Prima BioMed

Initial TACTI-mel data

Initial LAG-3 combo data presented

Pharma & biotech

Prima BioMed has presented encouraging early signs of efficacy from the TACTI-mel trial of IMP321 in combination with Keytruda, with one of the six melanoma patients in the first (1mg/kg) cohort experiencing a complete response. Recruitment in the second cohort is complete and the final cohort is expected to be fully recruited by Q317. Preliminary efficacy data from the 15-patient, run-in phase of the AIPAC breast cancer study are expected mid-year (recruitment in the 226-patient Phase IIb component is ongoing). Our valuation is unchanged at $192m ($9.24 per ADR).

Year end	Revenue (US$m)	PTP (US$m)	EPADR ($)	DPADR ($)	P/E (x)	Gross yield (%)
06/15	1.0	(9.8)	(0.65)	0.0	N/A	N/A
06/16	1.5	(10.4)	(0.43)	0.0	N/A	N/A
06/17e	1.0	(9.7)	(0.47)	0.0	N/A	N/A
06/18e	8.0	(3.1)	(0.15)	0.0	N/A	N/A

Note: Converted at A$1/US$0.76 for the table above and throughout the note.

A complete response in low-dose TACTI-mel cohort

The TACTI-mel trial is using IMP321 (Prima's LAG-3-based antigen presenting cell activator) to enhance efficacy in melanoma patients who have had a suboptimal initial response to the PD1 immune checkpoint inhibitor Keytruda. A presentation to the Immune Checkpoint Inhibitors conference in Boston showed that that one of the six patients (17%) in the first cohort experienced a complete response (CR). Even though there is only one patient with a CR, the initial CR rate compares favorably with rates of 2-6% seen in Merck's Phase III trials of Keytruda monotherapy in melanoma. The combination has been well tolerated so far. Recruitment in the third and highest (30mg) dose cohort is expected to complete in Q317, so we expect efficacy data from the final cohort in H118.

Initial efficacy data from AIPAC run-in due mid-year

Initial efficacy data are expected mid-2017 (possibly at ASCO in June) from the 15 metastatic breast cancer patients treated with IMP321 in combination with paclitaxel during the safety run-in phase of the AIPAC study (the response rate in a previous Phase I study was 50%). Dosing began in January in the 226-patient randomized Phase IIb component of AIPAC; top-line PFS data could mature sometime between late 2018 and mid-2019. Patients will receive either 30mg of IMP321 or placebo, in combination with paclitaxel.

Valuation: Unchanged at $192m, $9.24 per ADR

Our valuation is unchanged at $192m, which is equal to ($9.24 per ADR) on an undiluted basis or $6.37/ADR after accounting for dilution from options, warrants and convertible notes. Guidance is that the cash balance of $12.6m at 31 December will be sufficient to fund operations through Q1 CY18, excluding any milestone payments from partners Novartis and GSK. Milestone revenue (we model ~$7m in FY18) would extend the cash runway.

23 March 2017

Price	**US$2.48**
Market cap	**US$52m**
ADR/Ord conversion ratio	100/1
Gross cash ($m) at 31 December 2016	12.6
ADRs in issue	20.8m
ADR code	PBMD
ADR exchange	NASDAQ
Underlying exchange	ASX
Depository	BNY

ADR share price performance

52-week high/low	US$3.8	US$2.1

Business description

Prima BioMed is an ASX-listed biotechnology company focused on cancer immunotherapy. Its pipeline is based on three products using a LAG-3 immune control system, IMP321 for cancer chemo-immunotherapy and partnered products IMP731 (GSK) and IMP701 (Novartis). It has out-licensed CVac, an autologous dendritic cell vaccine.

Next events

AIPAC immune monitoring and activity data from run-in phase	Mid-2017
Further TACTI-mel dose escalation safety and activity data	2017
IMP761 preclinical data	2017

Analysts

Dennis Hulme +61 (0)2 9258 1161

Dr Susie Jana +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

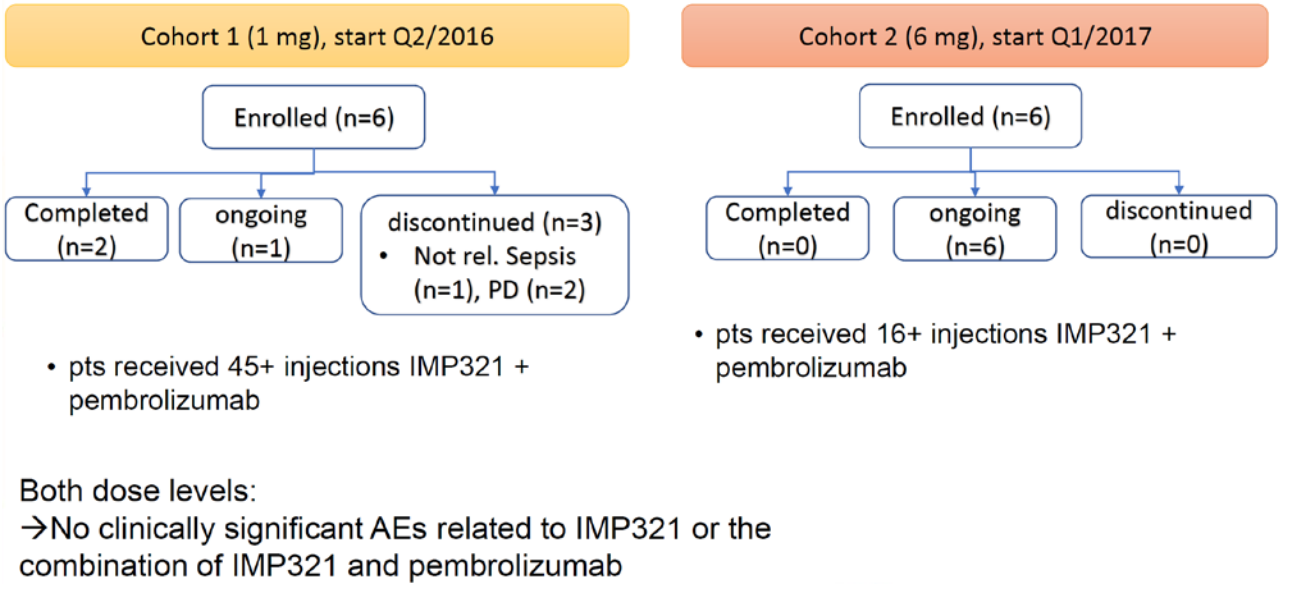
Complete responder in first TACTI-mel cohort

On 16 March Prima's chief medical and scientific officer, Dr Frédéric Triebel, presented an update on the Phase I TACTI-mel trial, including preliminary efficacy data from the first cohort, at the Immune Checkpoint Inhibitors conference in Boston, Massachusetts. This study will test three doses of IMP321 (1, 6 and 30mg/kg) in combination with the anti-PD-1 immune checkpoint inhibitor Keytruda (pembrolizumab, Merck) in 18 patients with advanced melanoma. Recruitment in the first two cohorts is complete, as shown in Exhibit 1.

The trial is investigating IMP321 in subjects who have had a suboptimal response to initial treatment with Keytruda. Subjects are assessed after they have undergone three cycles (nine weeks) of treatment with Keytruda; patients with stable disease or slow progression not requiring urgent intervention are eligible to participate in the trial and receive IMP321, starting with the fifth Keytruda cycle at week 13.

Six patients were enrolled in the first dose cohort (1mg/kg every two weeks), which began in Q216. The second cohort of six patients is fully recruited, and all subjects continue to receive three-weekly injections of Keytruda and fortnightly injections of IMP321 at 6mg/kg. No clinically significant adverse events related to IMP321 or the combination of IMP321 with Keytruda have been observed at either dose level so far. Recruitment in the third and highest (30mg) dose cohort is expected to complete in Q317.

Exhibit 1: TACTI-mel Phase I status and preliminary results

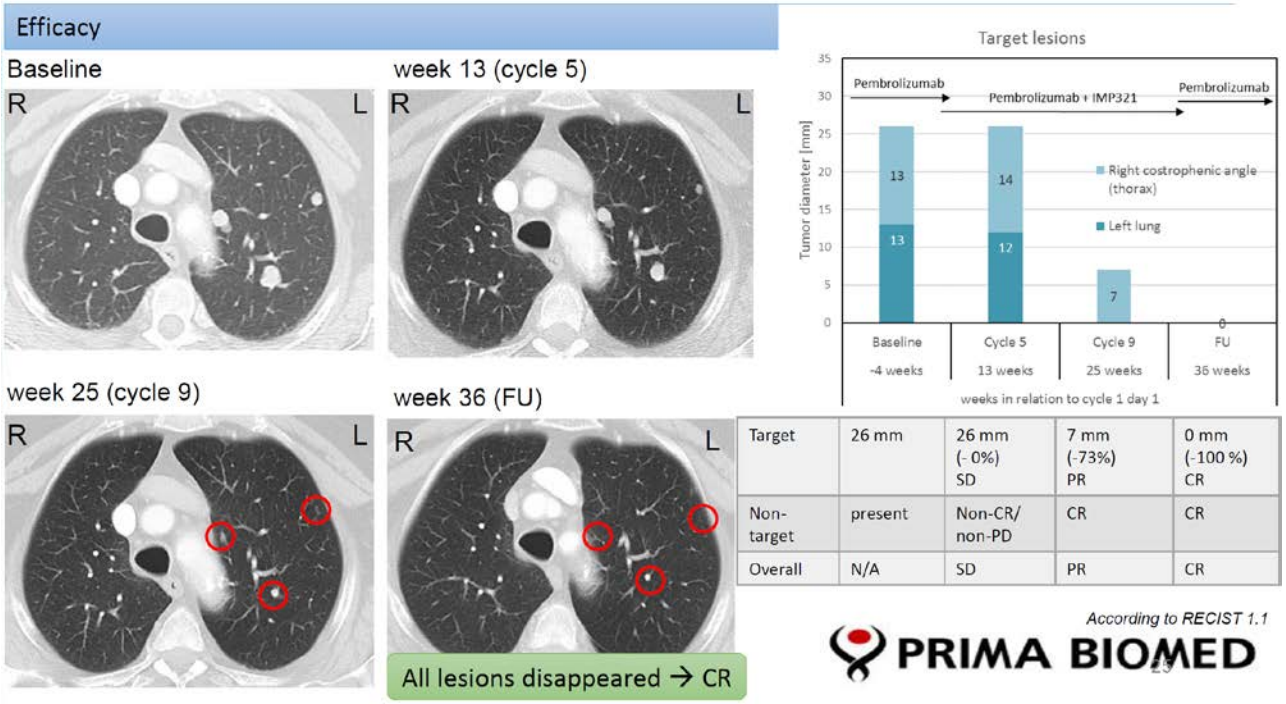


Source: Prima BioMed presentation at Immune Checkpoint Inhibitors conference, Boston, Massachusetts

One of the six patients receiving the lowest dose of IMP321 experienced a complete response (CR, Exhibit 2). After the completion of four cycles (12 weeks) of Keytruda monotherapy there was no shrinkage in this patient's tumors, but after four cycles of combination therapy with Keytruda and low dose IMP731 the lung metastases had shrunk by 73%; 23 weeks after initiation of IMP321 combination therapy the tumors had disappeared altogether. Of the other five patients, two experienced disease progression (tumor growth), one withdrew due to unrelated sepsis and there is no information about the other two, although they appear to have completed 26 weeks of treatment with IMP321 without disease progression. One should not read too much into a single tumor response, particularly given that the dose of IMP321 was low and delayed responses are a well-recognized feature of therapy with ICI, but it is encouraging that the tumor shrinkage appears to

have coincided with the initiation of combination therapy. Again, while the number of patients is small, the preliminary CR rate of 17% (1/6) compares favorably with CR rates of 2-6% seen in Phase III trials of Keytruda monotherapy in melanoma.

Exhibit 2: TACTI-mel first cohort (1mg/kg IMP321) complete responder and preliminary results



Target	26 mm	26 mm (- 0%) SD	7 mm (-73%) PR	0 mm (-100 %) CR
Non-target	present	Non-CR/ non-PD	CR	CR
Overall	N/A	SD	PR	CR

Source: Prima BioMed presentation at Immune Checkpoint Inhibitors conference, Boston, Massachusetts

Exhibit 3: Financial summary

US$000s	2015	2016	2017e	2018e
Year end 30 June	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	1,015	1,481	952	8,028
Cost of Sales	(6,804)	(5,365)	(5,526)	(5,692)
Gross Profit	(4,350)	(5,307)	(5,413)	(5,575)
EBITDA	(10,142)	(9,191)	(9,987)	(3,239)
Operating Profit (before GW and except.)	(10,390)	(9,329)	(9,990)	(3,244)
Intangible Amortization	(772)	(1,515)	(1,426)	(1,298)
Exceptionals	(13,937)	(36,076)	0	0
Operating Profit	(25,099)	(46,920)	(11,416)	(4,542)
Other	409	(1,304)	0	0
Net Interest	146	194	317	185
Pre-Tax Profit (norm)	(9,835)	(10,439)	(9,672)	(3,059)
Pre-Tax Profit (IFRS)	(24,543)	(48,029)	(11,099)	(4,357)
Tax	108	898	0	0
Profit After Tax (norm)	(9,727)	(9,541)	(9,672)	(3,059)
Profit After Tax (IFRS)	(24,435)	(47,132)	(11,099)	(4,357)
	0.0	0.0	0.0	0.0
Average Number of Shares Outstanding (m)	1,490.1	2,236.3	2,061.6	2,073.1
Average Number of ADRs Outstanding (m)	14.9	22.4	20.6	20.7
EPS - normalized (c)	(0.7)	(0.4)	(0.5)	(0.1)
EPS - IFRS (c)	(1.6)	(2.1)	(0.5)	(0.2)
Dividend per share (c)	0.0	0.0	0.0	0.0
Earnings per ADR - normalized ($)	(65.3)	(42.7)	(46.9)	(14.8)
Earnings per ADR - IFRS (c)	(164.0)	(210.8)	(53.8)	(21.0)
Dividend per ADR (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	17,450	15,871	14,464	13,183
Intangible Assets	17,223	15,847	14,421	13,123
Tangible Assets	226	24	43	60
Other	0	0	0	0
Current Assets	6,098	16,470	6,779	3,702
Stocks	0	0	0	0
Debtors	240	128	128	128
Cash	5,137	15,868	6,177	3,101
Other	720	473	473	473
Current Liabilities	(3,329)	(1,119)	(1,119)	(1,119)
Creditors	(2,121)	(1,098)	(1,098)	(1,098)
Short term borrowings	(1,146)	(0)	(0)	(0)
Short term leases	0	0	0	0
Other	(61)	(21)	(21)	(21)
Long Term Liabilities	(1,455)	(4,381)	(4,381)	(4,381)
Long term borrowings incl. conv. note	0	(3,821)	(3,821)	(3,821)
Long term leases	0	0	0	0
Other long term liabilities	(1,455)	(560)	(560)	(560)
Net Assets	18,764	26,841	15,742	11,386
CASH FLOW				
Operating Cash Flow	(5,917)	(8,811)	(9,987)	(3,239)
Net Interest	0	216	317	185
Tax	(1)	0	0	0
Capex	(37)	(21)	(22)	(23)
Acquisitions/disposals	(15,894)	99	0	0
Financing	5,886	20,694	0	0
Dividends	0	0	0	0
Other	(125)	0	0	0
Net Cash Flow	(16,088)	12,176	(9,691)	(3,076)
Opening net debt/(cash)	(17,632)	(3,991)	(12,047)	(2,356)
HP finance leases initiated	0	0	0	0
Other	2,447	(4,120)	0	0
Closing net debt/(cash)	(3,991)	(12,047)	(2,356)	720

Source: Prima Biomed accounts, Edison Investment Research. Note: Solely for the convenience of the reader the financial summary table has been converted to US$ at a rate of US$0.76 to A$1. Prima reports statutory accounts in Australian dollars. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 8249 8342
Level 12, 95 Pitt Street,
Sydney NSW 2000
Australia