

Merck inks deal with Australian biotech firm Immutep

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The deal aims to evaluate the combination of Immutep's lead immunotherapy product candidate efitlagimod alpha with MSD's anti-PD-1 therapy KEYTRUDA in a new clinical trial that will evaluate the combination in several different solid tumours



Australia's biotech giant Immutep has announced that it has entered into a clinical trial collaboration and supply agreement with Merck & Co to evaluate the combination of Immutep's lead immunotherapy product candidate efitlagimod alpha ("efti" or "IMP321") with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a new clinical trial that will evaluate the combination in several different solid tumours.

The planned Phase II clinical trial, referred to as TACTI-002 (Two ACTive Immunotherapies), will evaluate the safety and efficacy of this novel immunotherapy combination in patients with non-small cell lung cancer ("NSCLC"), head and neck cancer, or ovarian cancer. The TACTI-002 clinical trial will be a Phase II, Simon two-stage, non-comparative, open-label, single-arm, multicentre clinical study.

The study plans to enrol 120 patients across the three indications are planned to be treated in medical centres in Europe and the United States with the trial expected to commence in the second half of 2018.

"We are extremely pleased to be collaborating with MSD, one of the world's leading immuno-oncology companies" said Marc Voigt, CEO of Immutep. "This clinical trial will evaluate a novel combination of two complementary immuno-oncology treatments in three cancer indications simultaneously, which could lead to more rapid drug development subject to successful

outcomes. The data generated thus far from our ongoing TACTI-mel clinical trial has supported our hypothesis that there is a compelling therapeutic synergy in administering ehti in combination with another immuno-oncology treatment. This new Phase II clinical trial significantly builds on the momentum we are delivering in the evaluation of ehti in cancer, with two Phase I clinical trials and now two Phase II clinical trials in our program for 2018.”

The trial combines two immuno-oncology treatments with complementary mechanisms of action, analogous to releasing the brakes and pushing the accelerator of the body’s immune system at two different positions in the cancer immunity cycle. Immutep’s ehti is a first-in-class antigen presenting cell (“APC”) activator which stimulates cancer-fighting T cells, while KEYTRUDA is an anti-PD-1 therapy that works by increasing the ability of the body’s immune system to help detect and fight tumor cells.

Immutep is a globally active biotechnology company that is a leader in the development of immunotherapeutic products for the treatment of cancer and autoimmune disease. The company’s current lead product is ehtilagimod alpha (“ehti” or “IMP321”), a soluble LAG-3Ig fusion protein based on the LAG-3 immune control mechanism.