

# INVESTOR UPDATE

by  **PRIMA BIOMED**

**SPECIAL EDITION**  
JUNE 2014 - ASCO

## Prima BioMed Data Highlighted at 50<sup>TH</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO)

In addition to its regular shareholder newsletters, from time to time Prima BioMed provides special editions such as this one to keep shareholders informed about important Company developments.

In this special edition we include a Q&A with Dr Heidi Gray, the lead investigator of Prima's CAN-003 randomized trial and the presenting author of the CAN-003 data at The American Society of Clinical Oncology's Annual Meeting (ASCO) being held in Chicago from 30 May to 3 June 2014.

Dr Gray's oral presentation, titled "Progression-free survival in ovarian cancer patients in second remission is improved with mucin 1-autologous dendritic cell therapy" highlights the key findings from the data including compelling final progression free survival (PFS) and interim overall survival (OS) data.

### About ASCO

The American Society of Clinical Oncology (ASCO) is one of the world's largest annual scientific events in oncology. The best and the latest global oncology research is presented at the conference to an audience of more than 25,000 professionals, who this year gathered in Chicago for its 50th Annual Meeting.

The ASCO 2014 meeting highlighted exciting advances in the field of immuno-oncology (I-O). Cancer treatments, including products like Prima BioMed's CVac, are garnering increasing interest as we better understand the way that different therapies work and where treatment like CVac may have the greatest benefit. When combined with chemotherapy, surgery, and/or other I-O products, cancer vaccines may have an important role in revitalizing the cellular immune response and re-stimulating the immune system potentially supplementing the efficacy of other treatments. Prima's CAN-003 trial, where CVac is showing promise in patients with recurrent cancer, is an important milestone.

### Q&A with Dr. Heidi Gray

We are pleased to introduce Dr. Heidi Gray, the lead investigator of Prima's CAN-003 trial and presenting author of the CAN-003 data at ASCO.



#### Dr Heidi Gray

Dr Gray is Gynecologic Oncologist in the Division of Gynecologic Oncology, Department of Obstetrics and Gynecology at the University of Washington School of Medicine, Seattle. She is also the Affiliate Investigator for the Division of Clinical Research at the Fred Hutchinson Cancer Research Centre in Seattle. Her expertise is in clinical trial design, execution and interpretation in gynecologic cancers.

**Dr. Gray shares some of her thoughts on the CAN-003 clinical trial and its interim and final data.**

**Dr. Gray, can you summarize what CAN-003 was about?**

*The CAN-003 trial was a 63-patient randomized open label phase 2 trial of CVac as a maintenance treatment of ovarian cancer patients after successful first- or second-remission.*

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## Q&A with Dr. Heidi Gray

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*The trial evaluated the safety of CVac, the immune responses generated by CVac as a surrogate for the mechanism of how CVac works, as well as the progression-free survival, that is the disease free interval as well as the overall survival outcomes of the patients. Based on the results of CAN-003, Prima has been able to refine its development strategy and target ongoing clinical trials in the patient population that demonstrated the greatest potential benefits from CVac treatment.*

### **And what are the key findings from this trial?**

*The study showed that CVac is very well tolerated – a topic which is often underestimated but very important for the quality of the patients life - and that CVac induces a cytotoxic or killer T cell response that is specific to mucin 1, which is the “marker” on ovarian cancer cells we target with CVac treatment.*

*As for progression-free survival (PFS), which is the period of time until a patient’s cancer comes back, there were some interesting results. For patients in first remission, there was no difference observed between CVac treated patients and the control group. However, there was a very compelling signal in the second remission patient population, i.e. patients that have been treated, regressed and have been treated again to get into remission. The median PFS time for CVac treated patients in this group was more than 12.9 months versus about 5 months for the control group. The caution is that this part of the study was in only 20 patients, a very small group but are nonetheless very encouraging and I feel worth exploring in a larger trial as is being planned. However, a more than doubling of the PFS is very intriguing and exciting for the ovarian cancer community. If confirmed, this is definitely clinically meaningful and fulfills an important unmet medical need.*

*Regarding overall survival (OS) of patients, i.e. the period of time before they pass away, it’s still too early to make a final analysis, especially with the first remission patients who have a median overall survival of 60 months. But with the second remission patients, we are seeing already a signal that the PFS advantage we have seen seems to translate into a potential overall survival advantage. In the second remission patient population, the median overall survival of the control group was about 26 months, which is exactly as we would expect for this group of patients based on numerous other industry trials. However, the CVac treated group on the whole, is surviving for much longer. After 30 months of observation, we are not even close to a median survival estimate, which requires half of the patients to have passed away.*

### **How does this data compare to your expectations going into the trial?**

*While it is important to point out that the CAN-003 trial included a relatively small number of patients second remission patients, it is fair to say that the data we are seeing in this population has exceeded our expectations. I fully share Prima’s conclusion from the trial*

*that CVac is certainly worthy of further investigation and its focus is now on seeing if it can confirm these results in a larger patient population, thus the recent launch of its new 210-patient trial. This trial is already open to patient enrolment in Europe and is generating much enthusiasm around the world.*

### **Why do you think there is such a difference in the CAN-003 data between the first and second remission patients?**

*It is difficult to say definitively why CVac may have a bigger impact in second remission patients. But there are a few potential theories on why this may happen. One suggestion is based on the heterogeneity of first remission patients which can provide a cohort of subjects with a diverse PFS window, while second remission patients are more homogeneous. Alternatively, the second remission group showed immune responses that were above background or baseline and may be indicative of the outcomes, however, the very small sample size makes this difficult to correlate as there is wide variability between patients. Nonetheless, the signal in second remission is intriguing.*

### **With CVac having demonstrated a near three-fold increase in PFS for second remission patients, would you expect that the final OS benefits would be similar?**

*To speculate on what the final data will show is not possible but it is worth noting that most evidence in cancer vaccine trials to date would indicate that products like CVac would have a larger impact on OS than PFS. This is because these products are often intended to have a longer term effect on the immune system that allows the body to control and kill cancer cells over a longer period of time.*

### **When do you expect to reach a median for overall survival in second remission patients?**

*I understand that the patients in the trial may reach a median in the fourth quarter of this calendar year, at which point Prima will announce the further OS data from CAN-003 to the market.*



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## Prima BioMed – Fast Facts

### Listings

Australian Securities Exchange (ASX), NASDAQ,  
Deutsche Börse

### Stock Codes

ASX: PRR, NASDAQ: PBMD,  
Deutsche Börse: ISIN: US74154B2304

### Issued Capital – Ordinary shares

1.23B (approximate as of 30 May 2014)

### Issued ADR's

3.7M (approximate as of 30 April 2014)

### Market Capitalization

A\$66.35M (approximate as of 30 May 2014)

### Cash Position

A\$26.74M (approximate as of 31 March 2014)

## Board of Directors

<b>Ms Lucy Turnbull, AO</b>	Non-executive Chairman
<b>Mr Albert Wong</b>	Non-executive Deputy Chairman
<b>Mr Matthew Lehman</b>	Managing Director and Chief Executive Officer
<b>Dr Russell J Howard</b>	Non-executive Director
<b>Mr Pete A Meyers</b>	Non-executive Director

## Senior Management

<b>Dr Sharron Gargosky</b>	Chief Technical Officer
<b>Mr Marc Voigt</b>	Chief Financial Officer
<b>Ms Deanne Miller</b>	General Counsel and Company Secretary