



# Cell Therapy

*A new paradigm for the treatment of disease*

*"If we can understand how the body heals itself, we can accelerate the pace of healing to a clinically acceptable timescale..... this is the reality of today's patient-focused cell-based therapy"*  
*(Pittsburg Gazette, November 2004)*



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# DR GEORGE MIHALY

*Chair, Prima Biomed Scientific Advisory Panel*

**Critical milestones are being achieved**

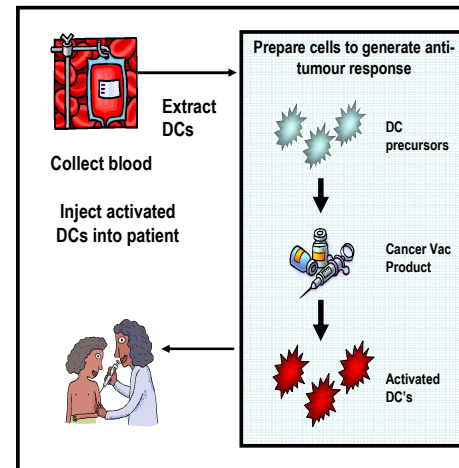
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## Prima's CVac Technology

- Dendritic cell therapy for the treatment of ovarian cancer
- Utilises the patients own dendritic cells, the key line of defence in the immune system
- Targets the tumour protein mucin-1
- After processing, dendritic cells trigger the patient's immune system to recognise and attack mucin-1 on the surface of the tumour

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## Delivery of CVac



- Immature DCs collected from blood by apheresis (1 = 6-12 months of therapy)
- DCs are activated by treatment with CVac in the lab
- DCs are injected into the skin of upper arm or thigh at multiple sites, a total of 7 times per year

Blood DCs can be stored frozen

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## Clinical Program

- **Phase IIa Trial**
  - Ovarian cancer in 28 patients
  - Austin Health – Principal Investigator, Dr Paul Mitchell
  - Recruitment by 4 leading gynaecological oncologists in Melbourne and others
  - Up to 12 months of treatment
- To determine clinical and immunological activity of CVac in ovarian cancer in an open design study
- **Second analysis of data released in May**
- Full results due December 2006

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## Endpoints of Phase IIa Trial

- **Disease responses**
  - Major – decline in CA125 of  $\geq 50\%$  over 1 month
  - Minor – decline in CA125 of  $< 50\%$  and  $\geq 25\%$  over 1 month
- **Stabilisation**
  - Change in CA125 of  $< 25\%$  over 3 months
- **Immunological response to mucin-1**
  - T cells
  - Antibody
- **Progression-free survival**

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## Second data analysis – Phase IIa

- **Patients recruited had**
  - Progressive disease (rising CA125 levels)
  - No other treatment options
- **4 out of 19 patients analysed demonstrated clinical responses or stabilisations**
- **No safety issues arising**
- **Patients on study to continue to receive therapy**
- **Accelerate planning for pivotal phase III trial comparative trial**

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## MR EUGENE KOPP

*Executive Chairman, Prima Biomed*

**Critical milestones are being achieved**

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## Why Ovarian Cancer?

- 90% of ovarian cancers express MUC-1
- Ovarian cancer is associated with 80% mortality within 5 years of diagnosis
- Current treatments (surgery and chemotherapy) are associated with significant side-effects
- Surrogate marker (CA125) allows monitoring of disease activity

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## Market Size – Ovarian Cancer

Region	Incidence	Prevalence	Mortality
Australia/NZ	1,553	4,072	957
Northern America	25,162	74,444	16,005
US, Europe, Australia, NZ, Japan	73,133*	205,618	47,004

- 'Incidence' – number of new cases diagnosed each year
  - 'Prevalence' – number of women living with ovarian cancer
- Source: Globoscan 2002 database

**\*Women who would benefit from DC therapy**

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## Market Opportunity

- About 80% of women with ovarian cancer have advanced/metastatic (Stage III/IV) disease
- Significant number of patients relapse post 1<sup>st</sup> and 2<sup>nd</sup> line treatment
- Limited chemotherapeutic options and drug resistance are major issues
- Immunotherapeutic treatments focus on improving a patient's immune response to cancer
- Other Immunotherapeutic approaches - antibodies cost patients \$40,000-\$100,000 pa

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## Market Drivers

### **Dendreon - key driver in autologous, ex vivo expanded DC therapy**

- BLA submission to FDA by Dendreon H2 2006
  - Using DCs with recombinant antigen
  - Application in Prostate cancer
- Cell therapy pipeline for ovarian, colorectal and breast cancer at Phase I

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## Competitive Landscape

Drug	Company	Phase I	Phase II	Phase III	Approved
Platin – chemotherapeutic					★
Taxane – chemotherapeutic					★
OvaRex – antibody	Virexx			★	
TELCYTA – chemotherapeutic	Telik			★	
XYOTAX – chemotherapeutic	Cell Therapeutics			★	
OMNITARG – antibody	Roche/Genentech		★		
AVASTIN – anti-angiogenesis	Roche/Genentech		★		
AS1401 – new class	Roche/Antisoma		★		
Ispinesib – new class	Cytokinetics		★		
Phenoxodiol – new class	Novogen		★		
<b>CVAC – cell therapy</b>	<b>PrimaBioMed</b>		★		
MORAb-003 – antibody	Morphotek	★			
APC8024 – dendritic cell therapy	Dendreon	★			

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## Competitive Advantage

- Low toxicity profile
- Boosts rather than suppresses immune system
- Proprietary adjuvant system that generates specific immune response – T cell's
- Delivery to patient requires minimal intervention and hospital/clinic time
- Mucin-1 is highly expressed target – potential broad application to a variety of cancer types

Alternative therapies have major side effects & costly

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## Business Strategy

### **ANZ & Asia**

- Progressing to pivotal Phase III in Australia via ANZGOG
- Marketing and distribution in Australia and New Zealand: local manufacturing via Cell Therapies Pty Ltd
- Extending into Asian territories
- Extending to phase IIa human trial in other indications

### **North America & Europe**

- Biomira commercialisation agreement
  - Assumption: IND pathway for phase II in ovarian cancer

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