ASX Announcement

Imugene Announces Presentation for Lead HER-2 Cancer Immunotherapy at the American Association for Cancer Research 2021 Annual Meeting

SYDNEY, Australia, 12 April 2021: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced Chief Medical Officer Dr Rita Laeufle presented on the HER-Vaxx cancer immunotherapy program at the American Association for Cancer Research (AACR) 2021 Annual Meeting.

The abstract presentation was entitled 'A PHASE 1B/2 OPEN-LABEL STUDY WITH RANDOMIZATION IN PHASE 2 OF IMU-131 HER2/NEU PEPTIDE IMMUNOTHERAPY PLUS STANDARD OF CARE CHEMOTHERAPY IN PATIENTS WITH HER2/NEU OVEREXPRESSING METASTATIC OR ADVANCED ADENOCARCINOMA OF THE STOMACH OR GASTROESOPHAGEAL JUNCTION.'[1]

Dr Laeufle expanded on previously presented interim analysis data in 2020. To recap previously released results;

- Interim analysis in the randomized Phase 2 showed statistically significant overall survival Hazard Ratio (HR) of 0.418 (80% 2-sided CI: 0.186, 0.942); HER-Vaxx showed a reduced risk of death of 58.2% in the HER-Vaxx plus chemotherapy group as compared to chemotherapy alone.
- The median overall survival (OS) for patients receiving HER-Vaxx plus chemotherapy was 14.2 months, compared to 8.8 months in patients treated with chemotherapy alone.
- The Phase 2 data represent a clinical proof-of-concept signal for HER-Vaxx when added to chemotherapy and indicate that B-cell activating immunotherapy vaccines can induce clinically active antibody responses.
- The Independent Data Monitoring Committee (IDMC) confirms a favourable survival outcome with no added toxicity for HER-Vaxx combined with SOC chemotherapy over chemotherapy alone and advises to lower the number of patients required for study completion.
- Recruitment of the Phase 2 trial was completed in January 2021.

The AACR presentation highlights and presents the following new data;

- Treatment with HER-Vaxx clearly demonstrates that all patients develop high levels of HER2-specific antibodies early in the treatment protocol.
- Analysis of the antibody data reveals high levels are maintained during the treatment and maintenance phases, with only minimal booster injections of HER-Vaxx required to maintain the high levels.
- The constant and high HER2 antibody levels correlate with the early separation of the Kaplan Meier (KM) Curves for overall survival (OS) and progression free survival (PFS) clinical trial endpoints. The Kaplan Meier Curve provides a recognised statistical estimation of the survival function which visually represents the probability of an event occurring for each treatment arm at a respective time interval.
- Overall, this interim data is suggestive that the treatment is effective and well tolerated with an overall survival benefit that is superior to chemotherapy alone.

Final tumour response, correlation of antibodies with tumour response, and final PFS and OS data is expected to read out in 2021.

Imugene's HER-Vaxx is a B-cell peptide cancer immunotherapy designed to treat tumours that over-express the HER-2/neu receptor, such as gastric, breast, ovarian, lung and pancreatic cancers. The immunotherapy is constructed from several B cell epitopes derived from the extracellular domain of HER-2/neu. It has been shown in pre-clinical studies and in Phase 1 and 2 studies to stimulate a potent polyclonal antibody response to HER-2/neu, a well-known and validated cancer target.

The content of the presentation including a voice-over by Dr Laeufle has been uploaded to the Imugene website.

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[1]AACR Annual Meeting 2021 Abstract for Category: CT02 Phase II Adult Clinical Trials

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Interim Analysis Results

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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 tumors. 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. 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