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Outcome from DSMB Safety Review and Extension of TACTI-mel Phase I Clinical Trial

SYDNEY, AUSTRALIA - Immutep Limited (ASX: IMM; NASDAQ: IMMP) ("Immutep" or the "Company"), announced today that the Database Safety Monitoring Board ("DSMB") confirmed that the combination of eftilagimod alpha ("efti", "LAG-3Ig", or "IMP321") with pembrolizumab (KEYTRUDA) is safe and well tolerated at doses up to 30 mg per subcutaneous injection.

In this first-in-man TACTI-mel (Two ACTive Immunotherapies in melanoma) Phase I clinical trial in Australia, efti is combined with pembrolizumab in unresectable or metastatic melanoma patients. The data to date shows no safety concerns from the combination with doses of efti at 1 mg, 6 mg, and 30 mg. No drug related serious adverse events have been reported and the DSMB concluded repeated injections of efti are safe and well tolerated.

The patients eligible to participate in the TACTI-mel Phase I clinical trial are those that have either had a suboptimal response or had disease progression with pembrolizumab monotherapy. In this clinical trial, the combination starts at cycle five of pembrolizumab and is limited to six months of treatment.

Encouraged by the TACTI-mel Phase I clinical trial interim results presented at the Society for Immunotherapy of Cancer (SITC) 2017 Annual Meeting in November 2017, Immutep now plans to expand the TACTI-mel study by six patients at 30 mg of efti in combination with pembrolizumab starting at cycle one and with a treatment duration of 12 months.

"There is limited clinical experience with combining an APC activator such as efti with an immune checkpoint inhibitor such as pembrolizumab, analogous to pushing the accelerator and also releasing the brakes on cancer-fighting T cells", said Dr. Frédéric Triebel, Immutep's Chief Scientific and Medical Officer. "Therefore, the TACTI-mel trial design included certain key safety measures such as starting with a low dose and at cycle five, which excludes patients with early severe adverse events to pembrolizumab, and limiting treatment to six months. The positive results now provide the basis to safely extend the clinical trial to start at cycle one with the recommended Phase II dose and for a 12-month duration, meaning patients could benefit earlier and for longer from the combination."

As previously disclosed, all three cohorts of the TACTI-mel Phase I clinical trial totalling 18 patients have been fully recruited and the data from these three cohorts is expected in H1 2018.

About Immutep

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. Immutep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

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

Immutep is listed on the Australian Stock Exchange (IMM), and on the NASDAQ (IMMP) in the U.S.

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