

ASX/Media Release

Immutep Announces GMP Manufacturing Process Developed for IMP761, a First-in-Class LAG-3 Agonist for Autoimmune Disease

Achievement Allows IND-enabling Studies in 1H'2023 and Subsequent Clinical Testing of IMP761 to Address Root Cause of Autoimmune Diseases

SYDNEY, AUSTRALIA – 06 December 2022 – [Immutep Limited](#) (ASX: IMM; NASDAQ: IMMP) ("Immutep" or "the Company"), a clinical-stage biotechnology company developing novel LAG-3 immunotherapies for cancer and autoimmune disease, announced today that a GMP compliant manufacturing process has been established for IMP761, its proprietary preclinical candidate for autoimmune diseases. The 200L scale attained by Northway Biotech, an end-to-end biopharmaceutical contract development and manufacturing organisation (CDMO), will ensure supply of IMP761 for IND-enabling studies and ensuing clinical trials.

As the first immunosuppressive agonist antibody to LAG-3 acting upstream on activated T cells to target the root cause of self-antigen-specific T cell induced disease, IMP761 is a potential game-changer in how autoimmune diseases are treated. Pre-clinical testing of IMP761 in oligoarticular juvenile idiopathic arthritis, published in [Pediatric Research](#) in May 2021, showed that agonistic activation of LAG-3 in this Th1-driven autoimmune disease setting resulted in a decreased secretion of nearly all measured cytokines, and that of IL-10, IL-12, IL-1 β , IL-4, and IL-6 reached the level of significance ($p < 0.01$).

Immutep CEO Marc Voigt said: "We are pleased to have a GMP manufacturing process for IMP761 in hand with our manufacturing partner Northway Biotech as we move towards initiating IND-enabling studies in the first half of 2023 and subsequent clinical development. As a first-in-class LAG-3 immunosuppressive antibody, IMP761 has been designed to address the root cause of autoimmune diseases by specifically silencing self-reactive exhausted effector T cells that express LAG-3 and accumulate at disease sites."

Vladas Algirdas Bumelis, CEO of Northway Biotech stated: "Our world-class team in Vilnius worked diligently and expeditiously to develop the capability to produce this unique LAG-3 antibody at 200L scale. We continue to work closely with Immutep to accelerate the development of its first-in-class LAG-3 therapy and help advance this novel approach against autoimmune diseases that impair so many patients on a global basis."

The manufacturing process was developed on a platform technology of [Northway Biotech](#) resulting in a final product of high quality. An engineering and a GMP manufacturing run at 200L have been successfully performed for bulk drug substance and final filled drug product, proving the robustness and reproducibility of the developed manufacturing process. A stability program according to ICH guidelines has been initiated and will support the definition of a shelf life of the drug in its current formulation. After final release and batch certification, the produced material will be used for further preclinical development, including IND-enabling studies, and Immutep's planned clinical trials of IMP761.

About IMP761

IMP761 is a first-in-class immunosuppressive agonist antibody to LAG-3. As a targeted immunosuppressive

antibody, IMP761 has the potential to address the root cause of autoimmune diseases by specifically silencing autoimmune memory T cells that accumulate at the disease site and which express LAG-3 as an “exhaustion marker” after being repeatedly stimulated with dominant self-peptides.

In early 2019, Immutep reported encouraging pre-clinical results from its studies with IMP761. The in vivo studies showed that IMP761 decreases inflammatory T cell infiltration induced by intra-dermal injection of an antigen. These findings were published in the [Journal of Immunology](#) in January 2020. Additional pre-clinical research findings from a juvenile arthritis ex vivo model were published in [Pediatric Research](#) in May 2021. In these studies, IMP761 was shown to decrease effector T cell cytokine secretion.

About Immutep

Immutep is a clinical stage biotechnology company leading the development of LAG-3 related immunotherapy products for the treatment of cancer and autoimmune disease. The Company 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 lead product candidate is efitilgimod 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 in multiple clinical trials. The Company is also developing an agonist of LAG-3 (IMP761) for autoimmune disease. Additional LAG-3 product candidates, including antibodies for immune response modulation, are licensed to and being developed by Immutep’s large pharmaceutical partners.

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

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This announcement has been approved for release by the Board of Immutep Limited.