# **PRIMA BIOMED** NASDAQ: PBMD, ASX: PRR

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# Prima BioMed

- Prima BioMed is a biotechnology company striving to become a leader in immunotherapeutic products for the treatment of cancer.
- Prima's main pipeline of products is based on the LAG-3 immune control mechanism that play a vital role in the regulation of the T cell immune response.
- Prima BioMed is listed on the Australian Stock
  Exchange and on the NASDAQ Global Market in the US.



### **Recent Developments**

- Aug 2015: Novartis milestone payment announced for IMP701 Phase 1 initiation
- Jul 2015: EMA advice supports initiation of Phase 2b clinical trial in breast cancer with lead product IMP321
- May 2015: Financing with Ridgeback Capital (completed in August)
- May 2015: New IP for lead product IMP321 (covering different combinations; expires 2035)
- Jan 2015: GSK milestone payment received for IMP731 Phase 1 initiation
- Dec 2014: Acquisition of Immutep SA with Lymphocyte Activation Gene 3 (LAG-3) technology with lead product of IMP321



# **Directors & Officers**



Lucy Turnbull, AO, Non-executive Chairman Businesswoman and philanthropist; Boards of the Cancer Institute of NSW and Australian Technology Park

Albert Wong, Non-executive Deputy Chairman Australian investment banker; several directorships





Marc Voigt, Executive Director & Chief Executive Officer 15+ years in leading positions in finance, venture capital and biotech industry

#### Prof. Frederic Triebel, PhD, CSO & CMO/Immutep SA

Clinical haematologist, and PhD in immunology (Paris University) and successfully developed several research programs in immunogenetics and immunotherapy, leading to 144 publications and 16 patents



**Pete A Meyers, Non-executive Director** CFO at TLOG; Previous Co-Head of Global Health Care Banking at Deutsche Bank

#### **Russell J. Howard, PhD, Non-executive Director** Scientist entrepreneur; CEO of Maxygen & Oakbio, positions at NIH, DNAX, Affymax

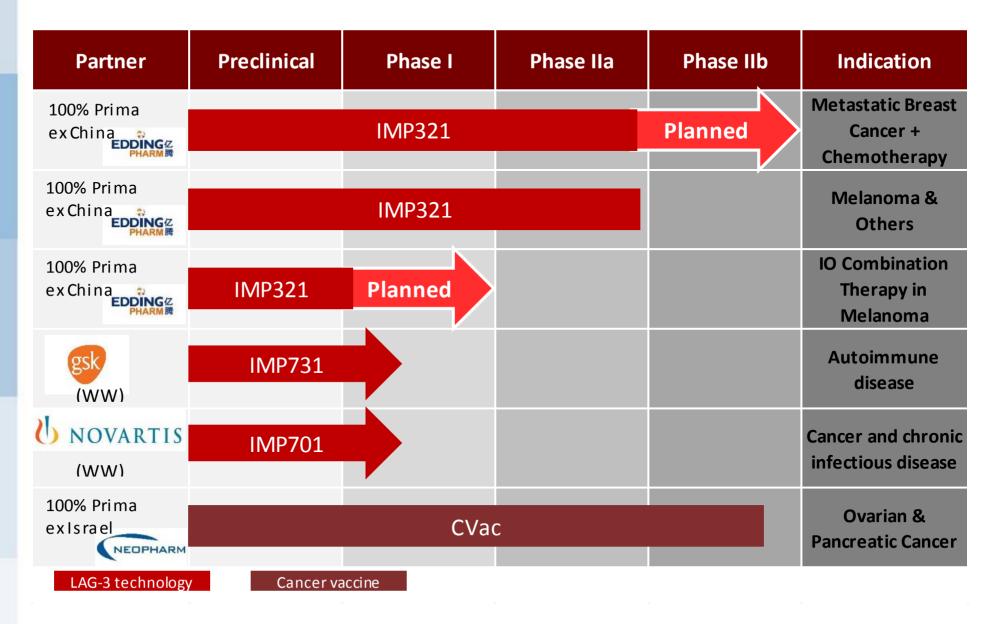


**Deanne Miller, General Counsel & Company Secretary** Lawyer; positions at RBC Investor Services, Westpac, Macquarie and ASIC

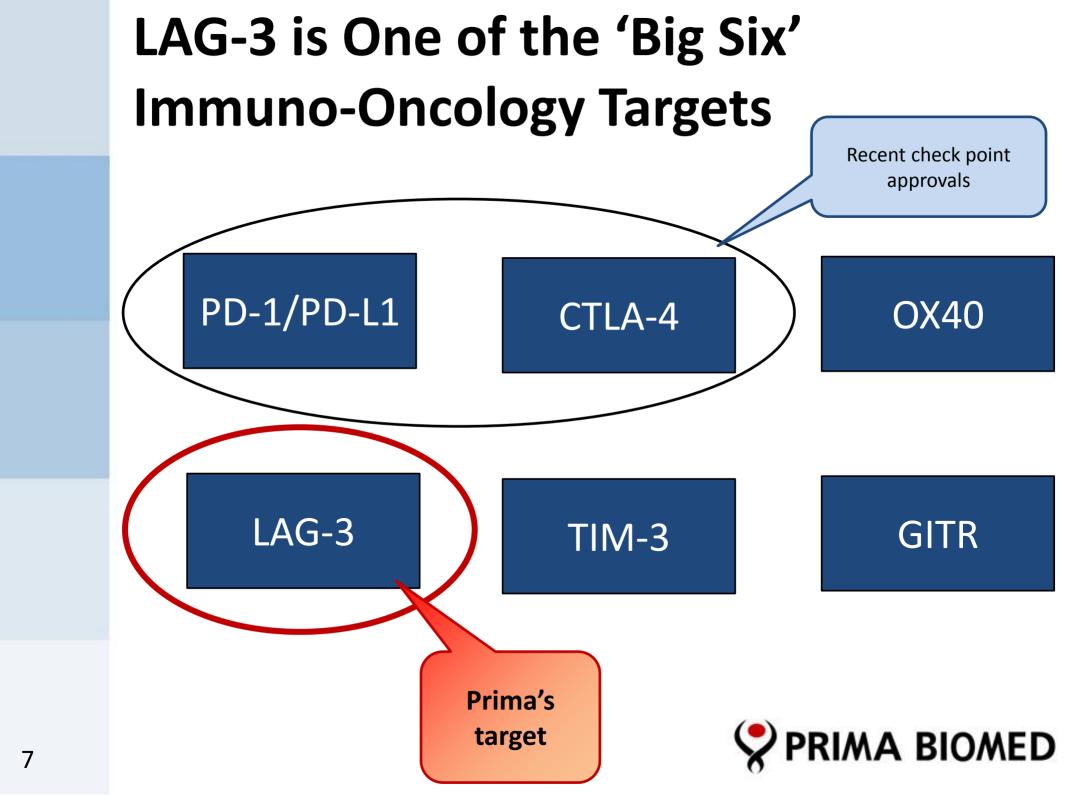




# **Pipeline**

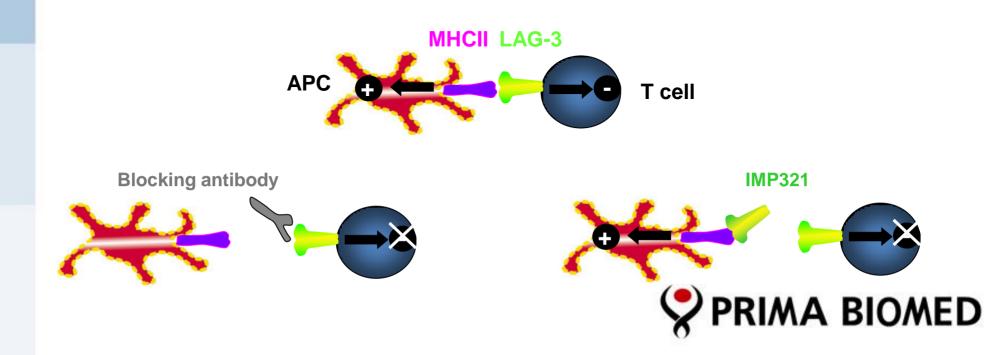




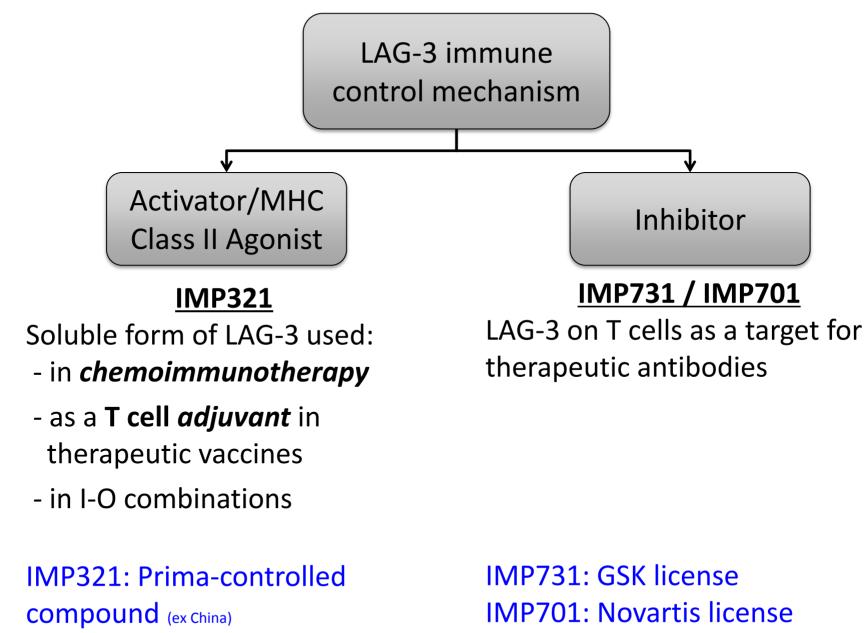


# **Technology: LAG-3 Background**

- LAG-3 is "Lymphocyte Activation Gene-3," involved in the regulation of T cells in immune responses.
- LAG-3 is a checkpoint expressed on activated T-cells (like PD-1). Tumors use mechanisms to bind LAG-3 and inhibit T-cell proliferation, activation and tumor cell killing.
- On APC (antigen presenting cells), LAG-3 is an activator. When used as a soluble protein (IMP321), it activates APCs and this leads to T cell proliferation and activation.

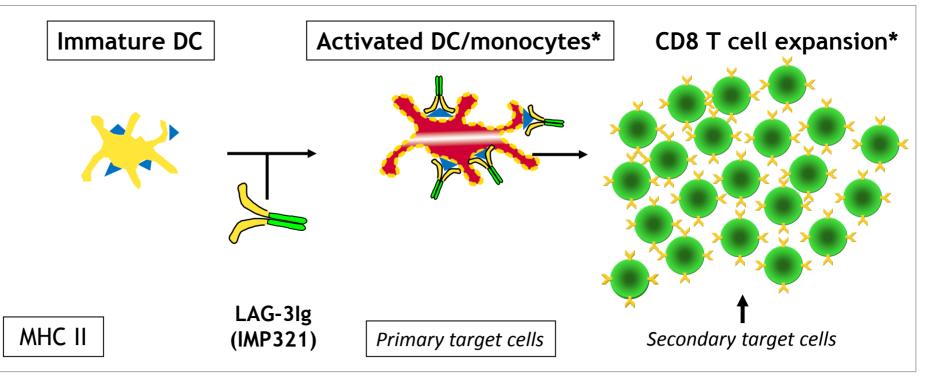


## **Dual Technology Platform**



### IMP321

- Soluble dimeric recombinant form of LAG-3 (fusion protein)
- Antigen presenting cell (APC) activator
- DC/monocyte activation induced, thereafter T cell expansion
- IMP321 may have the same effect as a checkpoint inhibitor by blocking the LAG-3 related inhibition of activated CD8 T cells.



- Highly efficacious in multiple animal models of cancer and infectious disease
- Shown to be safe, non-immunogenic and efficacious in humans
- At low doses can be used as a T cell adjuvant for cancer vaccines (Clin Cancer Res. 2008 Jun 1;14(11):3545-54)



#### **Competitive Landscape: APC Activators**

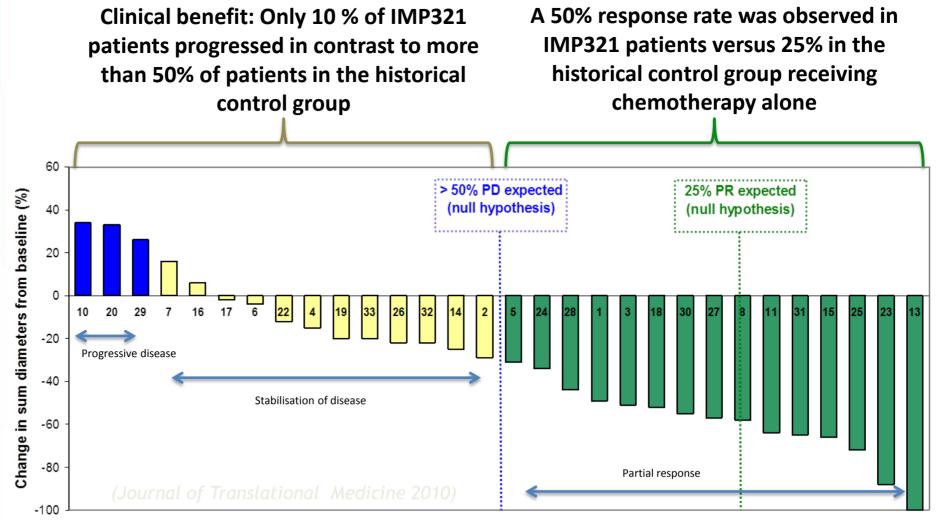
- CD40 / APC In development with anti-PDL 1 antibody by F. Hoffmann-La Roche Ltd
- Toll-Like Receptors
  - Dynavax (DVAX) TLR9 agonist (to be trialed with Keytruda)
  - Immune Design (IMDZ) TLR4 agonist
  - Celgene (CELG) partnered with VentiRx (private) for TLR8 agonist



# IMP321 Phase 2a Data in Metastatic Breast Cancer (MBC)

Compared to the historical control group

(254 patients with measurable disease at baseline on weekly, 3 weeks out of 4, paclitaxel (ECOG 2100 study)\*



Patient number

### IMP321

#### Planned Phase 2b Chemoimmunotherapy in MBC: AIPAC trial

- Multicenter, randomized, double blind, placebo-controlled
- Approx. 200 patients: IMP321 + paclitaxel
  vs. paclitaxel + placebo
- Primary objective: efficacy (as Progression-Free Survival)
- Scientific advice from EMA received
- Trial initiation expected in Q4 2015



### IMP321

#### Planned Phase 1 in Immuno-Oncology Combination

- Multicenter, open label, dose escalation
- Up to 30 patients with unresectable or metastatic melanoma
- Anti-PD-1 + IMP321 combination study
- Primary objective: safety, tolerability
- Trial initiation expected in early 2016





# IMP731 for Autoimmune Diseases

- GlaxoSmithKline holds exclusive worldwide rights to develop LAG-3 depleting antibodies for autoimmune diseases
- GSK's investigational product, GSK2831781, aims to kill the few activated LAG-3+ T cells that are auto-reactive in autoimmune disease leading to long term disease control without generalized immune suppression
- GSK2831781 is currently in Phase 1 clinical trials
- Up to £64m in total upfront and milestones + royalties
  - Jan 2015: Prima announced a single-digit million US dollar milestone for the commencement of GSK's Phase 1 study

# IMP701: Antagonist mAb

- IMP701 is an anti-LAG-3 antibody that blocks LAG-3-mediated immune down-regulation
- Prime target for immune checkpoint blockade as LAG-3 is readily expressed at a high level in many human tumors.
- Aug 2015: Start of Phase 1 study by Novartis
  - Novartis milestone payment to be received for IMP701 Phase 1 initiation
- Novartis holds exclusive rights to develop IMP701



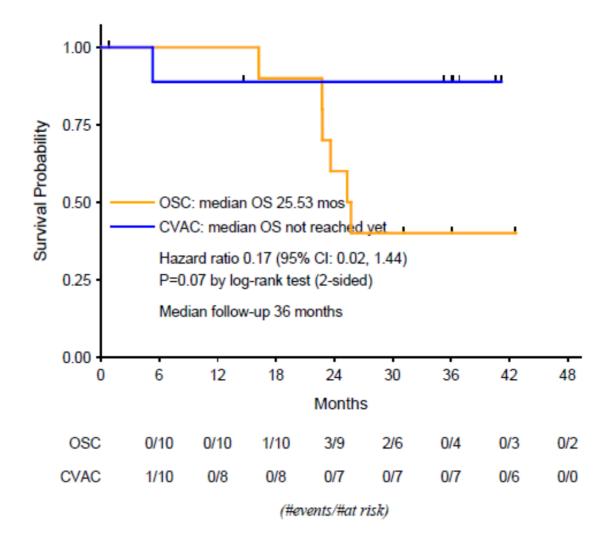
**NOVARTIS** 

# **CVac: Vaccine for Epithelial Cancers**

- CVac is *ex vivo* dendritic cell priming with a mannan + MUC-1 fusion protein
- MUC-1 is cell surface protein overexpressed in epithelial tumors, most notably ovarian and pancreatic (>80%)
- Oxidised mannan as adjuvant is designed to be taken up by dendritic cells
- Very good safety profile
- Phase 2b CAN-003 complete, studied CVac in ovarian cancer
- Seeking partnership for future development



## **Ovarian Cancer Second Remission Overall Survival Results**





Data from CVac CAN-003 protocol Overall Survival 9 Oct 2014

# **Clinical Development Goals**

- Q42015: Initiation of Phase 2b clinical study with IMP321 (metastatic breast cancer)
- Q12016: Initiation of Anti-PD-1 combination Phase 1 study (melanoma)
- Continued development of Phase 1 study with IMP731 (GSK)
- Continued development of Phase 1 study IMP701 (Novartis)



# **Corporate Snapshot**

| Ticker symbol        | PBMD (NASDAQ - ADRs)<br>PRR (Australian Securities Exchange)   |
|----------------------|--|
| Securities on issue* | 1.97 billion ordinary shares<br>77 million listed options @ A\$0.20<br>17.7M issued ADRs (approx. June 2015) |
| Cash & Term Deposits | ~A\$26 million   |
| Market Cap*          | A\$116.5 million (US\$81.6 million)  |
| Avg. Vol. (3 mo)*    | 8,730,000 ordinary shares on ASX<br>2,292,145 ADRs on NASDAQ   |
| Grant Support:       | Australian tax credit (43.5% of eligible R&D spent)<br>French tax credit (30% of eligible R&D spent)         |

\*Market references approximate as of 4<sup>th</sup> Sep 2015





# Thank you!