



**PRIMA BIOMED**

**NASDAQ: PBMD, ASX: PRR**

# Notice: Forward Looking Statements

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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 and autoimmune diseases.
- Prima's main pipeline of products is based on the LAG-3 immune control mechanism that plays 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

Oct.

Presentation "LAG-3Ig (IMP321) in combination with anti-PD-1 therapy" has been accepted for the SITC conference in Maryland, US

Oct.

Abstracts for poster presentation accepted for ESMO Symposium in Lausanne, Nov. 2016

Aug.

European patent grants for IMP731 antibody partnered with GSK

Jul.

New collaborative study investigating the intra-tumoural injection of IMP321 to activate dendritic cells within solid cancer tumors

Jun.

Announcement of first safety, pharmacokinetics and immuno-monitoring data from phase IIb clinical trial of IMP321

May

First patient dosed in the TACTI-mel study

May

Sale and licensing agreement with US-based Sydys Corporation to advance CVac™ program

# 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**

17+ years in leading positions in finance, venture capital and biotech industry

**Prof. Frédéric Triebel, MD PhD, CSO & CMO/Immutep S.A.S.**

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



**Pete A. Meyers, Non-Executive Director**

CFO at Motif BioSciences; 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



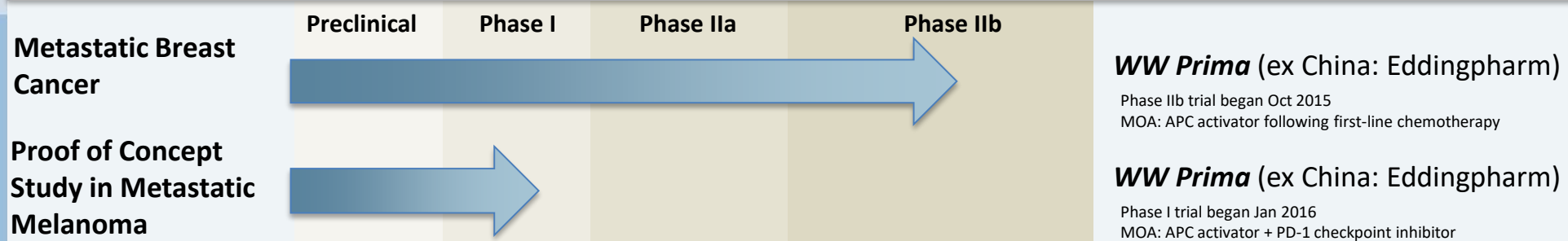
**Deanne Miller, General Counsel & Company Secretary**

Lawyer; positions at RBC Investor Services, Westpac, Macquarie and ASIC

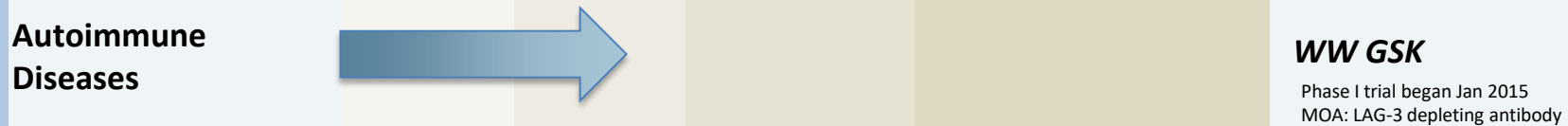
# Pipeline

## LAG-3 Technologies

### IMP321



### IMP731

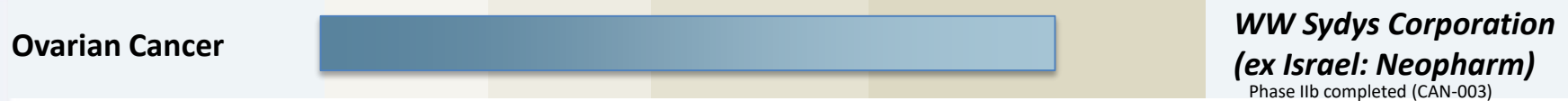


### IMP701



## Autologous Dendritic Cell Therapy

### CVac™

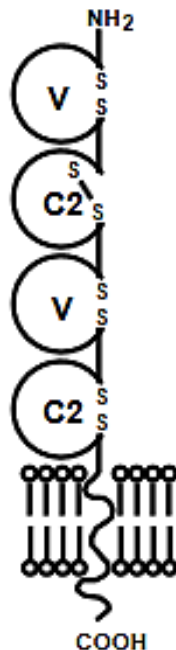


# LAG-3 technology

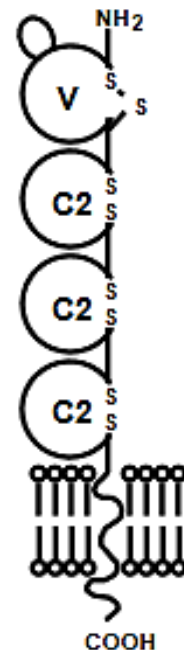


# Lymphocyte Activation Gene-3 (LAG-3 or CD223)

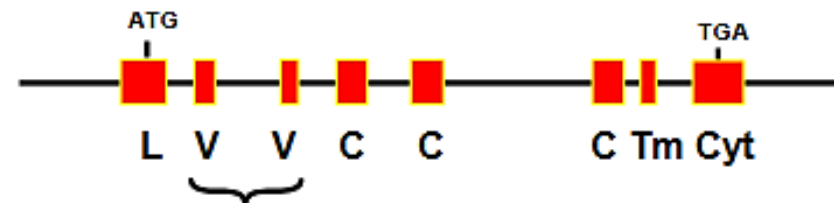
**CD4**



**LAG-3**



**Genomic LAG-3** 1 kb

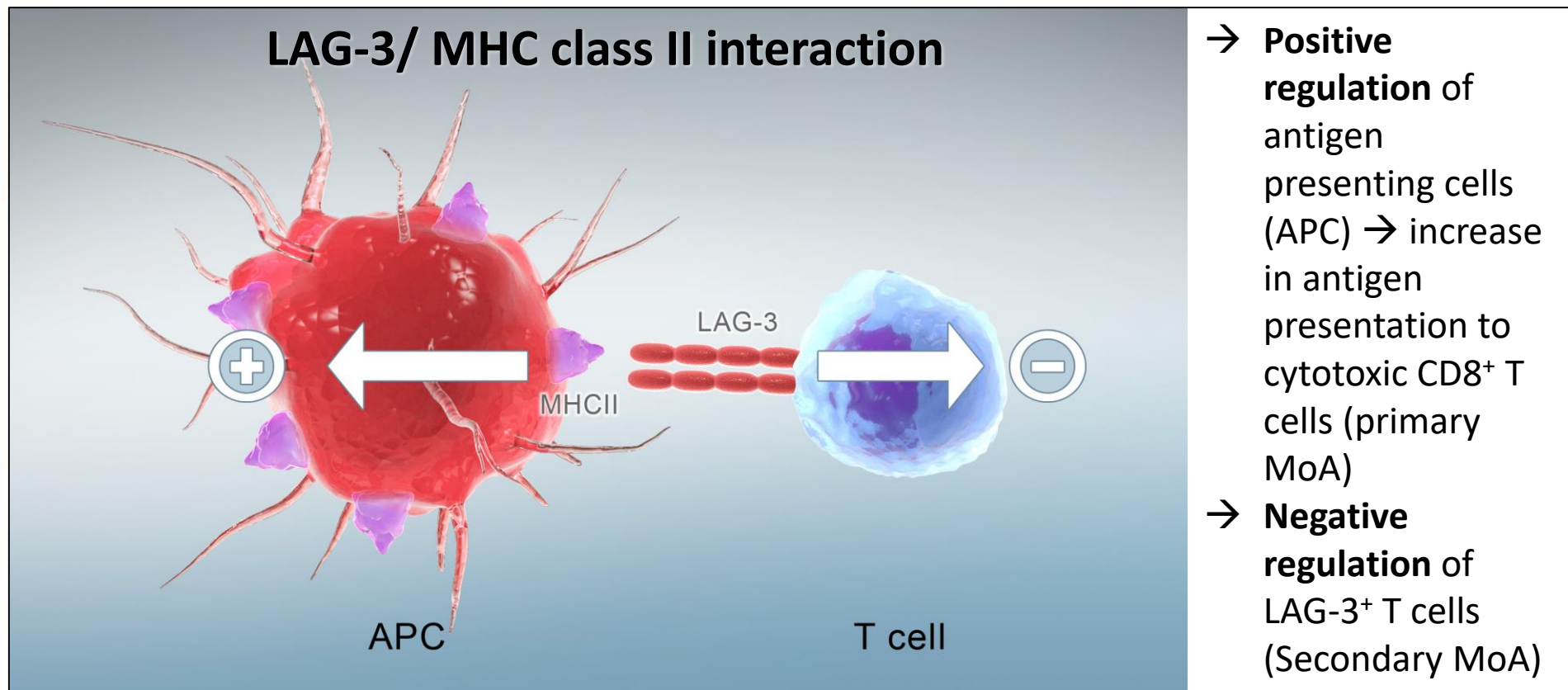


- 4-IgSF domain transmembrane proteins.
- Same genomic organization (intron in D1, duplication event D1D2 vs D3D4)
- Close proximity on 12p13.



# LAG-3 technology

- LAG-3 is widely expressed on tumor infiltrating lymphocytes (TILs) and cytotoxic T cells
  - Prime target for an immune checkpoint blocker (like PD-1)
- Functionally similar to CTLA-4 (targeted by Yervoy®) and PD-1 (Keytruda®)



# LAG-3 is a hot target in I-O

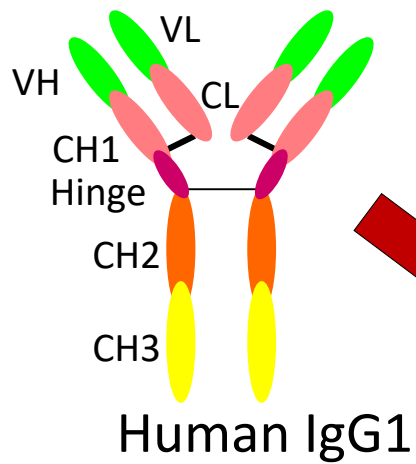
- Prof. Triebel was the first identifying and describing LAG-3 in the 90's, followed by discovery of LAG-3 ligand MHC class II and its importance in the immune system
- Currently 363 publications dealing with LAG-3 are available on pubmed:
  - 102 publications of LAG-3 in immune system
  - 141 publications of LAG-3 in context of I-O
  - 16 publications of promising pre-clinical data on LAG-3 and cancer immunotherapy<sup>1</sup>
- 14 companies developing anti-LAG-3 mAb in pre-clinical & clinical studies (including Prima BioMed and partners)
- LAG-3's potential synergistic function with PD-1 and PD-L1 is very promising<sup>2</sup>:  
*Simultaneous blockade of LAG-3 and PD-1 synergistically enhance T-cell activity and antitumor immunity in mouse models<sup>1</sup>*

1 He Y. et al. Lymphocyte-activation gene-3, an important immune checkpoint in cancer. Cancer Sci. 2016 Sep

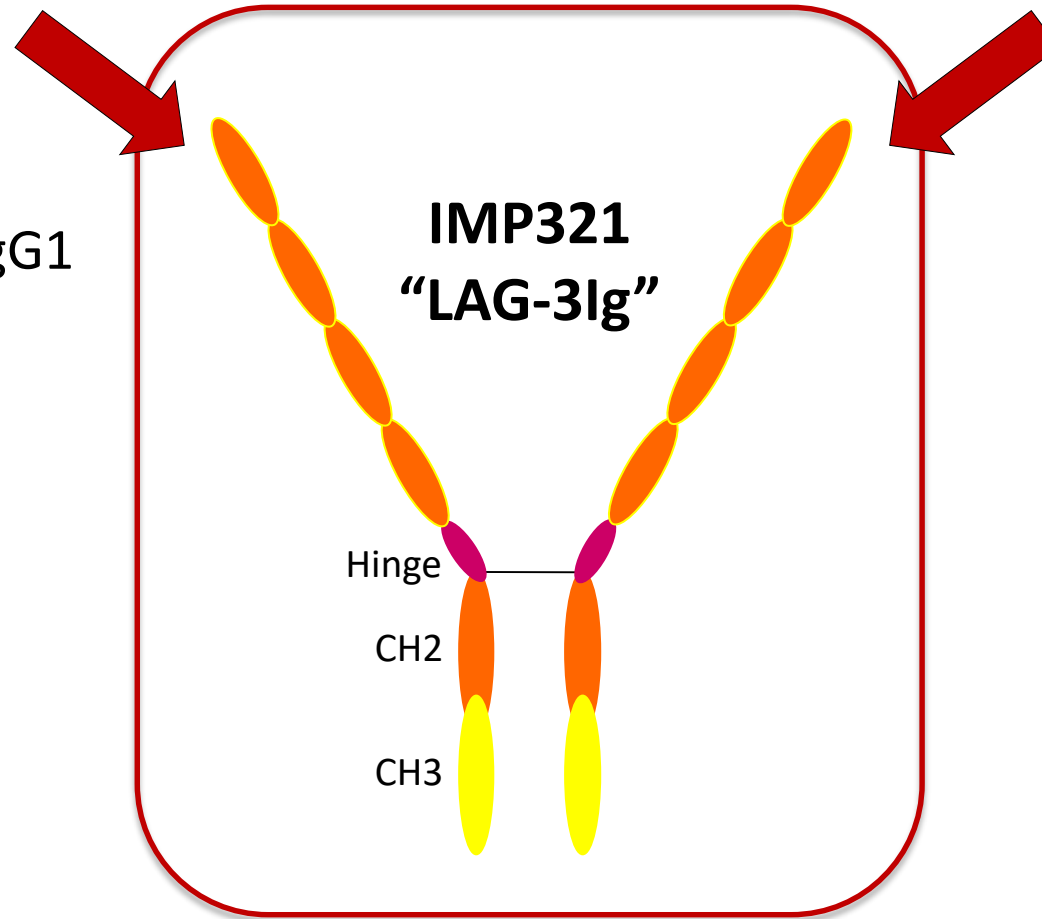
2 Woo et al. Immune inhibitory molecules LAG-3 and PD-1 synergistically regulate T-cell function to promote tumoral immune escape. Cancer Res. 2012

# LEAD PRODUCT IMP321





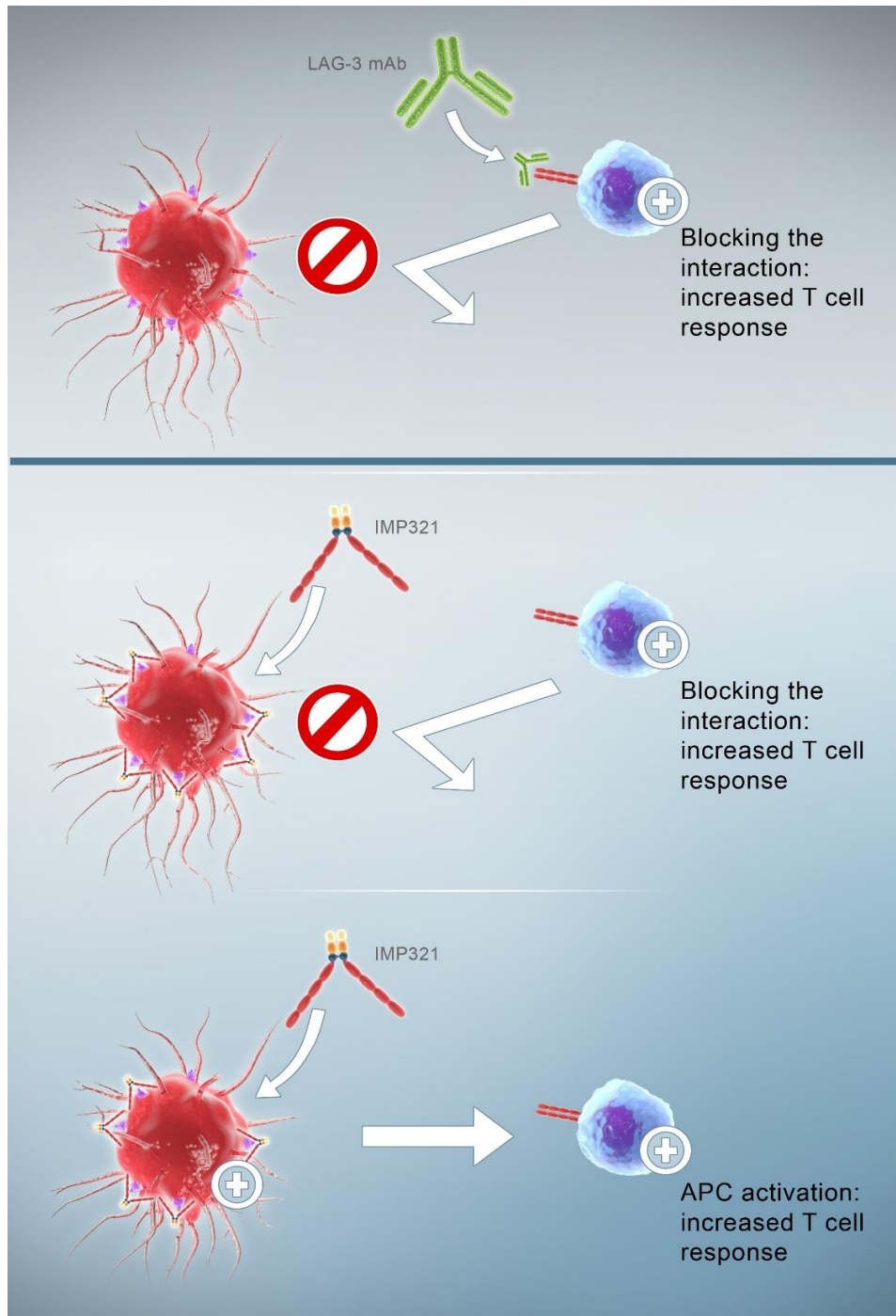
# IMP321



- **Soluble recombinant form of LAG-3**
- Human fusion protein
- Dimeric, very stable, high affinity for DC
- Antigen presenting cell (APC) activator
- Unique and first in class



# MoA of IMP321 in cancer



→ LAG-3 **blocking** mAb:  
immune checkpoint inhibitor

→ LAG-3Ig fusion protein  
(IMP321): **immune checkpoint inhibitor** (Secondary MoA)

→ Binding to LAG-3<sup>+</sup> T cells leads to blocked LAG-3-MHC II interaction and an increased T cell response

→ LAG-3Ig fusion protein  
(IMP321) as **APC activator** (primary MoA)

→ activation of APC network resulting in a boosted and sustained CD8<sup>+</sup> T cell response

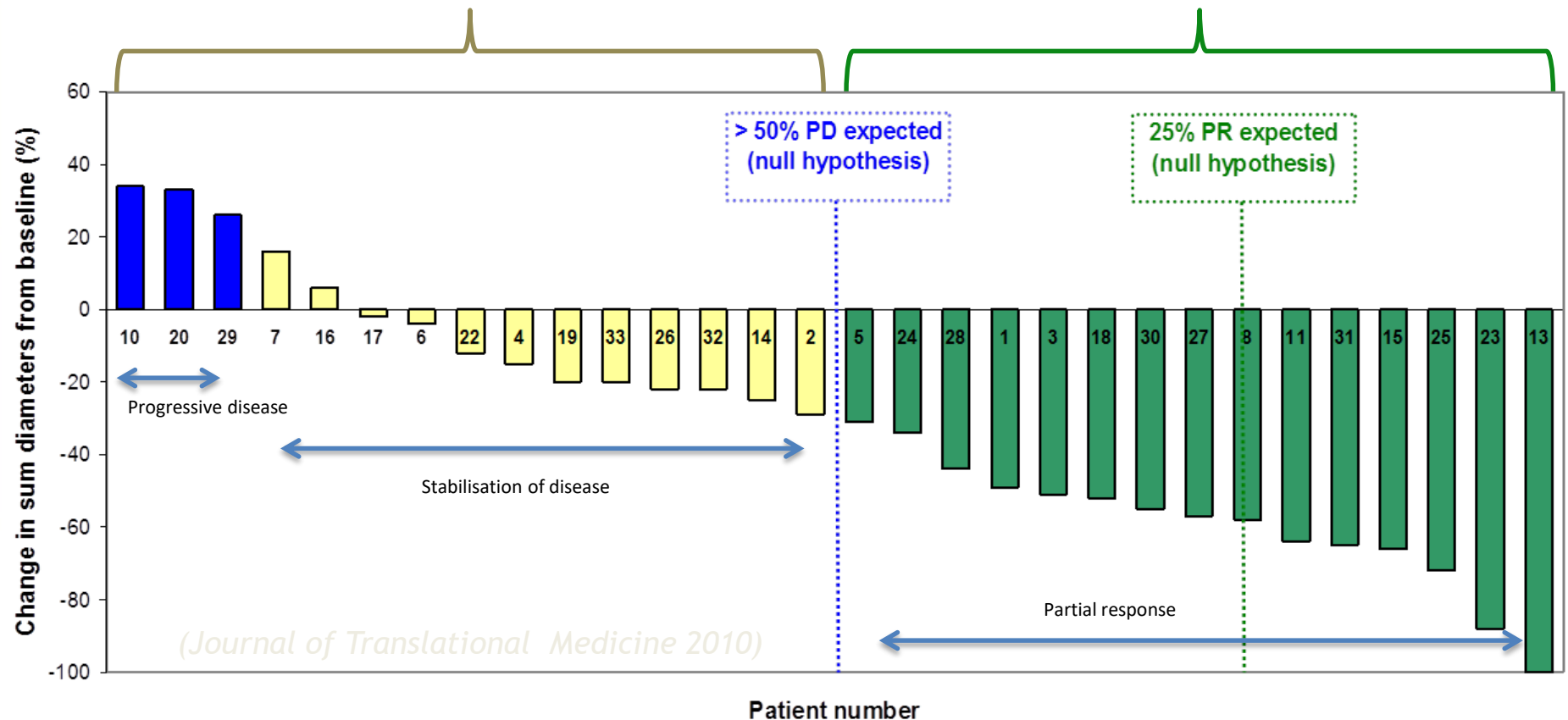
# IMP321 Phase IIa Data in Metastatic Breast Cancer (MBC)

Compared to the historical control group  
(254 patients with measurable disease at baseline on weekly, 3 weeks out of 4, paclitaxel (ECOG 2100 study)\*

Brignone *et al. Journal of Translational Medicine* 2010, 8:71  
<http://www.translational-medicine.com/content/8/1/71>

**Clinical benefit: Only 10 % of IMP321 patients progressed in contrast to more than 50% of patients in the historical control group**

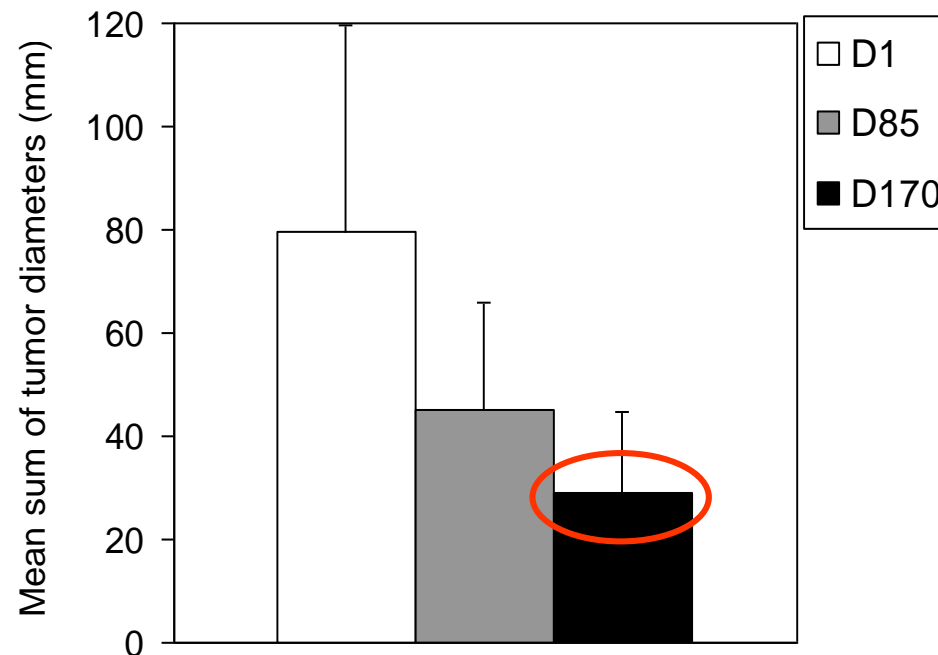
**A 50% response rate was observed in IMP321 patients versus 25% in the historical control group receiving chemotherapy alone**



\*J Clin Oncol. 2009 Oct 20;27(30):4966-72.

# The “Late Response Effect”

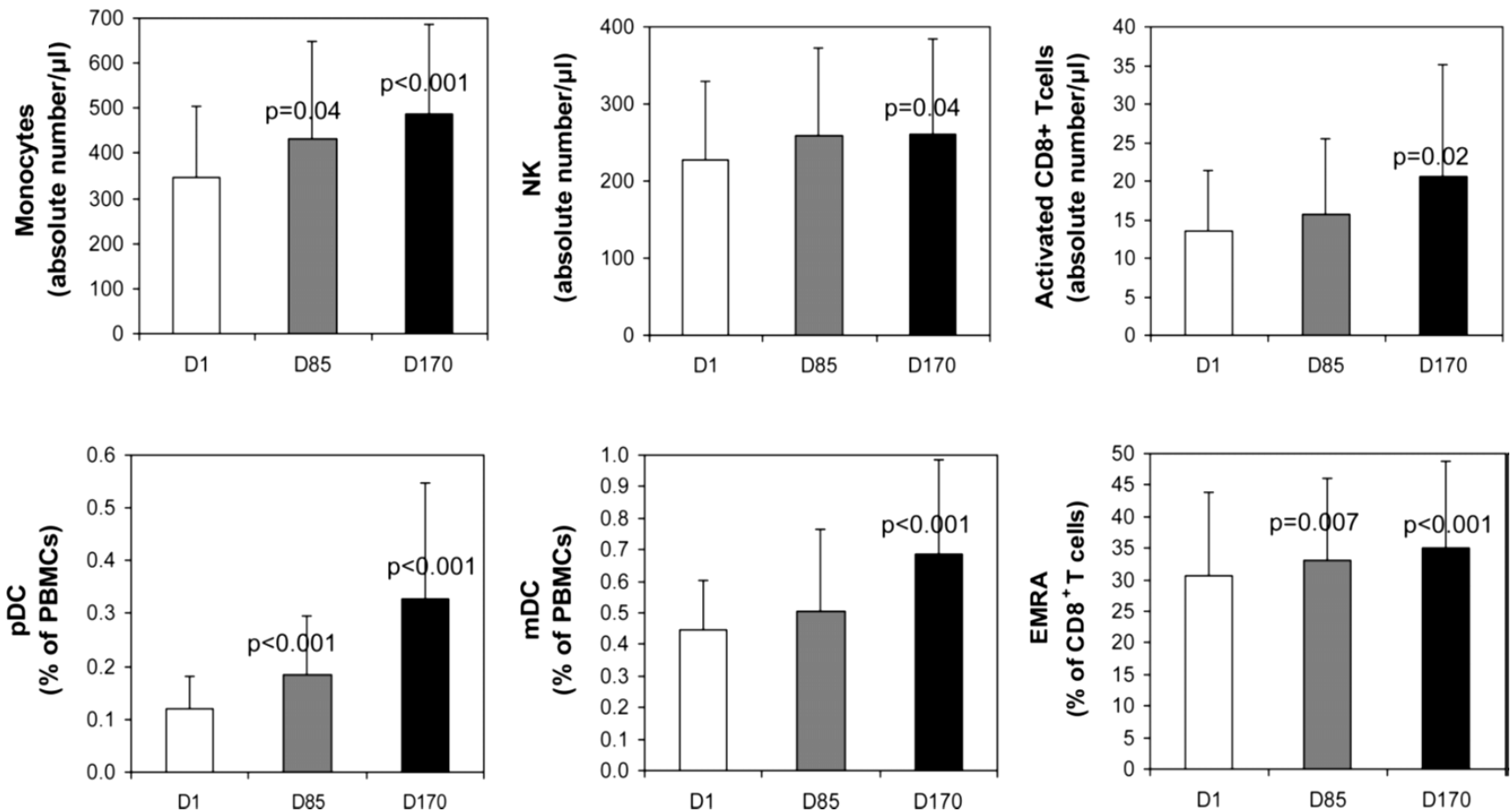
- Clear evidence of immune involvement
- Further tumor regression between day 85 and day 170 which is not seen with chemo alone
  - Such late responses are characteristic of immunotherapy



# Sustained increase in primary and secondary target cells

Brignone *et al. Journal of Translational Medicine* 2010, 8:71  
<http://www.translational-medicine.com/content/8/1/71>

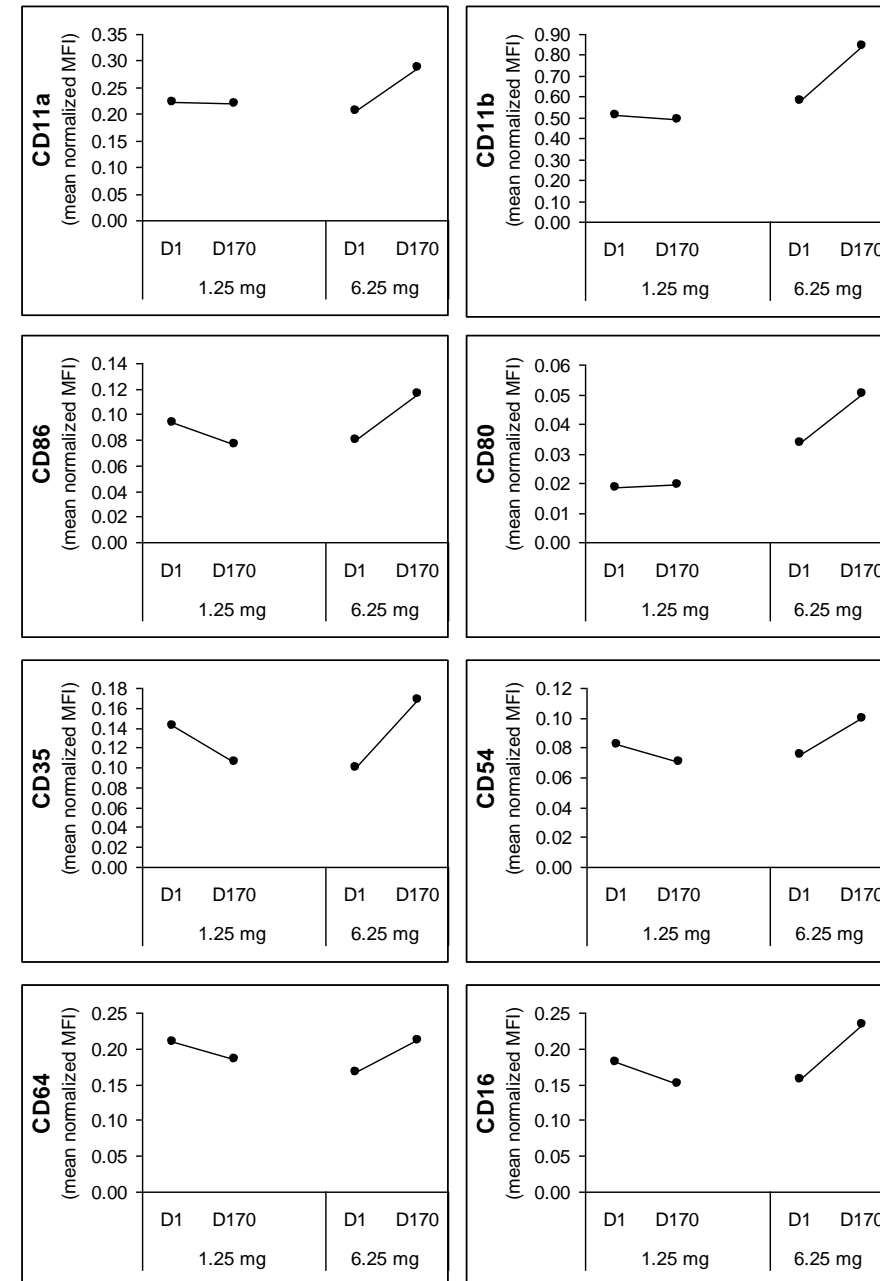
- Increased monocyte, dendritic cell, NK and activated CD8 and memory CD8 T cell counts
- **Sustained for at least six months**
- Analyzed samples: 13 days after the last injection (i.e. just before the next IMP321 injection)





# Activation of monocytes by IMP321: all markers are up

- 8 activation markers: CD11a, CD11b, CD16, CD35, CD54, CD64, CD80 and CD86, analyzed on fresh CD14<sup>+</sup> whole blood cells
- IMP321 dose-response activation** of residual monocyte responses at day 13 post-injection in all 8 cases (D170 versus D1)
- Activation seen in the 6.25 mg dose group only
- Activation long-lasting for months; samples are analyzed 13 days after the last injection



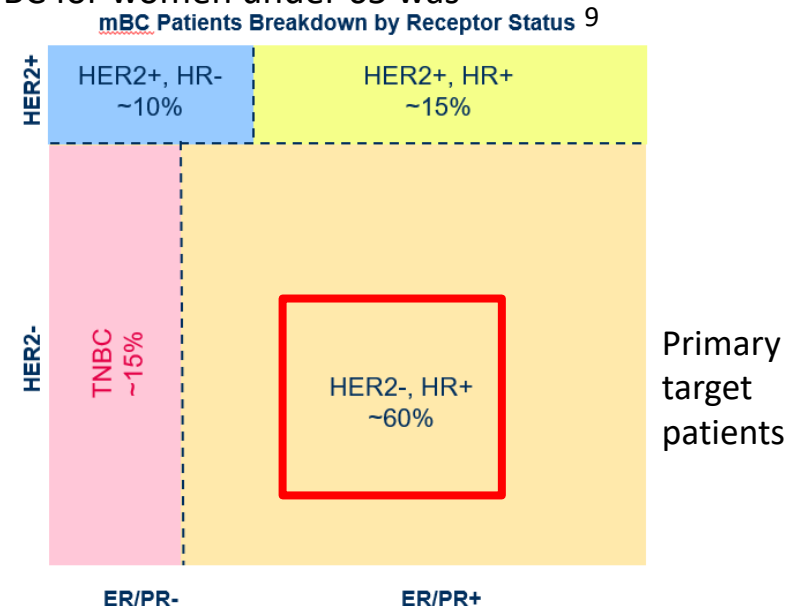
# Metastatic Breast Cancer Market

- **30%** of breast cancer patients are metastatic (at diagnosis or more frequently through recurrence)<sup>1</sup> and 2 out of 3 are HR positive<sup>2</sup>
- Metastatic breast cancer (MBC) patients have a **median survival of 2-4 years**<sup>3</sup>
- **5-year relative survival rate** is only approximately **22%**<sup>4,5</sup>
- MBC currently remains almost **incurable**<sup>6</sup>
- In the U.S., **annual indirect cost to society** attributable to MBC for women under 65 was estimated to be **over US\$ 572 million** including<sup>7</sup>:

US\$ 270 million	Premature deaths
US\$ 253 million	Lost productivity
US\$ 50 million	Caregiving

The global breast cancer treatment market will reach **US\$17.2 billion** by 2021.<sup>8</sup>

- HER2<sup>-</sup> HR<sup>+</sup> patient group is our primary target: currently only hormone therapy followed by chemotherapy is applied with limited outcome improvement<sup>9</sup>



Other fields will follow → label extension

1. O'Shaughnessy J. Extending survival with chemotherapy in metastatic breast cancer. The Oncologist. 2005  
 2. American Cancer Society. (2014). Hormone therapy for breast cancer. Breast Cancer. Accessed on September 30, 2014 from <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-treating-hormone-therapy>.  
 3. Mosher, C. E., Johnson, C., Dickler, M., Norton, L., Massie, M. J., DuHamel, K. (2013). Living with metastatic breast cancer: A qualitative analysis of physical, psychological, and social sequelae. Breast J. 19, 3, 285-92.  
 4. <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-survival-by-stage>  
 5. Madell, R. Metastatic breast cancer: Life expectancy and prognosis. Healthline. 2014 at <http://www.healthline.com/health/breast-cancer/metastatic-prognosisF#Overview1>.  
 6. American Cancer Society. (2013). Detailed Guide: Breast cancer. American Cancer Society. Accessed on September 6, 2014 at <http://www.cancer.org/acs/groups/cid/documents/webcontent/003090-pdf.pdf>.  
 7. Sorensen, S. V. et al. (2012). Incidence-Based Cost-Of-Illness model for metastatic breast cancer in the United States. International Journal of Technology Assessment in Health Care, 28, 1, <http://dx.doi.org.proxy1.athensams.net/10.1017/S026646231100064X>.  
 8. [http://www.researchandmarkets.com/research/mg3gms/breast\\_cancer](http://www.researchandmarkets.com/research/mg3gms/breast_cancer)  
 9. Decision Resources 2010

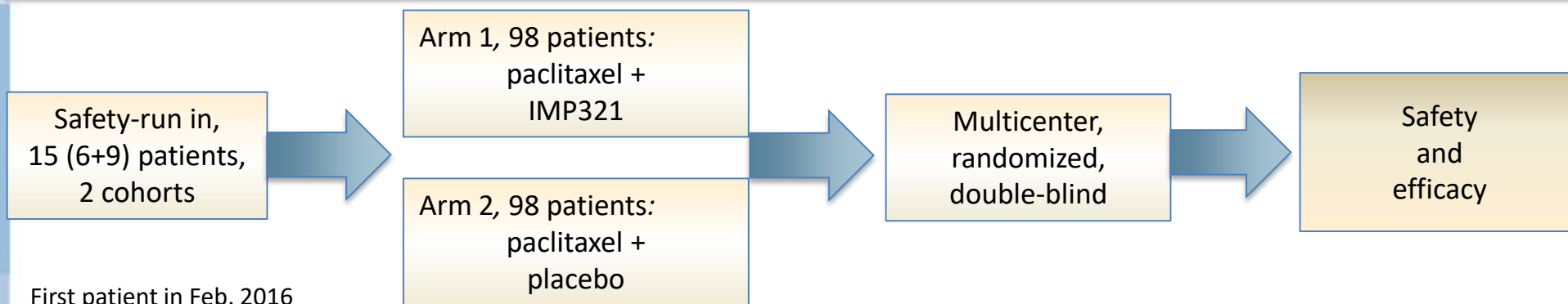
# CURRENT CLINICAL TRIALS



# IMP321 – AIPAC

AIPAC trial: Active Immunotherapy PAClitaxel

Phase IIb chemo-immunotherapy in metastatic breast cancer in different EU countries



## Overview

<b>Design</b>	Phase IIb, randomized, placebo controlled, double blinded, multinational
<b>Primary Objective</b>	Run-In: Recommended phase II dose Randomized: paclitaxel + IMP321 vs. paclitaxel + placebo
<b>Other Objectives</b>	Safety, efficacy
<b>Patient Population</b>	Patients with advanced metastatic breast cancer indicated to receive first line chemotherapy with weekly paclitaxel
<b>Treatment</b>	Safety run-in: IMP321 + Paclitaxel Arm 1: Paclitaxel + Placebo Arm 2: Paclitaxel + IMP321
<b>Current Countries</b>	NL, BL, HUN (11 sites as of Oct 16) , stage II will be conducted in more countries

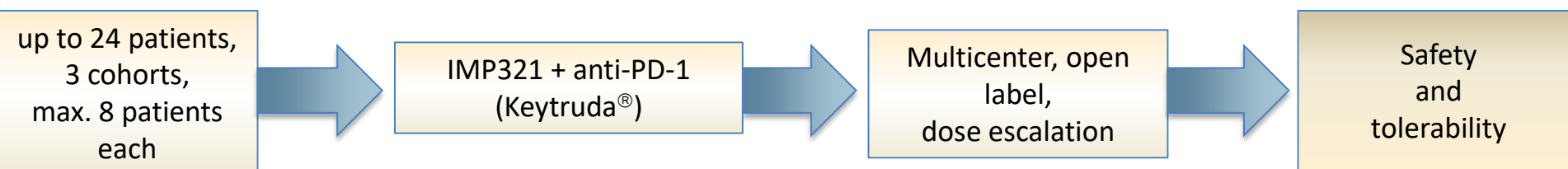
## Status report

- Initial safety data of the first cohort of patients confirmed the safety and tolerability of IMP321 with no dose limiting toxicities, June 2016
- Recruiting in the safety-run in is ongoing
- Decision on recommended phase II dose expected end of 2016

# IMP321 – TACTI-mel

TACTI-mel trial: Two Active Immunotherapeutics in melanoma

Phase I study in immuno-immuno combination in unresectable or metastatic melanoma in Australia



First patient in May 2016

## Overview

<b>Design</b>	Phase I, multi-centre, open-label, dose escalation
<b>Primary Objective</b>	Safety, tolerability and recommended dose finding for phase II with pembrolizumab + IMP321 in unresectable or metastatic melanoma
<b>Other Objectives</b>	Pharmacokinetic and pharmacodynamic of IMP321, objective response rate, time to next treatment, progress-free survival
<b>Patient Population</b>	Patients with asymptomatic or suboptimal response after three cycles of pembrolizumab
<b>Treatment</b>	Up to 24 patients 3 cohorts: 1/6/30 mg IMP321; s.c. q2w + pembrolizumab; starting with the 5 <sup>th</sup> cycle of pembrolizumab

## Status report

- 6 clinical sites are approved and all are activated
- Dose escalation decision of the interim data of the first cohort will be expected at the end of this year



# IMP321 – potential applications

**Potential combo partner for various different applications:**

- **Chemo-immunotherapy** in different cancer indications
  - combo therapy with active agents like Taxanes (e.g. Paclitaxel), anthracyclines, alkylating agents, anti-metabolites, vincas
- **I-O option** in different cancer indications
  - immuno-immuno combo
- **Cancer vaccine**
  - To locally stimulate the immune system

# PARTNERED PROGRAMS



# IMP731 for Autoimmune Diseases

GSK's investigational product, GSK2831781, which is derived from IMP731 antibody, aims to kill the few activated LAG-3<sup>+</sup> T cells that are auto-reactive in autoimmune disease leading to long term disease control without generalized immune suppression.

- GlaxoSmithKline holds exclusive WW rights to IMP731
- Jan 2015: Prima announced a single-digit million US\$ milestone
- Up to £64m in total upfront and milestones + royalties
- Study completion date: April 2018 with 63 pts. (see <http://www.gsk-clinicalstudyregister.com/study/200630#ps>)
- GSK2831781 in Phase I trials with potential regulatory filing expected within 2021-2025 timeframe (See from slide 108 of GSK investor presentation, 11/03/15)
- European Patent grants with patent number 142210 in August 2016



# IMP701: Antagonist mAb for cancer

IMP701 is an anti-LAG-3 mAb that blocks LAG-3-mediated immune down-regulation

LAG-3 is a prime target for immune checkpoint blockade as it is readily expressed at a high level in many human tumors.

- Novartis holds exclusive WW rights
- Aug 2015: Start of Phase I study by Novartis (Novartis milestone payment to be received for IMP701 Phase 1 initiation)
- 13 different indications
- Estimated study completion date is October 2018
- Enlarged enrollment from 240 up to 416 pts.
- LAG-525 is used in combination with PD-1 in solid tumours

# COMPETITIVE LANDSCAPE



# Competitive landscape: APC activators

- Agonist anti-CD40 mAb: in development with anti-PDL-1 antibody by F. Hoffmann-La Roche Ltd

Phase I, 135 patients with locally advanced and/or metastatic solid tumours, estimated completion in Dec.2017

- Toll-Like Receptors
  - Dynavax (DVAX) – TLR9 agonist SD101 (in trials with Keytruda)
  - Immune Design (IMDZ) – TLR4 agonist
  - Celgene (CELG) partnered with VentiRx (private) for TLR8 agonist

# Main players in the LAG-3 field

clinical trials	pre-clinical trials
Novartis (Prima's partner)	Agenus
GSK (Prima's partner)	Tesaro
BMS	Sanofi/Regeneron
Merck	Macrogenics
Boehringer Ingelheim	Peregrine Pharmaceuticals
	RXi Pharmaceuticals Corporation/MirImmune, Inc

# POTENTIAL MILESTONES



# Expected LAG-3 data 2016 & 2017

- 4Q 2016: IMP321 Phase IIb trial (AIPAC) dose escalation decision (safety run-in phase)
- 4Q 2016: IMP321 Phase I trial (TACTI-mel) dose escalation decision
- 2017: further interim data of IMP321 clinical trials
- 2017: partnered program updates

# Corporate Snapshot

Ticker symbol	PBMD (NASDAQ - ADRs) PRR (Australian Securities Exchange)
Securities on issue*	2.07 billion ordinary shares 77.38 million listed options @ A\$0.20 21.2 million issued ADRs
Cash & Term Deposits*	~A\$18.19 million
Market Cap*	A\$78.72 million (US\$59.77 million)
Avg. Vol. (3 mo)	1,150,067 ordinary shares on ASX (10 <sup>th</sup> Oct.2016) 90,119 ADRs on NASDAQ (10 <sup>th</sup> Oct.2016)
Grant Support:	Australian tax credit (45% of eligible R&D spent) French tax credit (30% of eligible R&D spent)
Cash reach	extended into 4Q CY 2017

# Analyst Coverage

## Company

- Maxim Group
- Roth Capital Partners
- FBR & Co.
- H.C. Wainwright & Co.

- April 18, 2016
- December 30, 2015
- December 3, 2015
- October 14, 2015

## Price Target

- US \$5.00\*
- US \$6.00
- US \$6.00
- US \$3.00

## Rating

- Buy
- Buy
- Outperform
- Buy



### Biotechnology

#### PBMD - NASDAQ April 18, 2016

Closing Price 04/18/2016	\$0.91
Rating:	Buy
12-Month Target Price:	\$4.00
52-Week Range:	\$0.42 - \$0.48
Market Cap (M):	63
Shares O/S (M):	68.7
Float:	0.0%
Avg. Daily Volume (000):	190
Debt (M):	\$0
Dividend:	\$0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	June

Total Expenses ('000)			
	2016E	2017E	2018E
H1	6,405	6,725	7,061
H2	6,938	7,285	7,650
FY	13,343	14,010	14,711

GAAP EPS			
	2016E	2017E	2018E
H1	(0.11)	(0.03)	0.04
H2	(0.10)	(0.03)	0.04
FY	(0.20)	(0.06)	0.07



### PRIMA BIOMED LTD

Buy

**LAG-3: Hitting the Next Checkpoint ; Initiating Coverage With a Buy Rating and \$4 Price Target**

#### Summary

- Prima's portfolio of LAG-3 checkpoint modulators and big pharma partnerships may position the company as the LAG-3 leader in what could be the next paradigm shift in immunotherapies for both oncology and autoimmune disease.
- LAG-3 has a multifunctional role in the immune system that can be synergistic with blockbuster checkpoints like Keytruda, Yervoy, and Opdivo, as well as vaccines, chemotherapies, and CAR-T.
- Novartis (NVS - \$76.30 - NR) and GlaxoSmithKline (GSK - \$43.16 - NR) have already licensed two LAG-3 antibodies from Prima: IMP701-targeting solid tumors and IMP731-targeting LAG-3 T cells in autoimmune diseases, respectively.
- Proof of concept (POC) is in hand for Prima's lead in-house LAG-3, IMP321, a soluble form of LAG-3 that ramps up the immune system after chemotherapy. A phase IIb registration study is now underway and, if positive, could mean commercial launch by 2020. We expect another big pharma partner to follow Novartis and GSK for IMP321.
- Conclusion: Three LAG-3 checkpoints (and two more undisclosed in development), three blockbuster indications, and the right partners should translate into multiple opportunities for Prima to capture significant royalties and drive value for investors, in our opinion.

#### Details

**The LAG-3 platform.** The LAG-3 (lymphocyte activation gene-3) checkpoint is rapidly emerging behind PD1 and CTLA-4, in our view. LAG-3 has a multi-functional role which can be exploited in different ways to alter immune responses and is potentially synergistic with other immunotherapies (vaccines, other checkpoint, CAR-T) and chemotherapy. Prima BioMed's acquisition of Immutep SA (private) in 2014 brought a portfolio of LAG-3-targeting assets into the Prima pipeline and positioned the company as the LAG-3 leader. In addition, Immutep's founder, Frédéric Triebel, MD, PhD has joined Prima as Chief Medical Officer to oversee LAG-3 product development. Dr. Triebel discovered the LAG-3 gene in 1999 while



### Prima BioMed Ltd. (PBMD - \$1.08\*)

Armadale, Victoria, Australia  
December 3, 2015

STOCK DATA			
52-Week Range	\$6.48 - \$0.42		
3-Month ADTV	\$23,802		
Market Cap (mil)	\$74.1		
Shrs Outstanding (mil)	68.6		
Beta	0.79		
Float (%)	94.6		
Fiscal Year-End	June		

EARNINGS DATA			
Adj. EPS	2014A	2015A	2016E
H1	(\$0.14)	(\$0.12)	(\$0.15)
H2	(\$0.17)	(\$0.46)	\$0.01
FY	(\$0.33)	(\$0.63)	(\$0.14)

EPS (Earnings per ADR) for each period is adjusted for the AUD vs USD spot exchange rates on June 30 and December 31. Quarterly EPS may not sum to total due to rounding.

FINANCIAL DATA			
FY	2014A	2015A	2016E
Rev. (mil)	3.1	2.1	11.4

BALANCE SHEET DATA			
			2015
Cash & Equivalents			\$6.8
Current Assets			\$6.0
Total Assets			\$31.0
Total Liabilities			\$6.3
Total Stockholder Equity			\$24.7
Total Debt			\$0.0

In millions of Australian dollars (AUD). Cash position does not reflect \$25 million AUD in calendar year 2 H15.

#### Important disclosure

### Targeting Next-Gen Immunotherapies Initiating at Outperform

**Summary and Recommendation**  
We are initiating a price target of \$4.00 in 2014, the development of LAG-3 rapidly being believed to be the c of the significant pipeline.

#### Key Points

- We look at a planne significant IMP321 the ECO since we potentia
- We look registrat advice fr agency's the EMA AIPAC re We do r



### H.C. WAINWRIGHT & CO.

Initiating Coverage  
Healthcare  
October 14, 2015

Prima Biomed Ltd. (PBMD)  
Rating: Buy

Sriyampakula Ramakrishna, Ph.D.  
212-356-0544  
sramakrishna@hccresearch.com  
Sean Lee  
212-356-0521  
slee@hccresearch.com

Leading the LAG-3 Race; Initiating with a Buy and \$3.00 PT

Stock Data		10/13/2015
Price		\$1.22
Exchange		NASDAQ
Price Target		\$3.00
52-Week High		\$6.48
52-Week Low		\$0.42

**Prima BioMed is a leader in LAG-3 therapies.** Immunotherapies, such as checkpoint modulators (CPMs) that regulate T cell function, are revolutionizing cancer treatment. Prima BioMed, a biotechnology company based in Sydney, Australia, is developing novel CPMs targeting Lymphocyte-Activation Gene 3 (LAG-3), a key modulator of the immune system. While several companies have LAG-3 programs under development, Prima is an early mover in this space with



Joseph Pantiginis, Ph.D., (646) 358-1907  
jpantiginis@roth.com  
Sales (800) 933-6830, Trading (800) 933-6820

COMPANY NOTE | EQUITY RESEARCH | December 30, 2015

### Healthcare: Biotechnology

### Prima BioMed, Ltd. | PBMD - \$1.09 - NASDAQ | Buy

#### Initiation of Coverage

Stock Data	
52-Week Low - High	AUD0.42 - AUD0.48
Shares Out. (mil)	68.61
Mkt. Cap (mil)	\$74.8
3-Mo. Avg. Vol.	959,016
12-Mo. Price Target	\$6.00
Cash (mil)	AUD24.4
Tot. Debt (mil)	AUD0.0

EPS SAUD			
Yr	2014—	2015—	2016E—
		Curr	Curr
1Q	-	(0.01A)	0.00E
2Q	(0.01A)	(0.01A)	0.00E
3Q	(0.01A)	(0.02A)	0.00E
4Q	(0.01A)	(0.02A)	(0.01E)
YEAR	(0.01A)	(0.02A)	(0.01E)

Prima announces financial results on a half-yearly basis. Results represent add-to-full year based on increases in share count and rounding.

Revenue (SAUD millions)			
Yr	2014—	2015—	2016E—
		Curr	Curr
1Q	-	-	-

### PBMD: Immuno-Threat From Down-Under; Initiating Coverage at Buy

We are initiating coverage of Prima with a Buy rating and \$6 price target. We believe Prima is in a leading position in the development of new checkpoint inhibition pathways, based on the discovery of LAG-3 by Prima's CEO/CSO. Initial clinical efficacy has been promising and has also delivered two global pharma partnerships. We recommend building positions in Prima.

#### Event

Prima has undergone a significant transformation, in our belief. The company was founded in 2001 in Australia. The primary focus for Prima was the development of the therapeutic cancer vaccine, CVac, primarily for ovarian cancer. Over the course of a few years, until May 2015, the stock experienced significant volatility based on two primary factors: 1) mixed results emerging from CVac studies and 2) management changes during those times. However we believe the company has now been transformed under the leadership of CEO Marc Voight and especially with the October 2014 acquisition of Immutep SA (private) for \$25 million, focusing on the Lymphocyte-activation gene 3 or LAG-3. LAG-3 is a major factor involved in the regulation of T-cells in immune responses. The company is now entirely focused on the LAG-3 program and in February 2015 announced that it was no longer enrolling CVac studies and the product is now available for partnering.





*Thank you!*