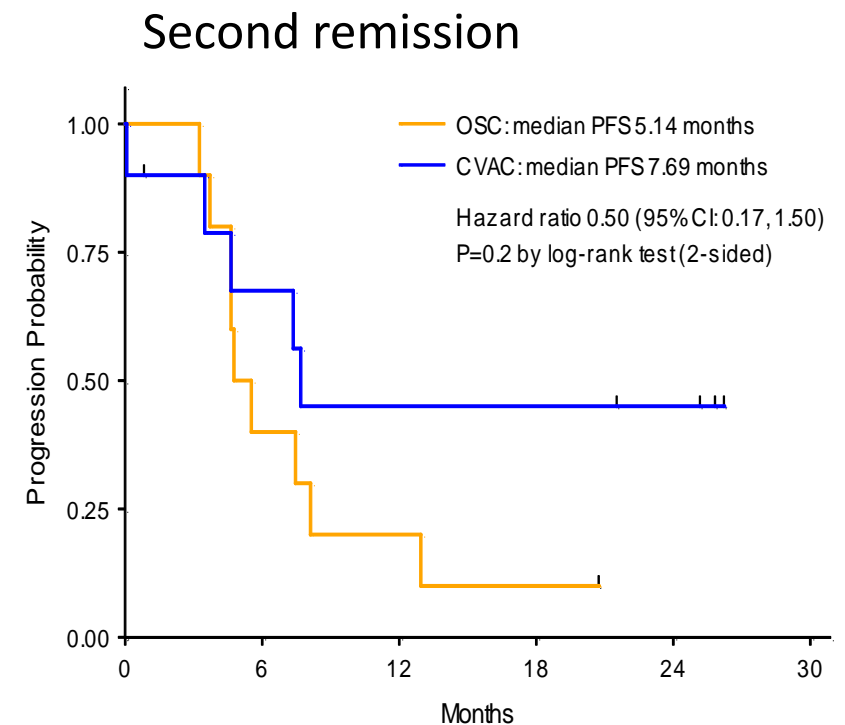
Kaplan-Meier Estimates of Progression-free Survival by Randomization Strata (ITT)

➔ *While not statistically significant, different PFS trends were observed in first remission as compared to second remission*



OSC	3/17	3/12	0/9	1/9	0/0
CVAC	5/19	5/14	2/9	2/7	1/2

(#events/#at risk)



OSC	6/10	2/4	1/2	0/1	0/0
CVAC	3/10	2/6	0/4	0/4	0/3

(#events/#at risk)

Overall Survival

⇒ ***OS data is immature; observation will continue***

- ***As of September 9, 2013:***
 - 5 patients had withdrawn consent => 58 patients
 - 8 have been confirmed as deceased
 - (4 CVac / 4 SOC)
 - 48 have been confirmed as alive
 - (28 CVac / 20 SOC)
 - 2 are unknown

CAN-003 Conclusions

- Multinational manufacture and distribution of CVac, an autologous-DC therapy, was feasible
- CVac was very well tolerated & induces cellular immune activity
- Similar to many recent trials of immunotherapy for solid cancer, there appears to be no clinically significant effect of CVac on PFS
- It will be important to observe signals in Overall Survival to assess the potential clinical benefit of CVac

Development implications

- CAN-003 trial extended to monitor patients for Overall Survival data (approximately end of 2014)
- Recruitment of new patients on CANVAS (CAN-004) on hold – re-start pending:
 - Review endpoints (immunological and clinical)
 - Review patient numbers
 - Agreement to revised trial design with regulators
- Prima to review designs and patient numbers of new phase 2 clinical trials prior to commencement
- Significant reduction in expenses going forward – updated financial guidance after next quarterly report