B Cell Immunotherapy
IMUGENE

ASX:IMU

Fact Sheet

HER-VAXX B CELL PEPTIDE VACCINE

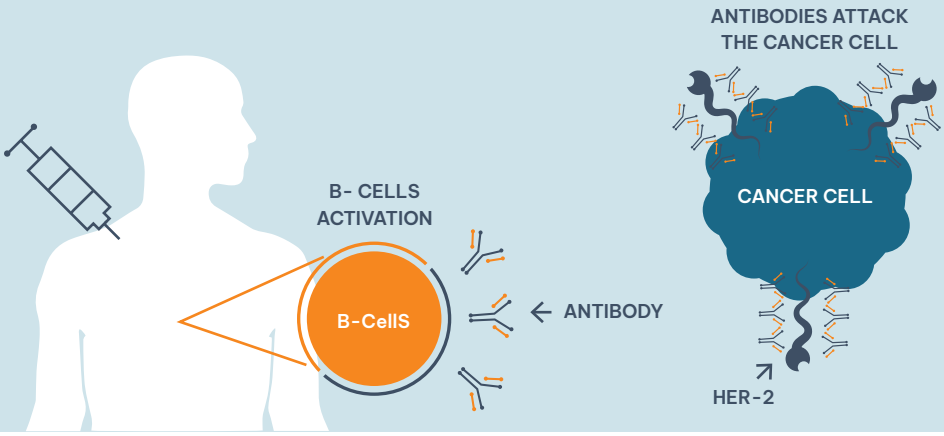
HIGHLIGHTS

- **The HER-2 oncogenic receptor is present and over-expressed in many cancer cells including gastric, breast, lung and colorectal.**
- **HER-Vaxx is a B-Cell cancer vaccine generating an antibody and cellular immune response to HER-2, as opposed to T-Cell cancer vaccines which promote only a cytotoxic T-Cell response.**
- **HER-Vaxx consists of three B-Cell epitopes derived from and targeting three regions of the extracellular domain of HER-2 (P4, P6, and P7) as opposed to monoclonal antibodies (mAbs) which only target a single region.**
- **HER-Vaxx induces a polyclonal antibody response with similar anti-tumour activity as marketed HER-2 mAbs.**
- **Unlike HER-2 targeting mAbs that are synthetically manufactured, Imugene's approach involves activating the patients' own immune system to produce a continuous supply of anti-HER-2 antibodies.**
- **HER-Vaxx Phase 1b/2 clinical trial in gastric cancer completed with a 42% overall survival benefit for patients treated with HER-Vaxx plus SOC chemotherapy compared to SOC chemotherapy alone (HR = 0.580) and a longer DOR (30 vs 19 weeks).**
- **HER-Vaxx has a tolerable safety profile, with no additive adverse events over SOC chemo.**
- **HER-Vaxx combination with checkpoint inhibitor and other HER-2 targeting therapies is ongoing.**
- **Robust IP to 2036 with the technology being extensively published in peer-reviewed journals.**

B-Cell VACCINE ADVANTAGES

- Lower cost of production: B-Cell immunotherapies are less expensive to manufacture than mAb drugs.
- The polyclonal antibody response may reduce the risk of the tumour becoming resistant to therapy and could potentially improve efficacy.
- The vaccine stimulates continuous antibody production and cellular response via a lasting immune activation that may inhibit tumour recurrence (memory).
- The natural polyclonal antibodies produced following vaccination are potentially safer than synthetic mAb drugs and may avoid toxic side effects of mAb administration, such as infusion reactions, ventricular dysfunction, congestive heart failure or anaphylaxis.
- Subcutaneous or intramuscular injection of the vaccine is more convenient and cost effective for health providers/payers than intravenous infusion of mAb drugs.

HOW IT WORKS



Clinical product, HER-Vaxx, a B-Cell peptide vaccine targeting the HER-2 cancer receptor, has completed Phase 1 and 2 clinical trials in advanced HER-2 positive + gastric cancer. Developed by leading scientists at Imugene and the Medical University of Vienna in Austria, the vaccine is constructed from three B-Cell epitopes from the extracellular domain of HER-2/neu.

Intellectual Property

Four patent families, long-life patent coverage out to 2036, all patents granted in all major jurisdictions

No known infringements or disputes – Freedom to Operate

PHASE 1/2 HER-VAXX CLINICAL TRIAL (COMPLETED)

- The Phase 2 HER-Vaxx HERIZON study was designed to measure the efficacy, safety and immune response in patients with metastatic gastric cancer overexpressing the HER-2 protein. The study was randomised into two arms of either HER-Vaxx plus SOC chemotherapy or SOC chemotherapy alone. The primary endpoint was overall survival and secondary endpoint was progression-free survival. Safety, tolerability and immune response was also measured.
- The Phase 2 trial was conducted at multiple sites across Eastern Europe and India where clinicians have limited access to approved antibody treatments such as Herceptin® and Perjeta® due to a lack of regulatory approval and reimbursement. There was also a high prevalence of gastric cancer in the countries selected.
- The final analysis results from the randomised clinical Phase 2 HERIZON study, which was designed with a specified 1-sided false positive probability of 0.10, showed a 42% overall survival benefit for patients treated with HER-Vaxx plus SOC chemotherapy compared to SOC chemotherapy alone. This translated into an overall survival HR of 0.580 (80% 2-sided CI: 0.368, 0.930) with a statistically significant p-value of 0.066 and a longer DOR (30 vs 19 weeks). There was no difference in safety events between the two treatment arms, suggesting that HER-Vaxx does not add toxicity to SOC chemotherapy.
- The longest HER-Vaxx treated patients remain alive 2.5 years (with one patient approaching 3 years) after starting therapy. It is noteworthy that these patients generated the strongest anti-HER-2 antibody levels from their dosing schedule on HER-Vaxx.

HER-Vaxx Literature

Transl Oncol. 2022 May;19:101378. doi: 10.1016/j.tranon.2022.101378
https://pubmed.ncbi.nlm.nih.gov/35259675/

Clin Cancer Res. 2021 Jul 1;27(13):3649-3660. doi: 10.1158/1078-0432.CCR-20-3742
https://pubmed.ncbi.nlm.nih.gov/33879458/

BMC Cancer. 2017 Feb 9;17(1):118. doi: 10.1186/s12885-017-3098-7
https://pubmed.ncbi.nlm.nih.gov/28183282/

ESMO Open, 2022, 7, 100361 doi.org/10.1016/j.esmoop.2021.100361
https://www.sciencedirect.com/science/article/pii/S2059702921003239

B Cell Immunotherapy
IMUGENE

ASX:IMU

Headquarted in Australia, Imugene is a clinical stage immuno-oncology company developing a range of new treatments that activate the immune system of cancer patients to identify and eradicate tumours.

info@imugene.com
imugene.com