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24 April 2013**

**PRESENTATION AT ANNUAL MEETING OF INTERNATIONAL SOCIETY FOR CELLULAR THERAPY**

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD; ISIN: US74154B2034) ("Prima", the "Company") announced that its Chief Technical Officer, Dr. Sharron Gargosky, will deliver a presentation entitled "Orchestrating Autologous Dendritic Cell Therapy Clinical Trials Across 15 Countries" at 1:45pm (Auckland local time) on April 24, 2013 at the 19<sup>th</sup> annual meeting of the International Society for Cellular Therapy (ISCT) to be held in Auckland, New Zealand.

Dr. Gargosky will discuss orchestrating Prima's CANVAS clinical trial of CVac across multiple clinical sites in 15 countries across the world. She will also provide an update and a review of Prima's accomplishments in the successful implementation of CANVAS manufacturing among the Company's three CVac manufacturing facilities in Australia, the USA, and Germany.

ENDS

**About Prima BioMed**

Prima BioMed is a globally active biotechnology company. As a leader in personalized bio-therapeutic products for cancer, Prima is dedicated to leveraging its current technology and expertise to develop innovative treatment options for patients and to maximize value to shareholders. Prima's lead product is CVac™, an autologous dendritic cell product currently in clinical trials for ovarian cancer patients who are in remission.

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# ***Orchestrating Autologous Dendritic Cell Therapy Clinical Trials Across 15 Countries***



**Dr. Sharron Gargosky**  
**Chief Technical Officer**  
**Prima BioMed**

## **Outline**

1. Background
  1. Introduction Prima BioMed
  2. Ovarian cancer
  3. Mucin 1
  4. Clinical Development Plan
2. CAN-004
  1. Design and Duration
  2. Organogram of systems
  3. CMO
  4. Blood Collection Centers / Clinical Sites / Radiology evaluations
3. CANVAS update and accomplishments

## Orchestrating Autologous Dendritic Cell Therapy Clinical Trials Across 15 Countries

*Why are we discussing clinical trials in a commercialization track session? Clinical trial data dictate final approval and label, thus market, reimbursement and success of uptake.*

- Clinical trial in a given patient population dictates your indication and label
- Clinical data integrity is predicated on vendors, monitors, management and oversight
- eCTD package and collection of data in CDISC compliant and CFR complaint data bases. Integration of data and addressing issues raised by each NCA is key.
- Interface between CMO and CRO is critical in cell therapies – unique to this area
- Final clinical endpoints efficacy dictate your market size and reimbursement
- Safety impacts risk-benefit analysis and reimbursement and label
- KoL in trial will impact market education and uptake

Today I will discuss Prima's learning lessons in cell therapy trials with focus on CANVAS the 1000 patient trial in 15 countries.



## Ovarian Cancer

- Each year **73,000 women** are diagnosed with ovarian cancer in the US, Europe, Australia and Japan. **318,000 women** are diagnosed globally with the disease.
- Since ovarian cancer is generally diagnosed at a late stage, only 20-30% of patients with late stage disease survive beyond 5 years
- ~80% of patients relapse within a year of chemotherapy
- Standard of care is surgery and chemotherapy
- Unmet medical need



## Why Target Mucin 1?

- Mucin 1 is a cell surface glycosylated phosphoprotein
- It is over expressed in a number of different adenocarcinomas

Nasopharyngeal	100%	Lung (NSCLC)	99%
Breast	91%	Renal	84%
Ovarian	83%	SCC HN	82%
Colorectal	81%	Pancreatic	81%
Prostate	79%	Myeloma	73%

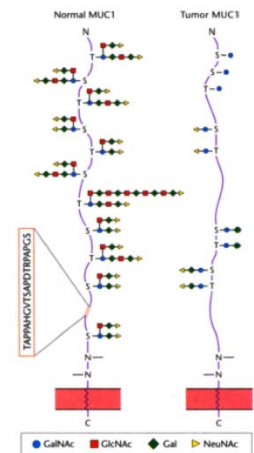
- The mucin 1 found in tumor cells is aberrantly glycosylated compared with normal cell mucin 1

Reference: Am J Clin Pathol 2004;122:61-69



## Mucin 1 immunotherapy

- **Stimulation of the immune system to target and destroy tumors, leaving normal tissue undamaged**
- Mucin 1 selected as the target for immunotherapy
- Up to a **40-fold increase** in the amount of mucin 1 present in cancer cells compared with normal cells
- Alteration in cellular distribution of mucin1 in cancer cells, with mucin 1 being found **ubiquitously throughout the cell** rather than at the secreting pole

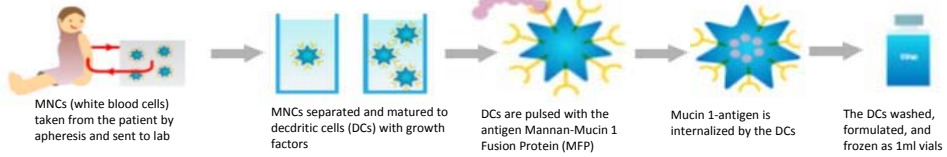


Differences in the structure of the mucin MUC1 expressed by normal and tumor cells. Normal MUC1 (left) has more complex O-linked sugar chains than tumor MUC1 (right), which has simpler (and fewer) sugar chains. The tandem repeat sequence of 20 amino acids is exposed in the under-glycosylated tumor MUC1 but not in normal tissue MUC1.

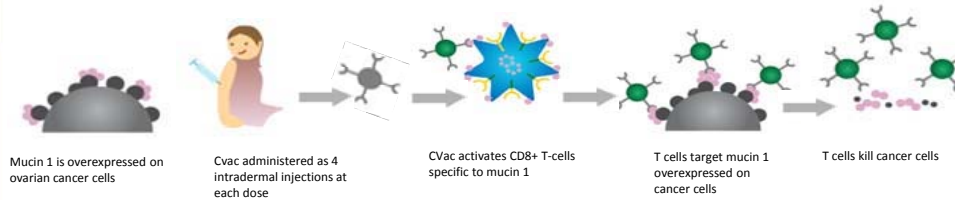


## CVac Overview

### Manufacturing of CVac



### Mechanism after injection



## CVac Clinical Development

Phase	Protocol	Population	Patients
1	CAN-001	Terminal cancer adenocarcinoma (breast, ovarian, fallopian tube, colon, lung, oesophageal)	10 AU
2	CAN-002	Ovarian cancer patients with no further treatment options	28 AU
2	CAN-003	Ovarian cancer patients in remission after 1st or 2nd line therapy	63 AU/ USA
2	CAN-003x	Ovarian cancer patients who have progressed on CAN-003	9 AU/ USA
2/3	CAN-004	Ovarian cancer patients in remission after 1st line surgery and chemotherapy	800 (est)

**CANVAS**



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## CAN-004 / CANVAS

A Randomized, **Double-Blinded**, Placebo-Controlled Trial of CVac as Maintenance Treatment in Patients with Epithelial Ovarian Cancer (EOC) in Complete Remission Following First-Line Chemotherapy

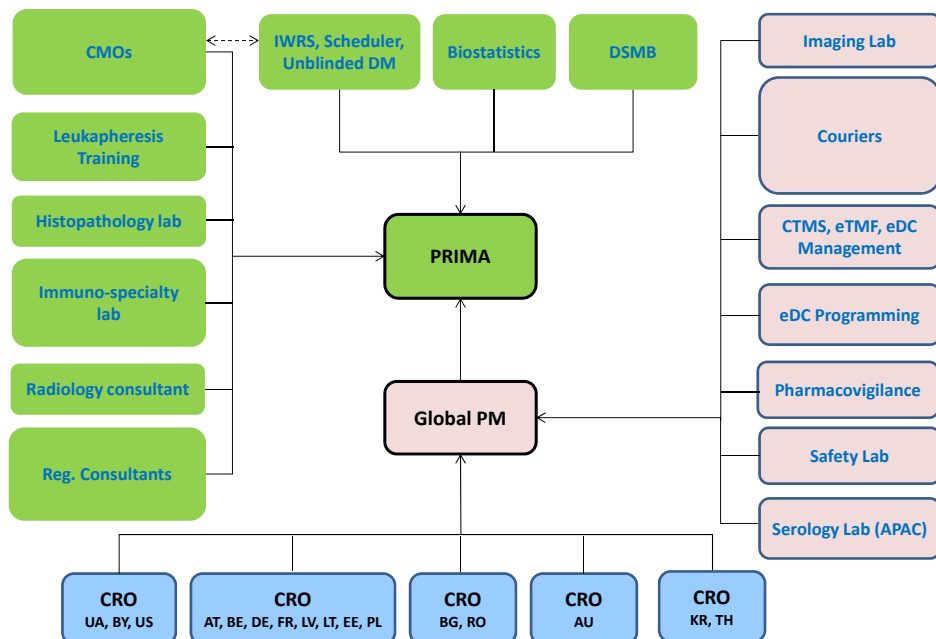


## CAN-004 (CANVAS) Overview

- Stage III/IV epithelial ovarian cancer
- Screening (~1000 pts) after optimal surgery
- 1:1 randomization (CVac:placebo)
- 800 dosed at baseline
- 6 doses in 45 wks
- Goal – compare Progression Free Survival between CVac and Placebo
- Started Q1 2012
- Will include > 100 sites in 20+ countries



## CAN-004 Project Organogram



## Contract Manufacturing Organization (CMO)

- Selection
  - Regional selection of CMO to cover clinical development needs (3 CMOs in AUS, US and EU)
  - CMO were selected after due diligence for Expertise, GMP facilities, Logistics viability, Quality systems
- Training
  - Overseen hands-on training to ensure consistency and harmonization across all sites
  - Full scale development and engineering runs prior to process qualification
  - Full oversight and review of all staff training and training records and of all manufacturing and QC documentation



## Comparability Between CMOs

- Achieved comparability of product manufacturing in three global facilities (Australia, USA, Germany)
- 3 consecutive, successful healthy donor batches were required to be manufactured at each CMO, with frozen CVac shipped and tested at all 3 sites.
- These protocols were accepted by regulators globally
- This has demonstrated our capability to transfer the technology into new facilities and it paves the way for future scale up into larger facilities when needed





## Raw Materials

- Vendor selection process was globally overseen to ensure quality source material
- Country specific import requirements have been met for critical materials
- Scaled up manufacturing of the mucin 1 antigen (M-FP)
- Planning for careful scale up of production capacity from 63-patient trial to nearly 1000-patient trial



## Clinical sites and Leukapheresis Centers

There is a similarity in cellular therapy trials with small drug trials in that clinical sites and blood collection centers require:

Qualification – PSSV clinical sites, Inspections of LU, assessment of qualification

Legal and contracts / Budgets

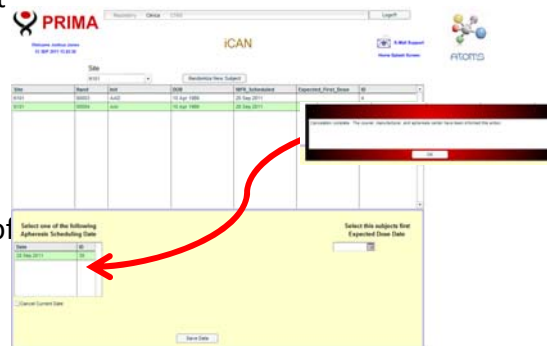
Specific Documentation – certification, CV, delegations, roles and responsibilities

Training – clinical specific, GCP, GMP, equipment specific



## MNC Collection Scheduling

- We have implemented automated logistics management software to coordinate manufacturing facilities, MNC collection centers, hospitals, couriers, our laboratories, and Prima's quality managers around the globe
- The logistics management software also interfaces with the manufacturers to generate country-specific transport and packaging labeling requirements to provide a greater control of sample logistics.



## MNC Packaging and Shipping

- Established a customized packaging system
- Qualified shipping under temperate extremes as well as IATA user profiles
- Managed through shipping logistics and courier airlines regulations for large volume blood product
- Linked interface of many parties through software platform to provide contacts, addressing and labeling logistics
- Managed the global and country specific label requirements
- Established successful cold chain distribution



## Labeling

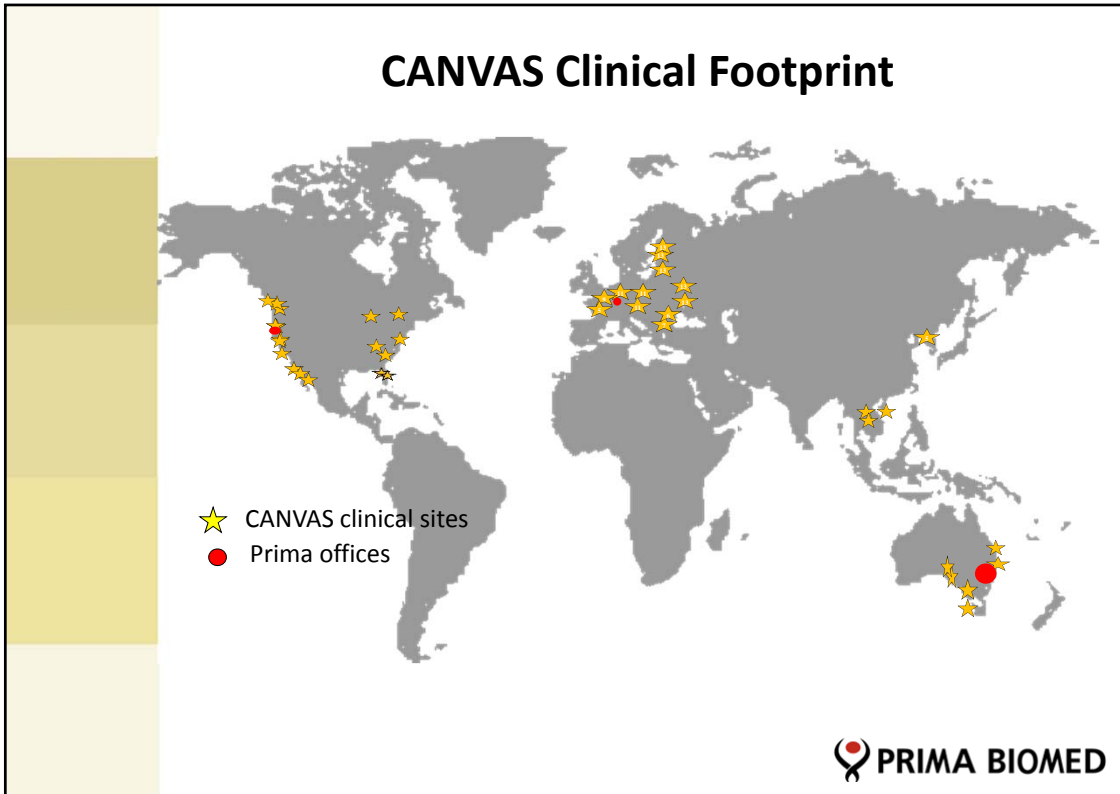
- We have developed region specific labeling controlled through a custom program that interfaces with iCAN system
- Labels are generated from controlled templates on PRIMA provided printer systems for all clinical labels used during MNC collection
- Labels are also integrated into CMO for all MFG and QC testing, final product labeling and product shipments
- Globally accepted in multiple languages



## Final Product Shipping

- Established a customized packaging system for  $\leq -110^{\circ}\text{C}$
- Qualified shipping under temperate extremes
- Linked interface of many parties through software platform to provide contacts, addressing and labeling logistics
- Managed import and customs
- Managed the global and country specific label requirements





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- PRIMA BIOMED

## Accomplishments CAN-004 Mfg

- Globalized Manufacturing capabilities by selecting US CMO
- Established manufacturing comparability between Australia and US CMOs
- Established Multi-center MNC cell collections and Cvac distribution logistics
- Created harmonized batch production and quality control records
- Demonstrated scale out capabilities of Cvac process
- Established courier relationships and proven logistics



## Accomplishments CAN-004 Leukapheresis Units

- To date we have inspected and qualified 41 Leukapheresis units (LU)
- 31 approved and active for collection of MNC product for production of Cvac
- Global documentation has been created to standardize across countries
- A program was established to provide feedback and address any MNC collection issues to the LU while maintaining the trial blind
- We plan for up to 50 cell collection centers in 15 countries integrated into our quality system through CY 2013



## Accomplishments CAN-004

As of April 15

- Approved by regulators in 10 countries (including Australia, Belgium, Bulgaria, Belarus, Germany, Latvia, Lithuania, Poland, Ukraine and the United States)
- 30 clinical centers activated by Prima and allowed to recruit patients
- 43 patients consented to participate; 32 patients have met study criteria and have been randomized
- 7 patients have been dosed



Thank you for your attention

I would be delighted to address  
your questions

