

Advanced B Cell Immuno-oncology Vaccine For HER-2+ Gastric and Breast Cancer

- *news update*
- *investor update*



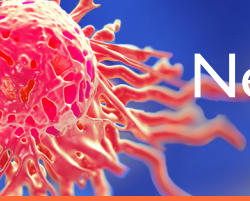
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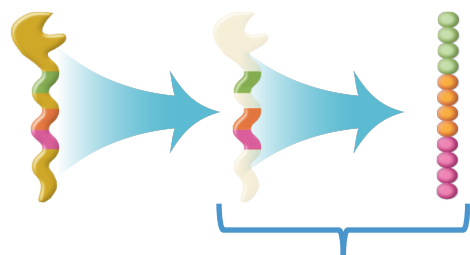
News Update: HER-Vaxx Reformulation Shows Dramatic 10x Increase in Antibodies (20 Apr 2015)

- Preclinical studies (announced Sep 14) determined a simpler vaccine conjugate than virosomes, CRM₁₉₇, gives rise to additional benefits for HER-Vaxx:
 - Earlier antibody titer increase
 - Significant after 2 vaccinations
 - Peak response after 3 vaccinations
 - Larger antibody titer production
 - Up to 10x previous formulation
- Benefits include
 - Potentially extending patent life from 2030 to 2036 – **more years at peak sales**
 - Improved cost of goods for final product – **greater margin when on market**
 - Simpler, lower cost and reduction of risk in manufacturing – **less risk and more efficient use of cash reserves**
 - **Improved chance of success in clinical trials**

Evolution of HER-Vaxx (I)

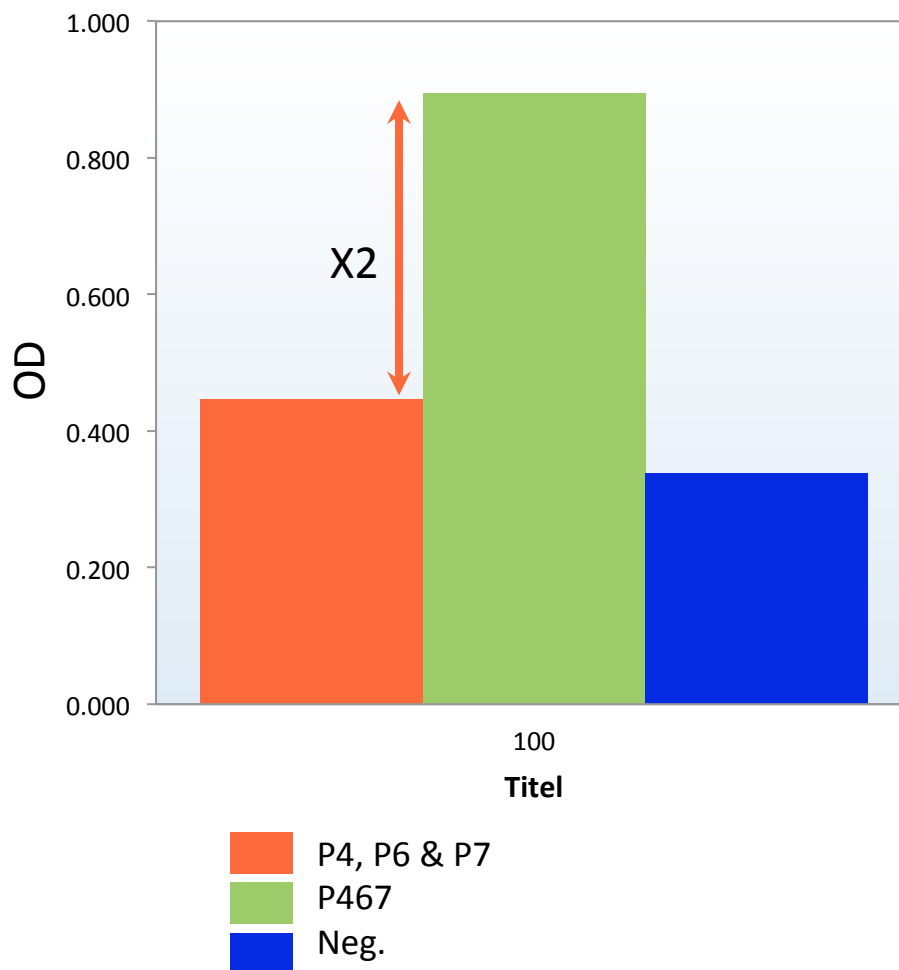


- Formulation improvements enhance immunogenicity and extend patent life
- Evolution 1: fuse three B-cell epitopes together to yield P467
- Result: strong ($>2x$) increase in antibody response c/w three single epitopes
- Evolution 1 extended patent life to 2026



HER-Vaxx: Evolution 1

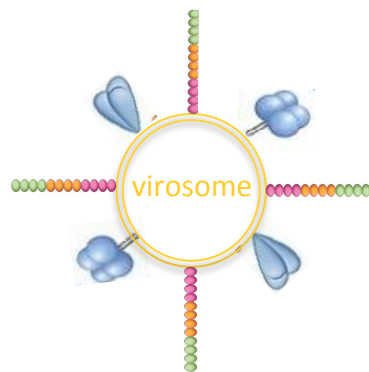
Reactivity against HER2 native protein



Evolution of HER-Vaxx (2)

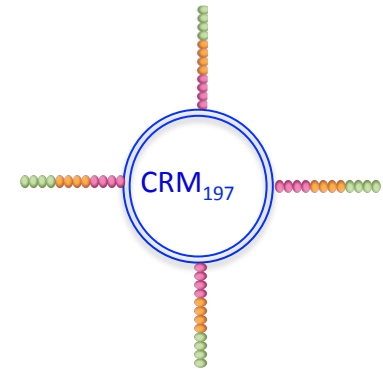


- Evolution 2: switch from influenza virosomes to well known alternate vaccine conjugate CRM₁₉₇ plus adjuvant (2015)



HER-Vaxx virosome
(Evolution 1)

HER-Vaxx: Evolution 2



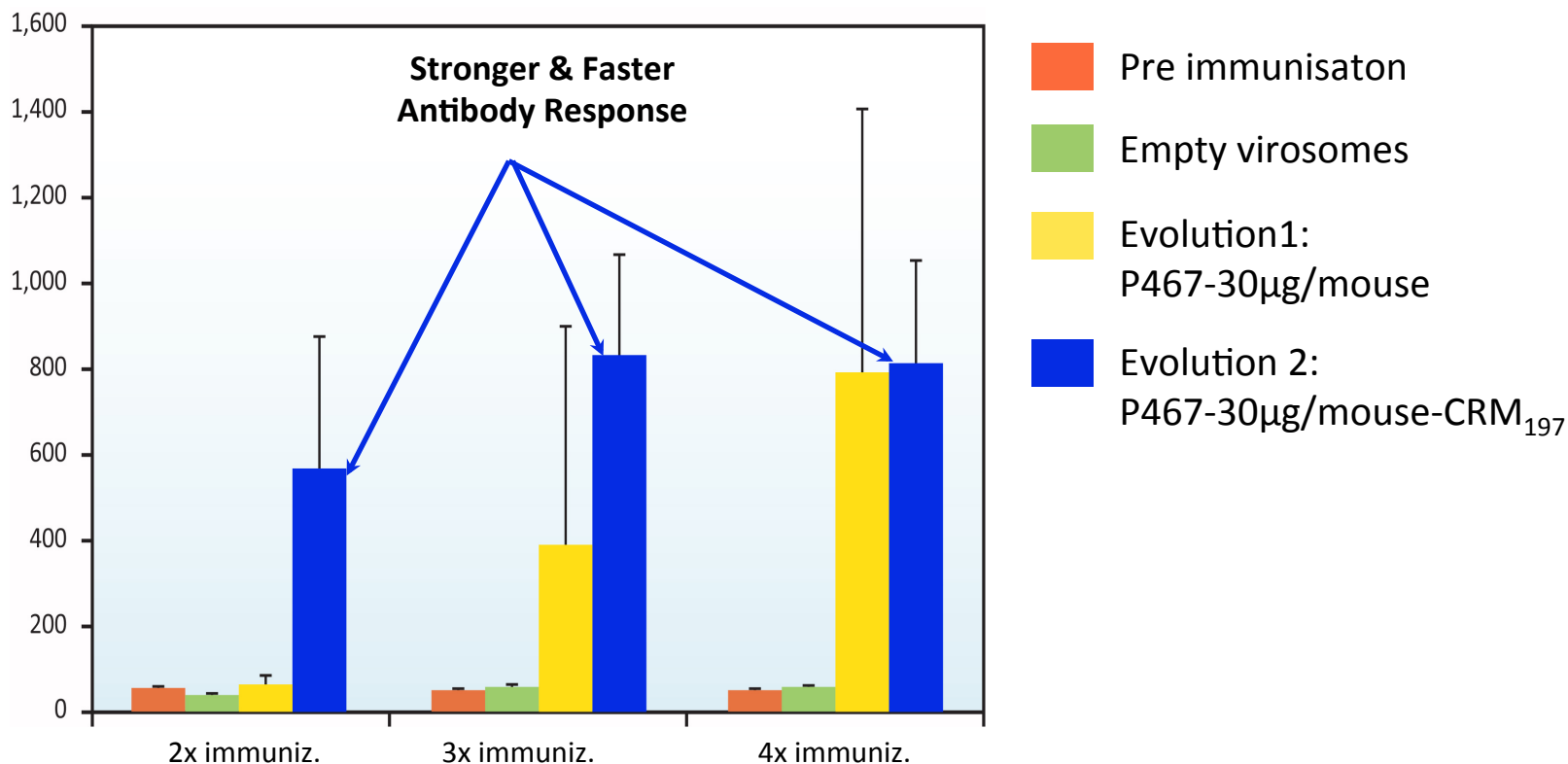
HER-Vaxx virosome
(Evolution 2)

- Result:
 - ***dramatic (up to 10x) increase in antibody response*** c/w Evolution 1 vaccine
 - ***faster onset of immune response***
- Potential extension of patent life from 2030 to 2036

Early Onset Of Response For New Formulation



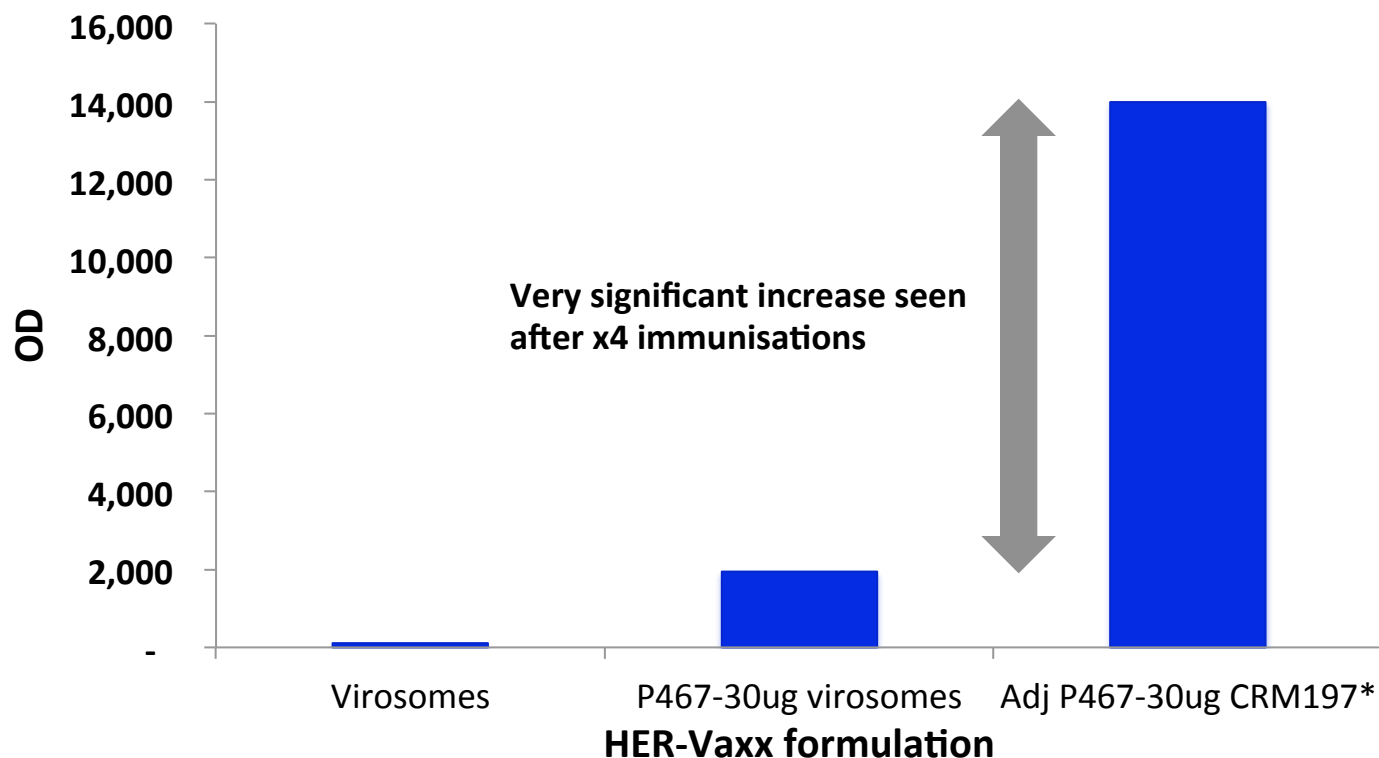
Antibody levels against HER-2/neu from P467 virosome and P467 CRM₁₉₇ conjugates



Up to 10 times Increase in Antibody Production

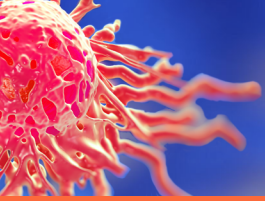


Anti-P467 Antibody Titres In Mice After 4 Immunisations For HER-Vaxx Formulations



* Data adjusted for comparison; original data generated for P467-30ug CRM₁₉₇ generated with 1/20th of the concentration of comparable virosome formulation. Adjustment may be subject to variation

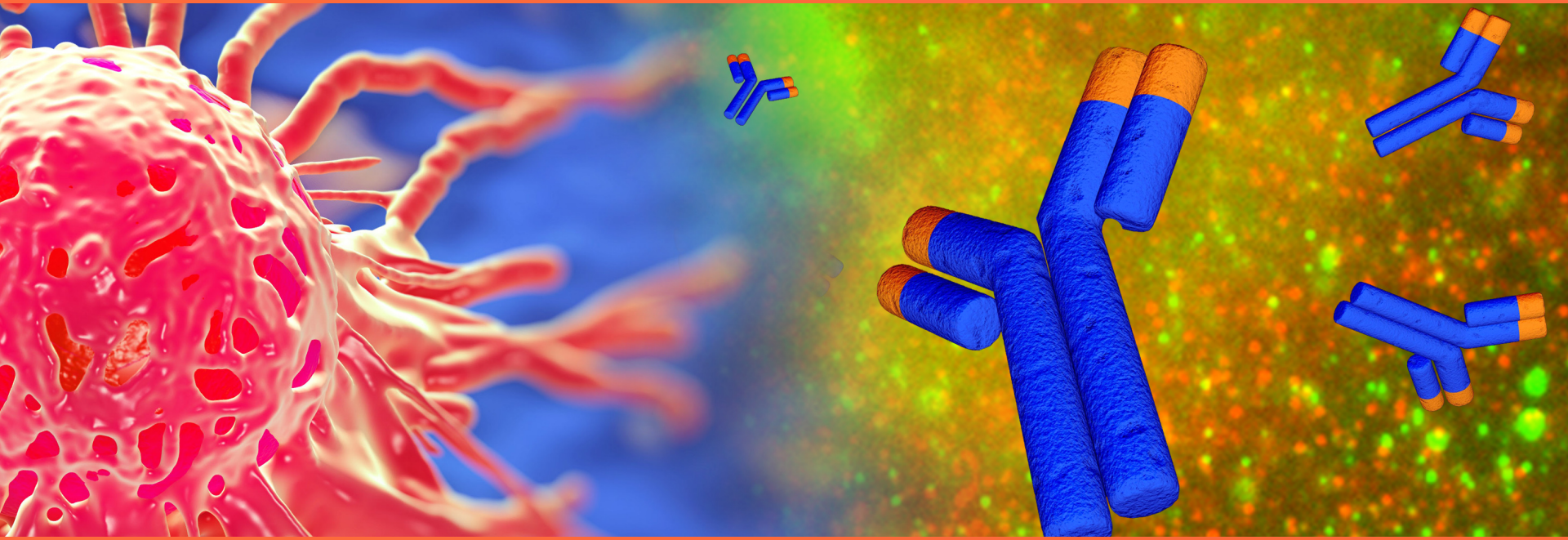
NOTE: Actual antibody levels vary depending on number of immunisations, dose used and characteristics of antibodies under observation.



Summary



- HER-Vaxx CRM₁₉₇ gives rise to additional benefits for HER-Vaxx:
 - Earlier antibody titre increase
 - Higher antibody titre production
- Benefits include
 - Potentially extending patent life from 2030 to 2036 – **more years at peak sales**
 - Improved cost of goods for final product – **greater margin when on market**
 - Simpler, lower cost and reduction of risk in manufacturing – **meet milestone targets**
 - **Improved chance of success in clinical trials**

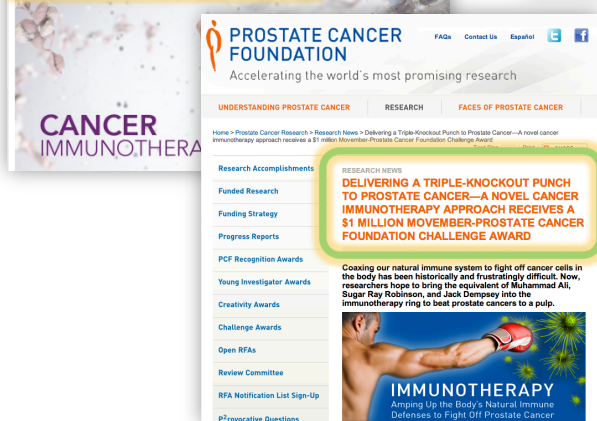
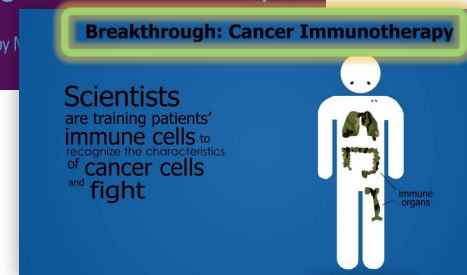
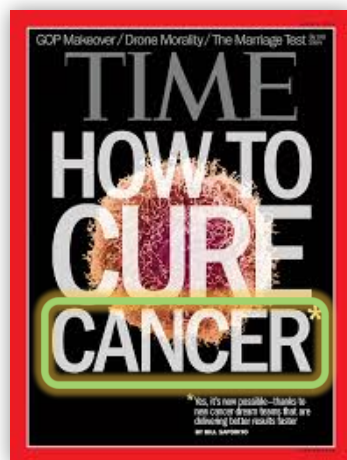


Corporate Presentation

IMU is in the Hottest Area of Oncology Today



Imugene is an immunotherapy company developing a B-cell based vaccine, known as HER-Vaxx, for HER-2 positive gastric & breast cancer, in the hottest area of oncology today – IMMUNO-ONCOLOGY

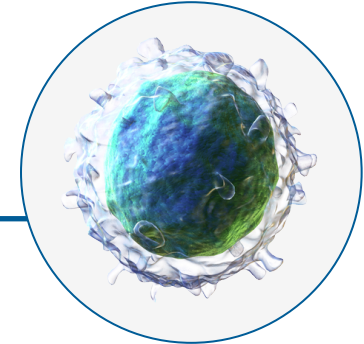


What is Immunotherapy?

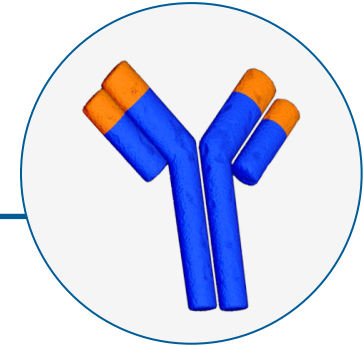


- Immunotherapy is the treatment of cancer with substances that stimulate the patient's immune response – known as active immunisation
- Unlike chemotherapy, immunotherapy drugs do not target the cancer directly
- Immunotherapy helps the patient's own immune system recognise & attack cancer cells
- Typical immune responses are:
 - B Cells making antibodies with anti-tumour activity
 - T cells help B cells make antibodies and help to attack the cancer

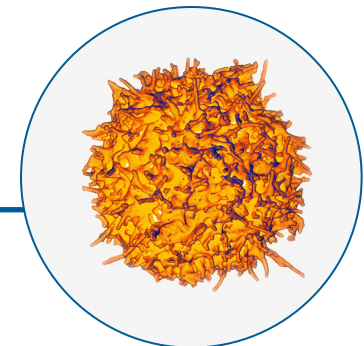
B Cell



Antibody



T Cell



Imugene At A Glance (ASX:IMU)



- Developing a B-cell based immunotherapy/vaccine known as HER-Vaxx, for HER-2 positive gastric & breast cancer
- Phase 1 trial completed in patients with HER-2+/++ breast cancer
- Phase 1b/2 trial to begin 2H 2015
- Technology originates from Medical University of Vienna, one of Europe's leading cancer institutes
- Market capitalisation (Apr 2015): AUD13.3m
- Share price (Apr 2015): AUD1.0¢
- Average daily trade: 1.01m shares
- Shares outstanding: 1,329,912,516
- Cash & equivalents (Dec 31 2014): AUD3.0m



AUSTRALIAN SECURITIES EXCHANGE

Investment Highlights



Compelling Science

- B-cell peptide cancer immunotherapy that induces antibody responses targeting HER-2 over expressing tumors

Phase 1 Completed

- Anti- HER-2 antibody responses, T helper cytokines, T reg cells suppressed, therapy safe

Commercially Validated Target

- Targeting same receptor as Roche's \$6.4 bn breast cancer drug Herceptin

News Flow

- Numerous milestone announcements & valuation inflection points over next 12-24 months

Robust IP

- IP with exclusivity until 2030, granted in all major jurisdictions. Aim now for 2036 with reformulation

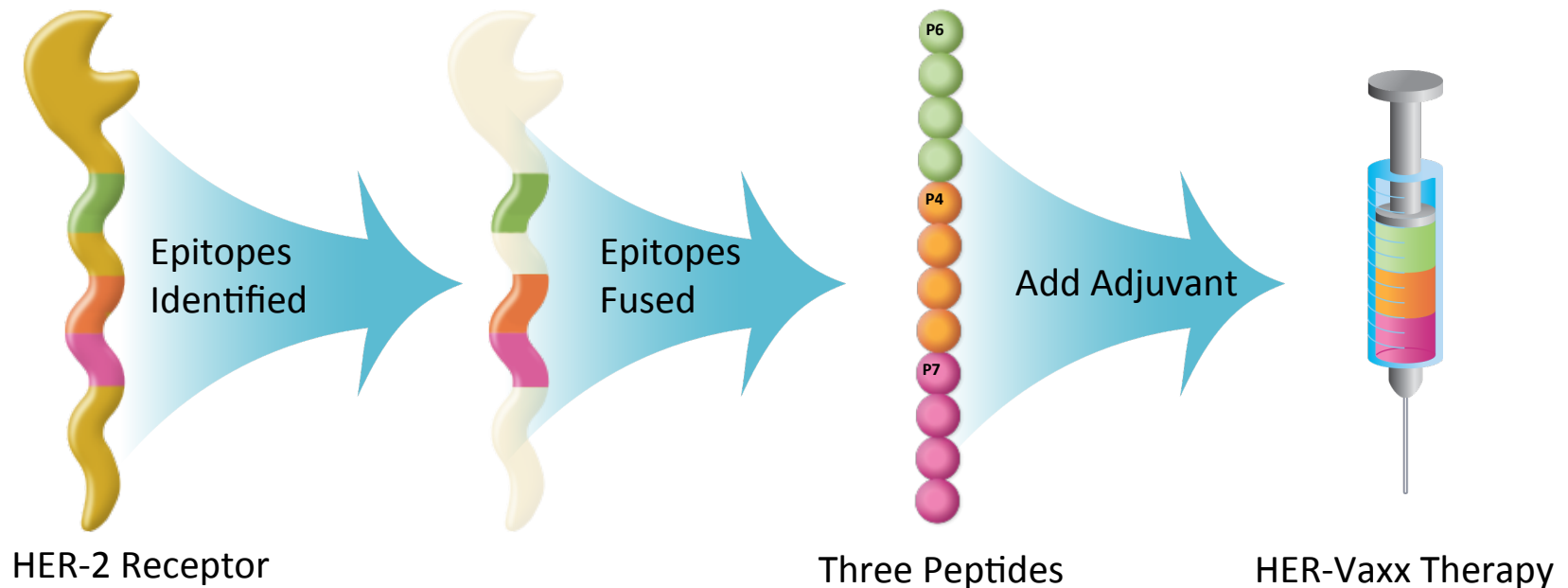
Leadership

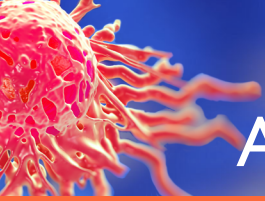
- Experienced management & board

What is HER-Vaxx Therapy?



- HER-Vaxx is a B-cell vaccine designed to stimulate a patient's own immune system to produce antibodies to repeatedly attack the cancer
- Stimulates a patient's B cells to produce polyclonal antibody responses that target cells with overexpressing HER-2 receptors on their surface
- Targets HER-2 positive cancer – about 20% of patients with gastric cancer are “HER-2 positive” i.e., they have the HER-2 receptor on their cancer cells





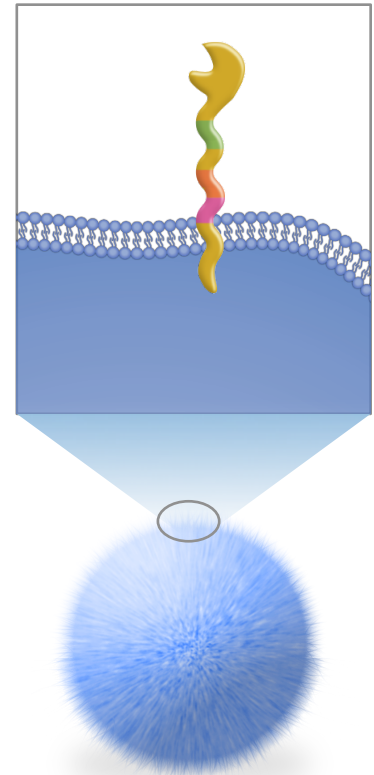
What is HER-2?



A Clinically & Commercially Validated Cancer Target

- HER-2 is a “hair-like” receptor found on the surface of many gastric & breast cancer cells (20-30%)
- HER-Vaxx targets HER-2 – if you attack Her-2 the cancer cell will die
- Too much HER-2 (over expression) in breast cancer is associated with:
 - High chance that the tumour grows quickly and spreads
 - Greater probability of local & systemic recurrence
 - Resistance to treatment
- HER-Vaxx targets HER-2 – if HER-2 is successfully targeted, the cancer will stop growing and die
- HER-2 is a clinically & commercially validated cancer target with Roche's Herceptin being the largest selling drug in the world for HER-2 positive breast cancer

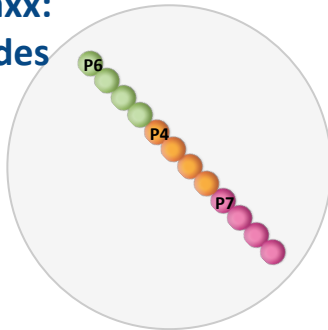
HER-2 Receptor



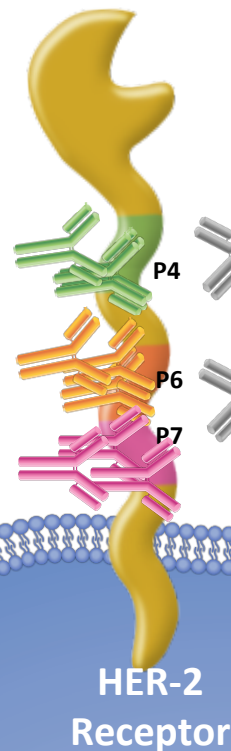
HER-Vaxx Attacks the Same Cancer Receptor as 3rd Largest Cancer Drug Worldwide



HER-Vaxx:
3 peptides



HER-Vaxx: x3
polyclonal
responses



HER-2
Receptor

Tumor cell

Binding site of
PERJETATM
pertuzumab

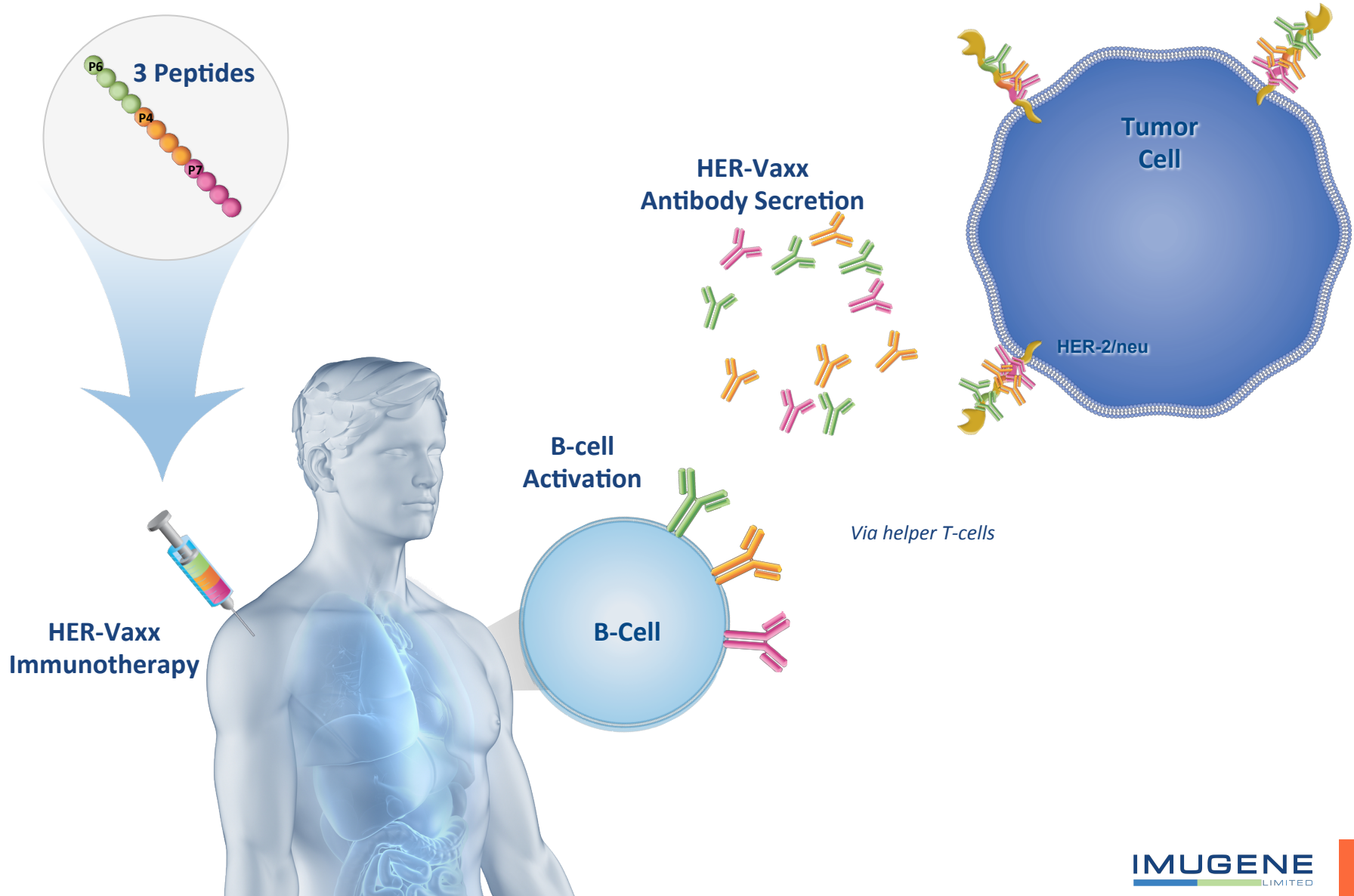
Binding site of
Herceptin[®]
trastuzumab

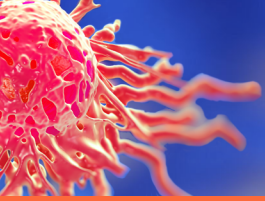


Monoclonal
response

\$6.4bn worldwide sales

HER-Vaxx: Mechanism Of Action – How it Works

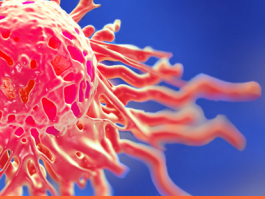




HER-Vaxx Key Differentiation



- B cell vaccines are an open frontier for immunotherapy, unlike T cell vaccines which have been exhaustively researched
- Her-Vaxx is a universal vaccine & can be used for all patient types irrespective of their “HLA haplotypes”, an issue which impacts T cell vaccines
- HER-Vaxx generates several polyclonal responses that may be superior to treatment with a monoclonal antibody like Herceptin
- Toxicity of Her-Vaxx is negligible
- HER-Vaxx induces IFN γ production that can influence the tumour micro environment and suppresses T Reg cells which are enhanced in cancer patients & which assist tumor evasion mechanisms – thereby the efficacy of the Her-Vaxx might be enhanced
- Potential as an adjuvant therapy i.e., post surgery
- **HER-Vaxx is active immunisation – Herceptin is passive immunisation**

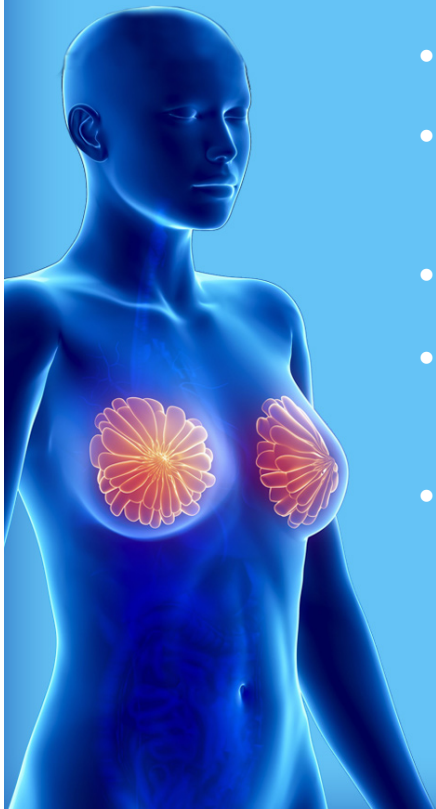


Active V. Passive Immunisation

Her-Vaxx: Active	Herceptin/Others: Passive
Stimulates patient's immune system to induce anti-tumour defense mechanisms, i.e. antibodies and cytokines; immune responses are long lasting	Product is manufactured & administered to patient. Short lasting, because the antibodies are naturally broken down, & if there are no B cells to produce more antibodies, they will disappear
Immunological memory is established – protection can be enhanced by booster vaccination	No memory – repeated dosing required to sustain efficacy
Likely to be safer since more natural to engage immune system response directly	Synthetic product does not engage immune system

Clinical Status:

Phase I Breast Trial Completed



Design

- n=10
- All metastatic breast cancer patients
- HER-2 +/-
- Life expectancy > 4 months
- Conducted at Medical University of Vienna

Clinical Endpoints

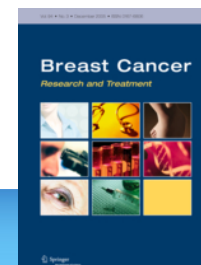
- 1 Safety and Tolerability
- 2 **Immunogenicity:** antibodies/humoral and cellular responses

Clinical Status:

Phase I Breast Trial Completed

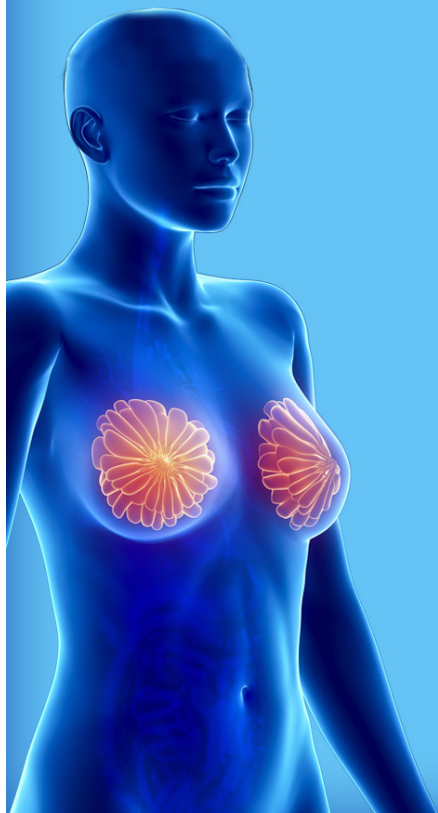


Wiedermann et al.,
Breast Cancer Res Treat
(2010)119:673 - 683



Observations

- Patients developed anti-HER-2 antibodies
- Induction of cytokines (Th1 biased; IFN γ)
- Induction of memory T & B cells post vaccination
- Reduction in T reg cells post vaccination, indicating strong vaccine response
- Antibodies induced displayed potent anti-tumor activity
- Results were even more promising given patients were in end stage of disease and not primary target group



Phase 1b/2 Trial Design Gastric Cancer



Combined Phase 1b/2 clinical trial under IND



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Phase 1b lead-in

- Open label
- US IND
- 18 patients, x3 groups of 6 patients
- Combination with chemo
- Endpoints:
 - Dose of HER-Vaxx to use in Phase 2 part of study
 - Safety: any HER-Vaxx toxicity
 - Immunogenicity (anti-HER-2 antibody titers)
 - Test booster schedule (q 4 weeks or 8 weeks)

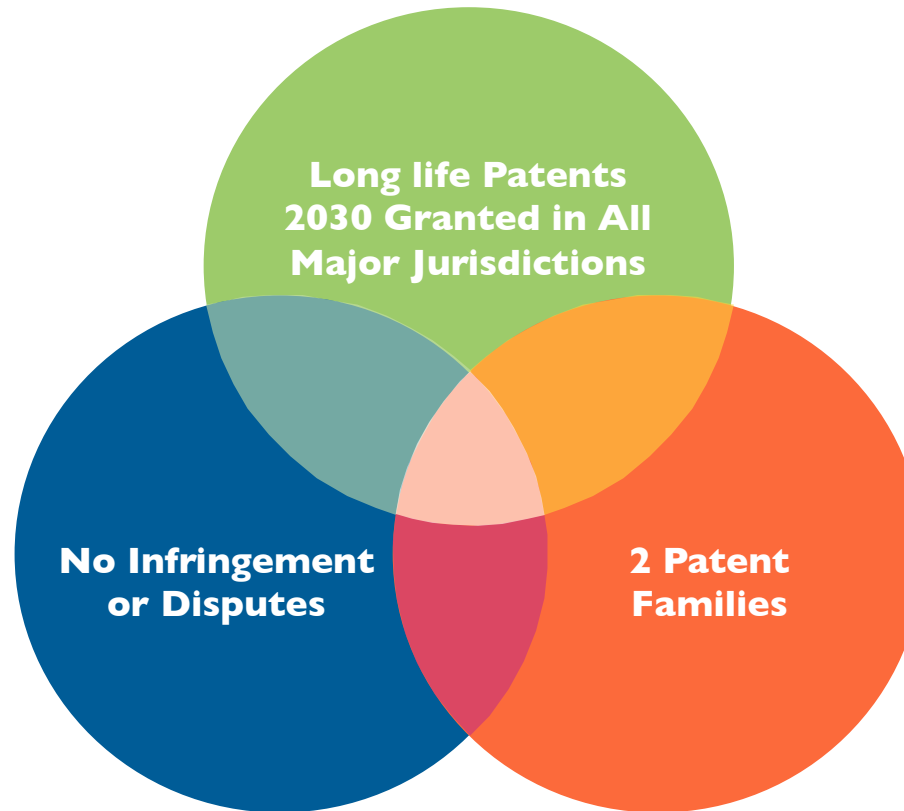
Phase 2 Trial

- ~68 patients from Australia & Europe
- Combination with chemo
- Efficacy, safety & immune response
- Randomised
- Endpoints:
 - Overall survival
 - Progression-free survival
- Secondary endpoint:
 - Immune response



Robust Intellectual Property Portfolio

100% Ownership



Patent Families

- ✓ Vaccine against cancer diseases that are associated with the HER-2/NEU oncogene
- ✓ Manufacturing patent for multi-epitope vaccine
- ✓ New patent filed for CRM₁₉₇ formulations with potential for coverage to 2036

Experienced Drug Development Team



Charlie Walker
Chief Executive
Officer



Prof Dr Ursula Wiederman
Scientific Founder
Principal Investigator,
Phase I, Preclinical
Imugene SAB

Professor of Vaccinology
Medical University of Vienna, Austria



Dr Axel Hoos
Director

VP, Oncology R&D, Glaxo SmithKline plc,
Head of the Discovery Performance Unit
for Immuno-Oncology & Combinations



Dr Chaline Strickland
Clinical & Reg.
Affairs

V-P Clinical & Reg Affairs at
Ground Zero Pharmaceuticals

Huge Gastric Market Opportunity



- Gastric cancer is the second leading cause of cancer mortality in the world & its management, especially in advanced stages, has evolved relatively little
- ~20% patients with metastatic gastric cancer are HER-2 positive
- Surgery, chemotherapy, radiation & Herceptin are the key treatments
- In many countries, particularly Asia, chemotherapy such as capecitabine and 5-FU, is the standard of care, not Herceptin
- Asia is the largest market for gastric cancer globally

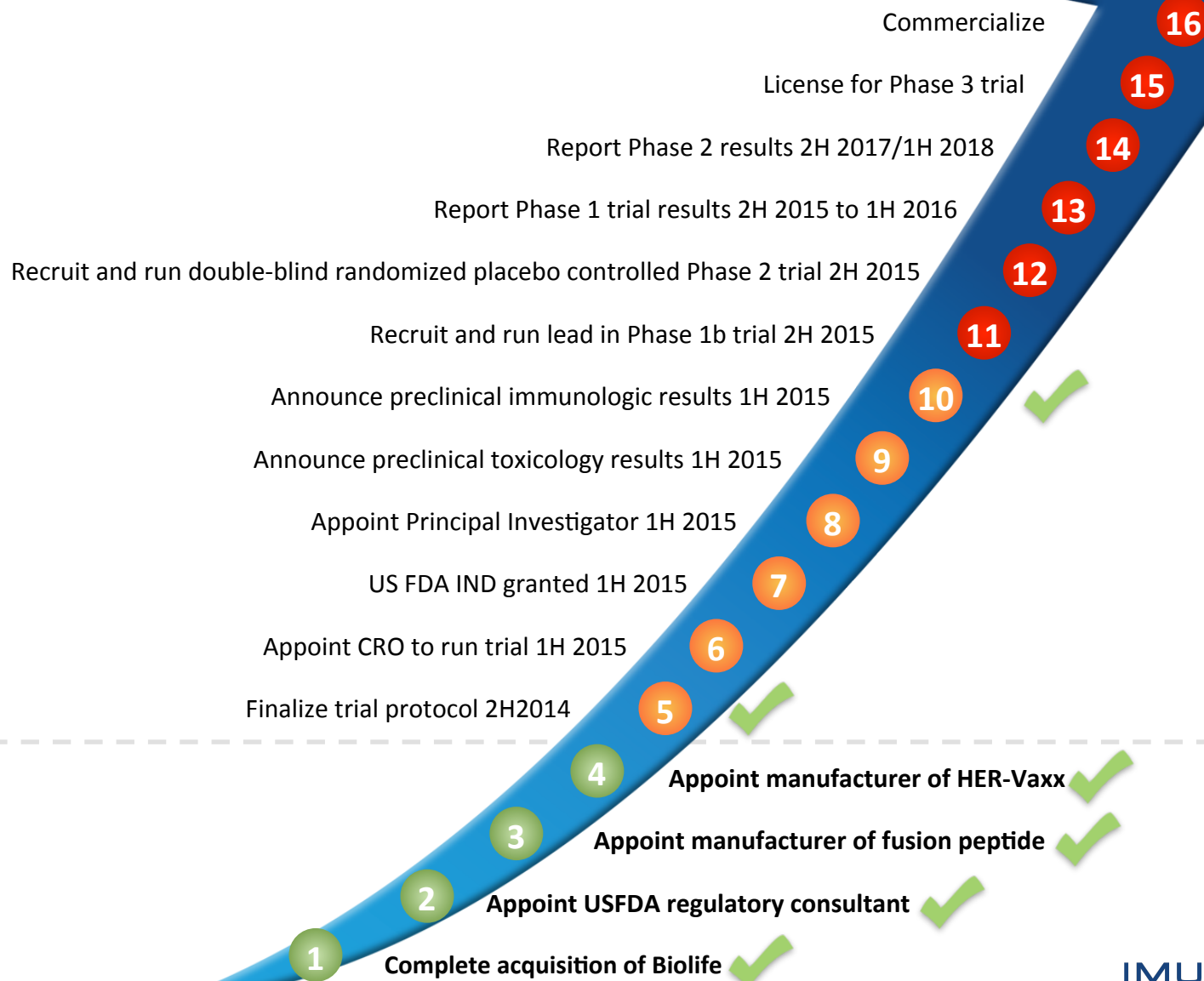


Chemotherapy



Monoclonal antibody

News Flow & Milestones



Leadership – Track Record



Charles Walker – *Managing Director*

- Former CEO and CFO of ASX-listed Alchemia
- 20+ years in the life science industry, including a decade in specialist corporate finance in London
- Executed ~50 capital markets transactions as principal and advisor



Paul Hopper - *Executive Chairman*

- Extensive international & ASX biotech capital markets experience particularly in immuno-oncology
- Head of Life Sciences Desk & Australia Desk at Los Angeles-based investment bank, Cappello Group
- Director Prescient Therapeutics, Chairman Viralytics, former Director pSivida, Somnomed & Fibrocell Science



Dr Axel Hoos - *Non-Executive Director*

- Currently Vice President Oncology R&D at GlaxoSmithKline
- Previously Clinical Lead on Ipilumimab at Bristol-Myers Squibb
- Co-Director of the think-tank Cancer Immunotherapy Consortium; Imugene is his only Board seat worldwide



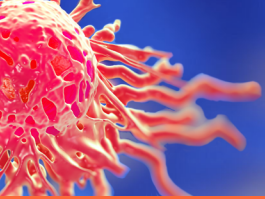
Otto Buttula - *Non-Executive Director*

- Extensive & successful experience in investment research & financial services management
- Active & substantial investor in the biotechnology sector with a particular focus on oncology
- Several significant positions in ASX-listed companies including Imugene



Dr Nick Ede - *Head of Manufacturing & Operations*

- Former CTO Consegna, CEO Adistem Ltd, CEO Mimotopes P/L, COO EQiTX Ltd (ZingoTX & VacTX)
- VP Chemistry Chiron (now Novartis), Research Fellow CRC Vaccine Technology



Why Imugene?

Scientific Provenance

- The subject of numerous peer reviewed published journals
- Medical University of Vienna, one of Europe's leading cancer institutes
- Technology developed over 10 years

In Good Company

- HER-Vaxx directed at validated target, HER-2
- HER-Vaxx addresses the multiple targets of Herceptin & Perjeta combined
- Herceptin sales USD6.4bn in 2013

Team

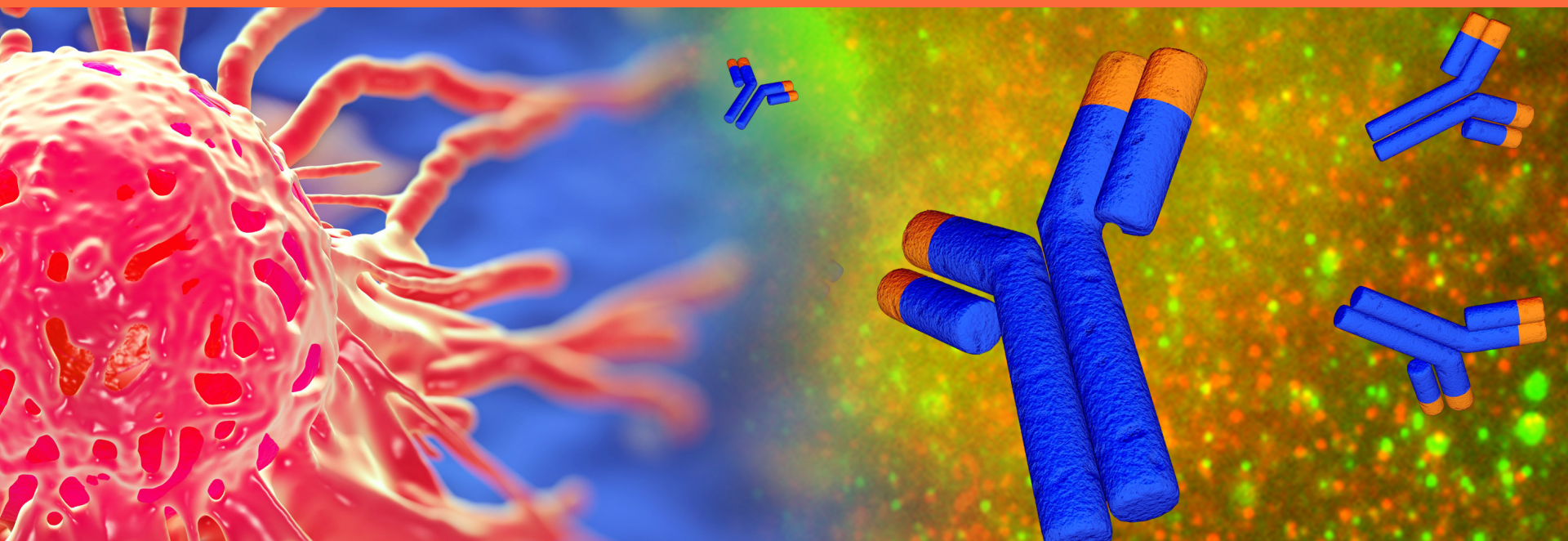
- Leading clinical & scientific experts; experienced management
- Board holds significant shares, aligning interests with shareholders

Phase 1 Results

- Safety & tolerability
- Immunogenicity: antibodies/ humoral & cellular responses

Data Points

- Focused 24 month program to deliver results/value inflection
- Attractively priced to capitalise on upcoming milestones



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