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PRIMA BIOMED UNVEILS PHASE I COMBINATION STUDY OF IMP321 + CHECKPOINT INHIBITOR

Highlights

- Prima to run a Phase I safety and dose finding study of IMP321 in combination with a checkpoint inhibitor in metastatic melanoma in Australia
- Potentially revolutionary study in immuno-oncology by combining APC activator with checkpoint inhibitor
- The Human Research Ethics Committee at the Greenslopes Private Hospital in Queensland has cleared the study protocol
- First patient expected to enter study in early 2016

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) today unveiled a new clinical trial of IMP321, to be called 'TACTI-mel', short for 'Two ACTive Immunotherapeutics in melanoma'. In this ground-breaking safety and dose finding study IMP321 will be combined with an approved checkpoint inhibitor in patients with metastatic melanoma.

The Human Research Ethics Committee at the Greenslopes Private Hospital in Greenslopes, Queensland has approved Prima's Phase I clinical trial protocol, and it is expected that the first patient in the TACTI-mel study will be dosed in the first half of 2016. This will represent one of the first clinical occasions in which an Antigen Presenting Cell (APC) activator has been combined with a checkpoint inhibitor.

Prima CSO and CMO Dr. Frederic Triebel commented: "The TACTI-mel study represents a significant development for Prima BioMed because the future of immuno-oncology lies in combination therapies. If we can combine IMP321 synergistically with a checkpoint inhibitor, as the pre-clinical evidence has suggested, then we will be well positioned in this revolutionary field."

The importance of the TACTI-mel study for Prima lies in the role that checkpoint inhibitors have started to play in the treatment of cancer. The checkpoint inhibitors are monoclonal antibody drugs which target certain inhibitory 'checkpoints' on immune cells. The regular function of such checkpoints is to supress an immune response and cancer is able to exploit the checkpoints to prevent the immune system from attacking tumours.

The checkpoint inhibitors, by foiling this tumour escape route, allow a more effective immune response, leading to significant beneficial outcomes for many patients. Three checkpoint inhibitors have gained FDA approval since 2011, all initially in metastatic melanoma. As previously outlined in its materials, Prima believes that the checkpoint inhibitors represent a cancer treatment

revolution[1], and that showing IMP321 to be synergistic with the checkpoint inhibitors will increase its clinical and commercial potential. The pre-clinical and clinical evidence to date has suggested that IMP321 can treat cancer by activating APCs 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. Prima advised the market in May 2015 that it had filed a provisional patent application over the use of IMP321 in combination with immune checkpoint inhibitors, thereby potentially providing patent exclusivity for the product to 2035 or beyond if granted. TACTI-mel now builds on the work that went into that patent filing by taking the concept into the clinic to evaluate its safety as well as the ideal dosing combination.

TACTI-mel will be the second clinical study to be initiated for IMP321 since Prima BioMed acquired the compound in December 2014.

Clinical trial summary

TACTI-mel will recruit 24 patients with Stage III/IV metastatic melanoma being treated with an approved checkpoint inhibitor and add IMP321 to the dosing regimen. Patients will receive ascending subcutaneous doses of IMP321 up to 30 mg per injection fortnightly for 13 injections. The study will mainly evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumour activity of IMP321 at the various doses as well as the nature of the immune response in the combination. The primary endpoint of the study will be safety.

About IMP321

IMP321, a first-in-class Antigen Presenting Cell (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)[2] to 50% when combined with IMP321[3].

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

[1] See the Prima BioMed Detailed Backgrounder presentation of 27 February 2015.
[2] Miller et. al., N. Engl. J. Med. 2007, 357: 2666-76.
[3] Brignone et.al., J. Transl. Med. 2010, 8:71.

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

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