PRIMA BIOMED MANAGEMENT PRESENTS CVAC™ PHASE 2 TRIAL RESULTS - CALL TRANSCRIPT

Prima BioMed (ASX: PRR; NASDAQ: PBMD; ISIN: US74154B2034)
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James Moses: Investor Relations Representative

Good morning ladies and gentlemen and welcome to Prima BioMed's presentation of the CAN-003 clinical trial analysis. My name is James Moses, Prima's Investor Relations Representative. With me today is Mr Matthew Lehman, the company's Chief Executive Officer, and Dr Sharron Gargosky, Prima's Chief Technical Officer.

Before we begin, I'd like to remind you that during this call, we will make forward looking statements that are subject to risks and uncertainties that may cause actual results to differ from the results discussed in the forward looking statements. Reference to these risks and uncertainties are disclosed in detail in our public announcements to the ASX and our disclosure filings with the US Securities and Exchange Commission.

The CAN-003 protocol is a phase 2 clinical trial of CVac for the treatment of epithelial ovarian cancer patients in remission after successful first or second line therapy.

As you'd be aware, the company announced top line analysis of this trial on September 18 and Dr Jeffery Goh, one of the study's lead investigators, presented the data analysis yesterday at the European Cancer Congress. For those interested, a copy of Dr Goh's presentation will be available via Prima BioMed's website.

Onto our call this morning, and during the call, Dr Gargosky will first present an analysis of the CAN-003 trial and then Mr Lehman will present some of the implications of the data and the forward looking development plans for CVac.

I'll now turn the call over to Dr Sharron Gargosky.

Sharron Gargosky: Chief Technical Officer

Thank you, James. Well hello everyone and thank you for joining us today. As James just mentioned, Dr Goh gave an excellent presentation on this CAN-003 analysis just yesterday in Amsterdam at the European Cancer Congress and I'm really pleased to report that Dr Goh's presentation was very well attended and well received by the leaders in the ovarian cancer space. However, as Dr Goh is currently on a flight back to Australia, I have the pleasure of delivering this summary update to the shareholders on behalf of Dr Goh and the CAN-003 study team.

So I'd like to start with reviewing the key study entry criteria and the design of the study, which is on slide 3. So 63 women were enrolled on the CAN-003 study after having achieved complete remission from first or second line treatment. Prior to joining the trial, all women underwent cytoreductive - or debulking - surgery to remove as much cancer as possible and completed the conventional chemotherapy. These patients were then allowed to enrol within twelve weeks of having achieved complete remission. Now, the first seven patients were not randomised and they received CVac. This was part of the trial and was intended to assess the manufacturing comparability between Australia and the United States manufacturing sites, which was successfully achieved.

After the first seven patients, 56 were then randomised to either receive CVac or to the standard of care, or control, group. The CVac group received ten doses of CVac over a 56 week period and each dose of CVac contains about 60 million dendritic cells that have been primed or treated with the mucin 1 antigen. The control group didn't receive any active treatment and was basically an observational control group. Observation, as many of you know, is the current standard of care for most women in remission with ovarian cancer.

So, in total, 43 patients who joined the study were in first remission and 20 were in second remission.

The CVac dosing started within ten weeks of enrolment into the trial and the trial specified monitoring patients until the disease progressed or for two years. So this progression was defined individually by each investigator based on their patients' CA-125 values and radiological evaluations. Progression-free survival

is defined as each patient's time interval between the time they were randomised and entered the study to the date that the disease progressed or death.

The two primary clinical objectives of this trial were to assess the safety profile of CVac and to assess CVac's impact on progression-free survival. The secondary clinical objectives of the trial were to assess CVac's impact on overall survival of the patients and to evaluate the immunological or immune responses to the CVac treatment.

Now when we look at safety evaluations in these trials, we use the data of all 63 patients, and that's referred to as the "safety population". But when we look at efficacy end points, we use the "intent-to-treat population, or sometimes referred to as the "ITT population". The ITT population includes all 56 patients who were randomised regardless of how long they stayed on the trial, but does exclude the seven non-randomised patients.

Now in terms of statistical powering and plans for the CAN-003 trial, this trial was not necessarily powered to detect a statistically significant difference in the progression-free survival. As is very common in phase 2 trials, however, the sample size was considered adequate on clinical grounds to assess the rates of disease progression, trends in immunological outcome, and potential disease markers and other clinical outcomes. And the purpose of such data is then to assist with the planning of the future studies.

If we move onto slide 4, in summary we were able to make the following conclusions from the CAN-003 trial data to date. On the safety objective, CVac was well tolerated and non-toxic. In terms of immune activity, CVac induced a Mucin-1 specific T-cell response and CVac did not induce an antibody response. On the progression-free survival or PFS objective, there were no statistical significant differences observed in PFS. We did, however, observe divergent trends between first and second line remission groups. And regarding the overall survival, eight patients have been confirmed to decease to date and we'll continue to monitor the overall survival signals in the trial.

I'd like to now go on and discuss a little bit more of each objective in detail. If we move onto slide 6, we'll start discussing the serious adverse events. There were ten adverse events in the past three years or more. Nine of these were "definitely not related" to study treatment and one SAE was considered to be "unlikely related" to the study treatment. One serious adverse event, SAE, resulted in death, but that SAE was

considered “definitely not related” to the study agent treatment. When looking at AEs on slide 7, or adverse events, the most common adverse events were defined as related to the CVac treatment, but included symptoms at the injection site such as localised pain, erythema, redness, swelling, burning and some broader symptoms of fatigue, lethargy and dizziness, but the majority of such events were mild and resolved within one day. There were few severe adverse events that we saw and only one that lasted longer than a day and that was a bunion considered “unlikely related” to CVac. Two severe events were classified as “probably related” or “possibly related” to CVac and those were widespread itch and headache. So, in general, from the CAN-003 data, we can conclude that CVac therapy is well tolerated and non-toxic.

Moving onto the immune monitoring analysis on slide 8. First, we looked at mucin 1 antibody responses in patients. Now, with cell-based therapies like CVac, we do not expect to see any antibodies developing in patients against mucin 1. And we were very pleased to see that when we measured this, we saw very low or undetectable levels of antibody. So these antibodies were not generated against the CVac treatment. Only a couple of patients showed detectable antibodies to mucin 1 and those patients were actually in the observational control group and not actually part of the CVac group. So we wanted to see with therapies like CVac what the potent T cell response would be, especially with respect to the CD8 and CD4 T cells. And in slide 9 we have a summary of each patient’s best immune response to the CVac treatment. And you can see that CVac induces a broad activity in the T cells. Most specifically, this chart summarises the T cell responses in CVac patients in either first or second complete remission. This is noted as CR-1, for complete remission 1, and CR-2, for complete remission 2.

We also looked at these patients combined as a group and that represents the CR-1 plus CR-2 line in this chart. It is then summarised that in here the statistical significance of the activity of each cytokine for each T cell type. One star represents a statistical significance at a p-value of less than 0.1 and two stars indicate a statistically significant response at a p-value of .05.

Additional work is ongoing at Prima to further investigate this immune response, but we’re very pleased to see this really strong good type of immunological activity with the important T cell types of CD4 and CD8

and their respective cytokine expression. And we believe that this type of T cell activity can yield positive clinical outcomes for our patients.

The next point we review is progression-free survival on slide 10. Now, what you can see here is the so-called Kaplan-Meier Estimate of progression-free survival for those 56 patients who were randomised in the ITT population. This graph estimates the percentage of patients who had not yet progressed at the continuous points in time. For example, you see that at about six months after randomisation, there's a slightly higher percentage of CVac patients - that is the blue line - that had not progressed compared to the observational arm. You also see a separation around the twelve month mark where again the blue line is a little above the observational line. But, however, when you look at the overall graph we did not observe a trend that indicates a difference in the progression-free survival between CVac and observational standard of care.

When you look at the same Kaplan-Meier estimates separately for the patients in first and second line remission, you'll see in slide 11 that there is a trend that would indicate that the observational group did better than the CVac group in first remission. And in second remission, the trend would indicate that the CVac patients did better than the observational group. However, we would caution that these are relatively small numbers of patients and that neither of these trends are considered statistically significant.

So finally moving on to the overall survival data in slide 12. As of mid-September, five patients had withdrawn their consent to participate in the CAN-003 study. We're monitoring the 58 remaining patients for longer term to collect their overall survival data. And currently, in the CVac group, four patients have deceased and 28 are confirmed alive. In the observational group, four patients have deceased and 20 are confirmed alive. There are two patients whose status has not been confirmed as of September, but we will continue to observe these patients and collect overall survival data.

With that now, I would like to turn the presentation over to Matt and he can review some of the conclusions and implications of our CAN-003 data analysis. Thanks Matt.

Matthew Lehman: Chief Executive Officer

Well, thank you Sharron, and thanks for that nice overview. So as we look here at slide 13 on the slide deck that was presented previously, we'll start here with some important conclusions that we can draw from the CAN-003 protocol analysis.

First, we are very pleased to have demonstrated the ability to transfer manufacturing technology and produce a comparable product in multiple manufacturing facilities. We do strongly believe that this capability is quite unique to Prima and it is important for the future commercial success of products like CVac.

Second, we are also very pleased to confirm that CVac is well tolerated and that it does induce the right type of cellular immune response in patients. This indicates to us that we have a promising product as we continue in development.

Similar to recent findings with a number of other cancer immunotherapies, we are not seeing a clinically meaningful trend on the progression-free survival endpoint. Our hypothesis, and the reason for choosing PFS as an endpoint in our CVac clinical trials, was because ovarian cancer patients do have a somewhat longer period in remission than a number of other cancer types - for example metastatic prostate or metastatic melanoma. So we believed, or our hypothesis was, that there would be enough time for a full course of 56 weeks of CVac dosing to have an observable effect on the PFS endpoint. But based on the data we have, and looking at data from other trials in cancer immune therapy that have reported since CAN-003 started three years ago in 2010, it certainly does not appear to be the case that CVac will have an important or clinically significant effect on PFS.

There is a lot of interesting scientific debate about why cancer immunotherapies may not have much impact on the time to progression or time to recurrence or progression-free survival. They're all similar measures of endpoints on these clinical trials. Paraphrasing, and I'll paraphrase here, and this is a recent article, it is in the July 2013 issue of *Nature Reviews Drug Discovery*. So, it says in there, "Drug developers have learned the hard way during the development of immunotherapies that it takes time to prime T cells to attack. Immunotherapies, as a result, take longer to induce an effect than do cytotoxic and targeted agents. Moreover, if new tumours developed during this lifetime, a patient will be classified as a

progressor under traditional trial guidelines even if she later has a complete and durable response. Such "failures" undermine the ability of trials to demonstrate efficacy."

Again, continuing on from this article, "Investigators are moving towards adopting more flexible immune-related response criteria that may account for these responders. But according to Gary Gilliland, Merck's Oncology Franchise Head, when it comes to regulatory approval, the old RECIST - the response evaluation criteria in solid tumours - these RECIST criteria remain the accepted benchmark."

Dr Gilliland is quoted as saying, and we at Prima also agree, that we need to obtain better alignment with regulators around which of those criteria are most appropriate.

I do very much encourage our listeners here to our presentation today to read more about the practical issues involving trial design of cancer immunotherapies. There are really a number of good resources on the web. We here at Prima, we will also be updating our website and we'll be including a section for more background research to be able to research cancer immunotherapy.

Certainly, it will be very important for us to continue observation of clinical signals based on overall survival data. We will continue with immune monitoring work on our upcoming CVac trials and there have been some very interesting new technologies developed even in the past couple of years that may give us even better immune signals than the intracellular cytokine staining we performed on CAN-003.

Nonetheless, the most important clinical outcome will be overall survival and that will likely be the endpoint reviewed by doctors and regulators for potential future approval and uptake by physicians of products like CVac.

So moving forward and looking at the last slide on the deck, these CAN-003 data analysis conclusions do have some important implications to our clinical development and business strategy. So number one, we will continue the CAN-003 trial to monitor overall survival data. Based on the best available information we have, we may see analysable trends in the OS data at approximately the end of 2014. So I'd say 12-15 months from now.

Number two, we have suspended the enrolment of new patients on the CAN-004 trial, the CANVAS program. We are reviewing the clinical endpoints for that trial, both immunological and survival endpoints, as that trial was initially designed with PFS as the primary endpoint. We are also reviewing the

patient numbers that may give us meaningful information to assess the clinical benefit of CVac and we will work to obtain agreement with various regulators on the updated clinical trial design.

Number three, we are also reviewing the design and the patient numbers for the new phase 2 clinical trials. This may delay the start of the phase 2 program a short time, although we don't see any lengthy delay – maybe a couple of months into early 2014.

With both the ovarian cancer program and the new phase 2 oncology programs, we will keep everyone up-to-date very regularly. We believe we'll be able to confirm the updated clinical trial designs in the next few weeks. However, we expect that the next trials will involve far fewer patients than the 800 patients originally expected for the CANVAS trial.

And importantly, the last major implication is that we expect a very significant reduction in our expenses for the foreseeable future as compared to previous financial guidance we had provided at the end of the last quarter. We will be able to give formal updated financial guidance in conjunction with our updated clinical development plan and after we've released our next quarterly financial report, which is about one month from today.

Well we are a bit disappointed, of course, by the outcome on progression-free survival and the fact that this will increase the time of our clinical trials. Overall, we are very pleased to see the positive activity of CVac on the immune system and the tolerability of the treatment in patients. I am also very pleased with what we have been able to do at Prima on the manufacturing side in reducing the cost and increasing the efficiency of producing CVac and products like CVac. We remain very confident of CVac as a therapy that will help cancer patients and we are dedicated to conducting the best quality research program to establish that benefit.

In concluding our presentation today, I would very much like to thank the 63 women who have participated on the CAN-003 trial and their families for their support and the time and the dedication they have put into this important research study. I would also very much like to thank the women who have thus far enrolled on the CAN-004 ,or the CANVAS, trial. I do want to assure these patients and your families we have not abandoned the trial, but you know, we do want to be sure that the study design we

execute is the most appropriate and the information we receive from that at the end is very helpful for everyone involved.

I would also like to thank the 18 physicians throughout Australia and throughout the United States and their research support teams who led the CAN-003 clinical trial.

I would also like to acknowledge the continuing support of the company's investors and many of whom have, you know, invested again into Prima earlier in 2013 with our last share purchase plan. I certainly understand the disappointment with our lower share price in recent times. Nonetheless, as a company, we have all the prerequisites in place to execute a successful and thoughtful clinical development plan. We have a very interesting product and a technology in CVac. We have maintained a strong cash balance at Prima, we have no debt, and we have significant non-dilutive grant support, in particular out of Germany, that will allow us to move the company forward in a productive fashion.

I'll leave you today with a positive outlook - again paraphrasing from the same recent Nature Review article I mentioned earlier. So talking about potential treatment combinations for cancer patients in the future, Dr Drew Pardoll who is the Director of the Cancer Immunology Program at John Hopkins University, he says, "The real excitement lies with cancer vaccines." Again, he says, "Their stock is very low right now, but cancer vaccines are going to come roaring back. We are just beginning to scratch the surface in terms of what we think we can achieve."

So with that, I do look forward to speaking with everyone again and, you know, certainly we have our regular quarterly conference call with analysts and, you know, general questions and answers. That will happen after we release our 4C, our quarterly report, in a few weeks. And then, of course, we have our annual meeting in the middle of November and management will be in attendance there in Sydney and I look forward to an opportunity to meet up with our investors and our shareholders in that context as well.

So I'll leave you with that and thank you and good day.

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