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ASIA EDITION

Immutep collaborates with Merck, Pfizer for Efti

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The clinical trial will evaluate the clinical benefits of releasing the brakes and pushing the accelerator of the body's immune system at two different positions in the cancer immunity cycle.



Immutep Limited has announced that it has entered into a clinical trial collaboration and supply agreement with Merck KGaA, Darmstadt, Germany and Pfizer Inc., to evaluate the combination of Immutep's lead immunotherapy product candidate eftilagimod alpha ("efti" or "IMP321") with avelumab, a human anti-PD-L1 antibody, in patients with advanced solid malignancies.

"We are delighted to have the opportunity to collaborate with Merck KGaA, Darmstadt, Germany, and Pfizer on this Phase I clinical trial that will evaluate the clinical benefits of combining our immune stimulator, eftilagimod alpha, with avelumab, a PD-L1 blocking mechanism of action. We feel that this new collaboration, with these industry leaders, further supports our hypothesis that there is a potentially meaningful therapeutic benefit in combining eftilagimod alpha with a checkpoint inhibitor in the treatment of cancer. We look forward to the initiation of this clinical trial, planned for later this year, and the prospects of further clinical investigations," said Marc Voigt, CEO of Immutep.

"This novel combination regimen adds to our clinical development program to further evaluate the potential in different challenging cancers," said Alise Reicin, Head of Global Clinical Development at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. "We are eager to assess the opportunity of combining eftilagimod alpha with avelumab to improve patient outcomes."

"We continue to focus on opportunities to advance combination trials with avelumab, as we believe the pathway to progress in immuno-oncology lies in combination approaches," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-Oncology, Early Development, and Translational Oncology, Pfizer Global Product Development. "We look forward to collaborating with Immutep on this clinical trial collaboration, which will help us accelerate and advance treatment options that will potentially benefit more patients."

The planned clinical evaluation will be an amendment to the existing INSIGHT Phase I clinical trial and will evaluate the safety, tolerability and recommended Phase II dose of efti when combined with avelumab in patients with advanced solid

malignancies. The Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany ("IKF") will be the sponsor of the clinical trial and it will be conducted under the existing protocol of the ongoing INSIGHT clinical study. Prof. Dr. Salah-Eddin Al-Batran, the lead investigator of INSIGHT and member of Immutep's clinical advisory board, will be the lead investigator of the trial.

Prof. Dr. Al-Batran commented: "We are excited to have the opportunity to sponsor this clinical trial of two complementary mechanisms of action and build upon the existing relationship between IFK and Immutep. This clinical trial will be conducted through an amendment to our existing protocol which will hopefully allow us to commence the clinical trial before the end of the year."

The clinical trial will evaluate the clinical benefits of releasing the brakes and pushing the accelerator of the body's immune system at two different positions in the cancer immunity cycle. Immutep's efti is a first-in-class antigen presenting cell ("APC") activator which stimulates cancer-fighting T cells, while avelumab is an anti-PD-L1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells.

Avelumab has received accelerated approval by the US Food and Drug Administration (FDA) for the treatment of patients with metastatic Merkel cell carcinoma (MCC) and previously treated patients with locally advanced or metastatic urothelial carcinoma (mUC), and is under further clinical evaluation across a range of tumor types under a global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer.

Avelumab is under clinical investigation for treatment of solid malignancies and has not been demonstrated to be safe and effective for these uses.