

ASX Announcement

Clinical Trial Supply Agreement with Imugene and Roche to Evaluate PD1-Vaxx in Combination with an Immune Checkpoint Inhibitor for Treatment of Lung Cancer

Sydney, Australia, 28 January 2022 AEDT: Imugene (ASX: IMU) today announced a new clinical trial supply agreement with Roche to evaluate the safety and efficacy of Imugene's PD1-Vaxx, a B-cell activating immunotherapy, in combination with atezolizumab (Tecentriq®), an immune checkpoint inhibitor targeting PD-L1, in patients with non-small cell lung cancer (NSCLC).

The objectives of the phase 1b trial, "An Open Label, Multi-Center, Dose Escalation/Expansion, Phase 1 Study of IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as monotherapy or in combination with atezolizumab, in Adults with Non-Small Cell Lung Cancer," are to determine safety, efficacy, and optimal dose of PD1-Vaxx in combination with atezolizumab as either first-line therapy in ICI treatment-naïve NSCLC patients or ICI pretreated patients. The study will be conducted at sites in USA and Australia.

Dual targeting of the PD-1/PD-L1 axis is an area of considerable interest with ongoing clinical results providing treatment options for patients with cancer. Combination with PD1-Vaxx may overcome treatment resistance to ICIs with dual inhibition of the PD-1/PD-L1 axis extending the treatment benefit of atezolizumab. In contrast to combination of two monoclonal antibodies, PD1-Vaxx has the advantage that it induces a unique polyclonal immune response which may increase response rates for the combination therapy.

Tecentriq has previously shown clinically meaningful benefit in various types of lung cancer, with six currently approved indications in the US. In addition to becoming the first approved cancer immunotherapy for adjuvant NSCLC, Tecentriq was also the first approved cancer immunotherapy for front-line treatment of adults with extensive-stage small cell lung cancer (SCLC) in combination with carboplatin and etoposide (chemotherapy). Tecentriq also has four approved indications in advanced NSCLC as either a single agent or in combination with targeted therapies and/or chemotherapies.

"It's an outstanding accomplishment to see Imugene collaborate with Roche, in combination with our PD1-Vaxx drug. PD1-Vaxx has shown a tolerable safety profile and encouraging efficacy in patients with NSCLC, and we are looking forward to evaluating PD1-Vaxx with atezolizumab in ICI treatment-naïve and pretreated NSCLC patients." said Leslie Chong, Managing Director & Chief Executive Officer of Imugene.

Imugene and Roche have entered into a supply agreement for a period of up to five years for the supply of atezolizumab. Imugene will be the sponsor of the study and will fund the clinical study from existing budgets and resources. Roche will supply atezolizumab for the duration of the study. In accordance with the terms of the supply agreement, all data generated in the performance of the study shall be the property of Imugene as the sponsor and all rights to all inventions and discoveries made or conceived in the course of the study relating to the combination of atezolizumab and PD1-Vaxx shall belong jointly to Roche and Imugene.

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About NSCLC

Lung cancer is one of the leading causes of cancer death globally. Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day. Lung cancer can be broadly divided into two major types: NSCLC and SCLC. NSCLC is the most prevalent type, accounting for around 85% of all cases.

About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CART's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

*Release authorised by the Managing Director and Chief Executive Officer
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