

ASX/Media Release

IMMUTEP ENTERS SECOND COLLABORATION WITH MSD FOR A NEW RANDOMISED PHASE IIB TRIAL IN HEAD AND NECK CANCER

- New Phase IIB trial called TACTI-003, to evaluate eftilagimod alpha in combination with MSD’s KEYTRUDA[®] (pembrolizumab) in 1st line head and neck squamous cell carcinoma (HNSCC)
- HNSCC is one of the more common cancers worldwide and has a high unmet medical need
- First patient is expected to be enrolled in mid-2021

SYDNEY, AUSTRALIA – 16 March 2021 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) (“Immutep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer, infectious disease and autoimmune disease, announces a second clinical trial collaboration and supply agreement with subsidiaries of Merck & Co., Inc., Kenilworth, NJ, USA (known as “MSD” outside the United States and Canada). Under the agreement, Immutep will conduct a new Phase IIB clinical trial in 1st line HNSCC patients, as initially described in the ASX announcement dated 28 September 2020.

The trial, called TACTI-003 (Two Active Immunotherapies), will be a 1:1 randomised, controlled clinical study in approximately 160 1st line HNSCC patients. It will evaluate the safety and efficacy of Immutep’s lead product candidate, eftilagimod alpha (efti or IMP321), when given in combination with MSD’s KEYTRUDA[®] (pembrolizumab), compared to pembrolizumab alone. TACTI-003 will take place in 20+ clinical sites in the United States, Australia and Europe, and the first patient is expected to be enrolled in mid-2021.

The combination of efti and KEYTRUDA is also being evaluated in Immutep’s ongoing Phase II TACTI-002 study. The promising clinical results generated to date from the TACTI-002 trial have prompted the initiation of the new TACTI-003 trial. The combination brings together two immuno-oncology treatments with complementary mechanisms of action at two different positions in the cancer immunity cycle. Efti is a first-in-class antigen presenting cell activator which stimulates cancer-fighting T cells, while KEYTRUDA is an anti-PD-1 therapy which blocks the immunosuppressive PD-1 pathway.

“We are excited to be deepening our collaboration with MSD through this second agreement and the TACTI-003 clinical trial. Advancing to this later stage Phase IIB trial will allow us to explore the combination therapy in the commercially relevant 1st line therapy setting which has a high unmet medical need,” said Immutep CEO Marc Voigt.

HNSCC is the sixth most common cancer by incidence worldwide, with 890,000 new cases and 450,000 deaths reported in 2018.^{1,2,3} HNSCC is an aggressive, genetically complex, and difficult to treat cancer.⁴ Furthermore, HNSCC is associated with high levels of psychological distress and compromised quality of life (QOL).⁵ As such, patients with HNSCC are very much in need of improved treatment options.

¹ Ferlay, J. et al. Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods. *Int. J. Cancer* 144, 1941–1953 (2019).

² Bray, F. et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J. Clin.* 68, 394–424 (2018).

³ Ferlay, J. et al. Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer (accessed 18 September 2020). *IARC* <https://gco.iarc.fr/today> (2018).

⁴ Alsahafi, E., Begg, K., Amelio, I. et al. Clinical update on head and neck cancer: molecular biology and ongoing challenges. *Cell Death Dis* 10, 540 (2019).

⁵ Johnson, D.E., Burtneiss, B., Leemans, C.R. et al. Head and neck squamous cell carcinoma. *Nat Rev Dis Primers* 6, 92 (2020).

About Immutep

Immutep is a globally active biotechnology company that is a leader in the development of LAG-3 related immunotherapeutic products for the treatment of cancer, infectious disease 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 is listed on the Australian Securities Exchange (IMM), and on the NASDAQ (IMMP) in the United States.

Immutep's current lead product candidate is efitlagimod alpha (efti or IMP321), a soluble LAG-3 fusion protein (LAG-3Ig), which is a first-in-class antigen presenting cell (APC) activator being explored in cancer and infectious disease. Immutep is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 products, including antibodies for immune response modulation, are being developed by Immutep's large pharmaceutical partners.

Further information can be found on the Company's website www.immutep.com or by contacting:

KEYTRUDA[®] is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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This announcement was authorised for release by the board of Immutep Limited.