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PRIMA BIOMED INITIATES PHASE I MELANOMA STUDY IN AUSTRALIA

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD), a leading immuno-oncology company, is pleased to announce the initiation of the first clinical trial site for TACTI-mel, a Phase I clinical study in melanoma using its lead compound IMP321, to be conducted in Australia.

'TACTI-mel' (Two ACTive Immunotherapeutics in melanoma) is a multicentre, open label, Phase I study in which patients with unresectable or metastatic melanoma will be dosed with IMP321 in combination with an approved checkpoint inhibitor. The study will evaluate safety as the primary endpoint and anti-tumour activity and the immune response to the combination as secondary endpoints.

The first clinical site, the Gallipoli Medical Research Foundation at the Greenslopes Private Hospital in Queensland, has been approved by the Australian Therapeutic Goods Administration (TGA). Recruitment for the trial can now commence under the direction of Dr. Victoria Atkinson, Principal Investigator for the trial. The TACTI-mel study will recruit up to 24 patients across 6 sites in Australia, with the first patients expected to be dosed in the first quarter of 2016.

Dr. Atkinson commented: "The TACTI-mel study will be the first human study combining IMP321 as an antigen presenting cell activator together with a PD-1 checkpoint inhibitor. With the highest incidence of melanoma in the world, we look forward to working with Greenslopes Hospital staff in treating Australian patients in this ground-breaking study."

Prima believes that checkpoint inhibitors represent a cancer treatment revolution. Showing IMP321 to be synergistic with checkpoint inhibitors could significantly increase its clinical and commercial potential.

The pre-clinical and clinical evidence to date has suggested that IMP321 can treat cancer by activating Antigen Presenting Cells (APC) to sustain an anti-cancer immune response. This is a markedly different mechanism of action from the checkpoint inhibitors and suggests that the two approaches can be used synergistically in combination.

About IMP321

IMP321, a first-in-class APC activator based on the immune checkpoint LAG-3, represents one of the first proposed active immunotherapy drugs in which the patient's own immune system is harnessed to respond to tumour antigenic debris created by chemotherapy. As an APC activator, IMP321 boosts the network of dendritic cells in the body that can respond to tumour antigens for a better anti-tumour CD8 T cell response.

IMP321 has been shown in an open-label Phase I study to be able to double the expected six-month response rate in HER-2 negative metastatic breast cancer patients receiving standard-of-care paclitaxel, from a 25% historic response rate (RECIST criteria)[1] to 50% when combined with IMP321[2].

About Prima BioMed

Prima BioMed is a globally active biotechnology company that is striving to become a leader in the development of immunotherapeutic products for the treatment of cancer. Prima BioMed is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

Prima's current lead product is IMP321, based on the LAG-3 immune control mechanism which plays a vital role in the regulation of the T cell immune response. IMP321, which is a soluble LAG-3Ig fusion protein, is an APC activator boosting T cell responses for cancer chemo-immunotherapy and in other combinations which has completed early Phase II trials. A number of additional LAG-3 products including antibodies for immune response modulation in autoimmunity and cancer are being developed by large pharmaceutical partners.

Prima BioMed is listed on the Australian Stock Exchange, and on the NASDAQ in the US. For further information please visit www.primabiomed.com.au

About TACTI-mel

Title of Study	**TACTI-mel** (Two ACTive Immunotherapeutics in melanoma): A multicentre, open label, dose escalation, Phase 1 study in patients with unresectable or metastatic melanoma receiving IMP321 (LAG-3Ig fusion protein) as an adjunctive therapy to anti-PD-1 therapy with pembrolizumab.
Objectives	**Primary Objective** • To evaluate the safety, tolerability and recommended phase 2 dose of IMP321 when combined with anti-PD-1 treatment in patients with unresectable or metastatic melanoma. **Secondary Objectives** • To assess the pharmacokinetics and pharmacodynamics of different doses of IMP321 when combined with anti-PD-1 treatment in patients with unresectable or metastatic melanoma. • To assess response to treatment by immune related response criteria (irRC) and response evaluation criteria in solid tumours (RECIST) version 1.1.

[1] Miller et. al., N. Engl. J. Med. 2007, 357: 2666-76.

	• To assess time to and duration of response, as well as the objective response rate (ORR), time to next treatment (TTNT), progression free survival (PFS).
Study Design	This is a multicentre, open label, dose escalation, Phase 1 study in advanced or metastatic melanoma patients. IMP321 will be administered as an adjunctive therapy to patients with asymptomatic irPD (slowly progressive, not requiring urgent intervention, and stable performance status) or sub-optimal response (irSD, irPR) after three cycles of pembrolizumab (Keytruda®). Three staged and sequential dose escalation cohorts of up to 8 patients each will be evaluated.
Planned Sample Size	24 patients
Study Population	**Key Inclusion Criteria** • Histologically confirmed diagnosis of locally advanced (unresectable Stage III) or metastatic (Stage IV) melanoma. • Patients received 3 cycles of pembrolizumab (Keytruda®) and achieved asymptomatic irPD (slowly progressive, not requiring urgent intervention, and stable performance status) or sub-optimal response (irSD, irPR). • Evidence of measurable disease as defined by RECIST version 1.1 **Key Exclusion Criteria** • More than four prior lines of therapies for advanced or metastatic disease. • Prior PD-1/PDL-1 targeted therapy. • Currently receiving chemotherapy, targeted small molecule therapy, radiotherapy, or biological cancer therapy (other than pembrolizumab (Keytruda®)) or less than 4 weeks since completion of these therapies and first dose of study treatment. • History of irAEs from ipilimumab of CTCAE Grade 4 requiring steroid treatment.

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