ASX/Media Release

IMMUTEP ANNOUNCES ADVANCEMENT OF PHASE II TRIAL FOR EFTILAGIMOD ALPHA IN COVID-19 PATIENTS TO RANDOMISED PORTION OF THE STUDY

- Independently reviewed safety run-in data prompts recommendation to initiate enrolment for the randomised portion of the Phase II EAT COVID study
- Up to 110 COVID-19 patients to participate in investigator-initiated study at the University Hospital Pilsen, Czech Republic

SYDNEY, AUSTRALIA – 27 January 2021 – Immunetep Limited (ASX: IMM; NASDAQ: IMMP) (“Immunetep” or “the Company”), a biotechnology company developing novel immunotherapy treatments for cancer and autoimmune disease, announced that an independent Data and Safety Monitoring Board (DSMB) has completed a safety run-in data review of the first six patients from the Phase II clinical trial of Eftilagimod Alpha Treatment by immune modulation in COVID-19 disease (EAT COVID), being conducted by the University Hospital Pilsen, Czech Republic. Following this data review, the DSMB recommended that the study advance with enrolment for the randomised portion of the study. All six patients (age range, 50-83 years; 2 women) received the three planned 10 mg efti injections and have since been discharged from hospital. No adverse events have been reported.

Professor Matejovic, Principal Investigator for the study, stated, “Sadly, hospitals and doctors in the Czech Republic are increasingly overwhelmed and are facing severe challenges treating the high volume of patients with COVID-19. Despite this, the DSMB has prioritized the review of the safety data for the first six patients in the EAT COVID Phase II study. We are pleased with their recommendation to continue the trial and move ahead with the randomised, placebo-controlled portion of the study.”

Dr. Frédéric Triebel, Immunetep CSO and CMO, commented, “There continues to be a significant need to develop therapeutics like efti to treat COVID-19 in patients with an insufficient immune response to overcome the viral spread. In the case of the EAT COVID study, efti is injected subcutaneously at close intervals, every three days. This strategy aims to quickly boost the rapidly evolving CD8 T cell responses seen in an acute infection.

The positive recommendation from the DSMB builds on efti’s strong safety profile reported in our clinical studies across several different indications to date. The results of the EAT COVID trial will also be valuable in providing insights into how efti could play a role in treating other acute infectious diseases that constitute a significant unmet medical need, as well as building preparedness for future epidemics and pandemics,” concluded Dr. Triebel.

About EAT COVID
The EAT COVID study (EudraCT n° 2020-002009-25) is evaluating the Company’s lead product candidate eftilagimod alpha (“efti” or “IMP321”) in hospitalised patients with COVID-19. The study aims to boost a patient’s immune response to prevent development of severe COVID-19 symptoms that require intensive
care and can lead to respiratory failure and death. As an antigen presenting cell (APC) activator, efti could help to control the viral load in hospitalized patients by boosting CD8 effector T cells.

Immutep has agreed to provide efti at no cost to the University Hospital Pilsen, which is funding the EAT COVID study. The trial is being led by Principal Investigator, Professor Martin Matejovic, the Head of Medical Department at University Hospital Pilsen, Professor of Medicine at University Hospital Pilsen and Charles University Medical School. The trial is also being conducted in collaboration with Dr. Dalibor Sedlacek, Associate Professor of Medicine and Head of the Department of Infectious Diseases, along with Dr. Marek Nalos, Associate Professor of Medicine and Head Medical ICU at Department of Intensive Care Medicine of the Nepean Hospital, Sydney.

The study is a placebo controlled, 1:1 randomised, double blinded Phase II clinical trial involving up to 110 adult patients hospitalised with COVID-19 at University Hospital Pilsen. Patients will receive subcutaneous injections of efti (10 mg) on days 1, 3 and 7, in addition to standard care. The study’s primary endpoint is the patient’s clinical status at day 15 as per the WHO recommended evaluation scale.

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 and autoimmune disease. Immutep is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize 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 eftilagimod 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:

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