

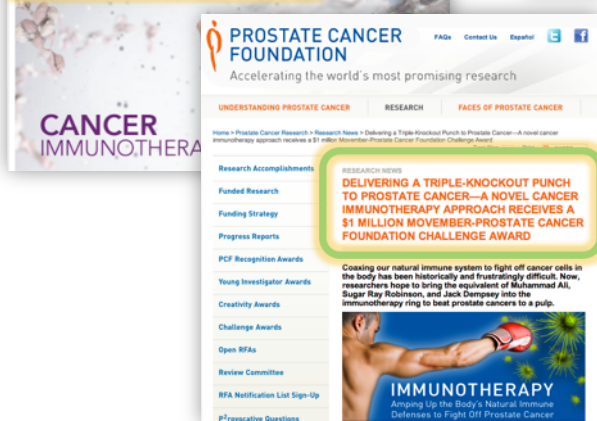
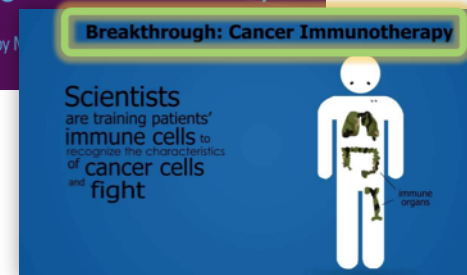
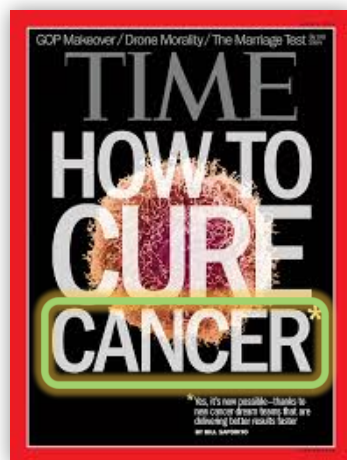
## Corporate Presentation Sept 2015

Paul Hopper – Executive Chairman

# 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

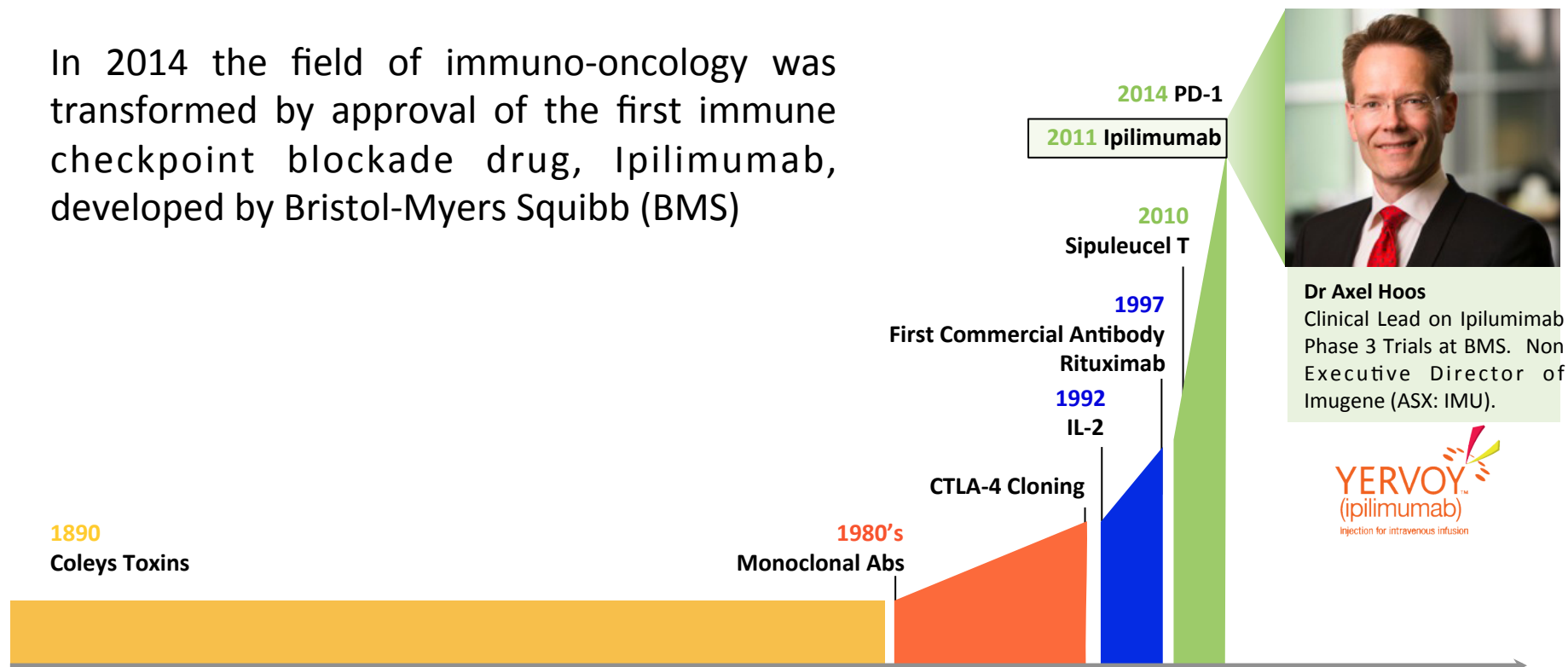


# Cancer Immunotherapy Progress



1890-2014

In 2014 the field of immuno-oncology was transformed by approval of the first immune checkpoint blockade drug, Ipilimumab, developed by Bristol-Myers Squibb (BMS)



# 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 early 2016
- Technology originates from Medical University of Vienna, one of Europe's leading cancer institutes
- Market capitalisation (Sept 2015): AUD15.0m (includes Sept raise)
- Share price (Sept 4 2015): AUD0.09¢
- Average daily trade: 1.1m shares
- Shares outstanding: 1.73B (post-Sept raise)
- Cash & equivalents (Jun 30 2015): AUD\$1.96m
- + Cash raised Sept 2015: AUD\$4.96m pro rata (excl expenses)



**ASX**  
AUSTRALIAN SECURITIES EXCHANGE

# Leadership – Extensive Drug Development Experience



**Leslie Chong** – *Chief Operating Officer*

- Previously Senior Clinical Program Lead at Genentech, Inc., in San Francisco, widely regarded as one of the world's most successful biotech companies with a significant oncology franchise including the best-selling breast cancer drug, Herceptin.
- Appointment as COO in August 2015



**Prof Ursula Weidemann** – *Chief Scientific Officer*

- Co-inventor of technology
- Prof of Vaccinology at Medical University of Vienna



**Dr Axel Hoos** – *Non-Executive Director*

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



**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



**Paul Hopper** – *Executive Chairman*

- International & ASX biotech capital markets experience particularly in immuno-oncology & vaccines
- 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

# Investment Highlights



## Compelling Science

- B-cell peptide cancer immunotherapy that induces antibody responses targeting HER-2 over expressing tumors + major new initiative into mimotopes

## 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

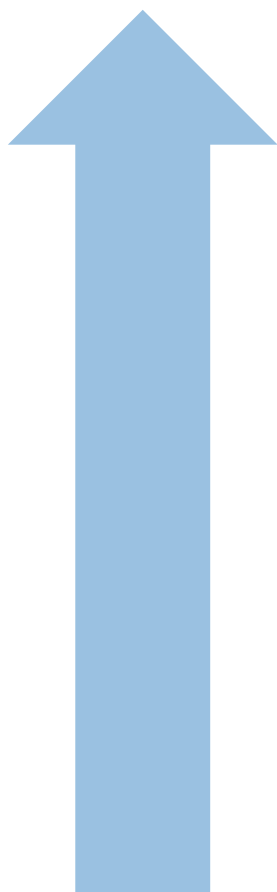
- Numerous milestone announcements & valuation inflection points over next 12-24 months

## Robust IP

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

## Leadership

- Experienced management & board

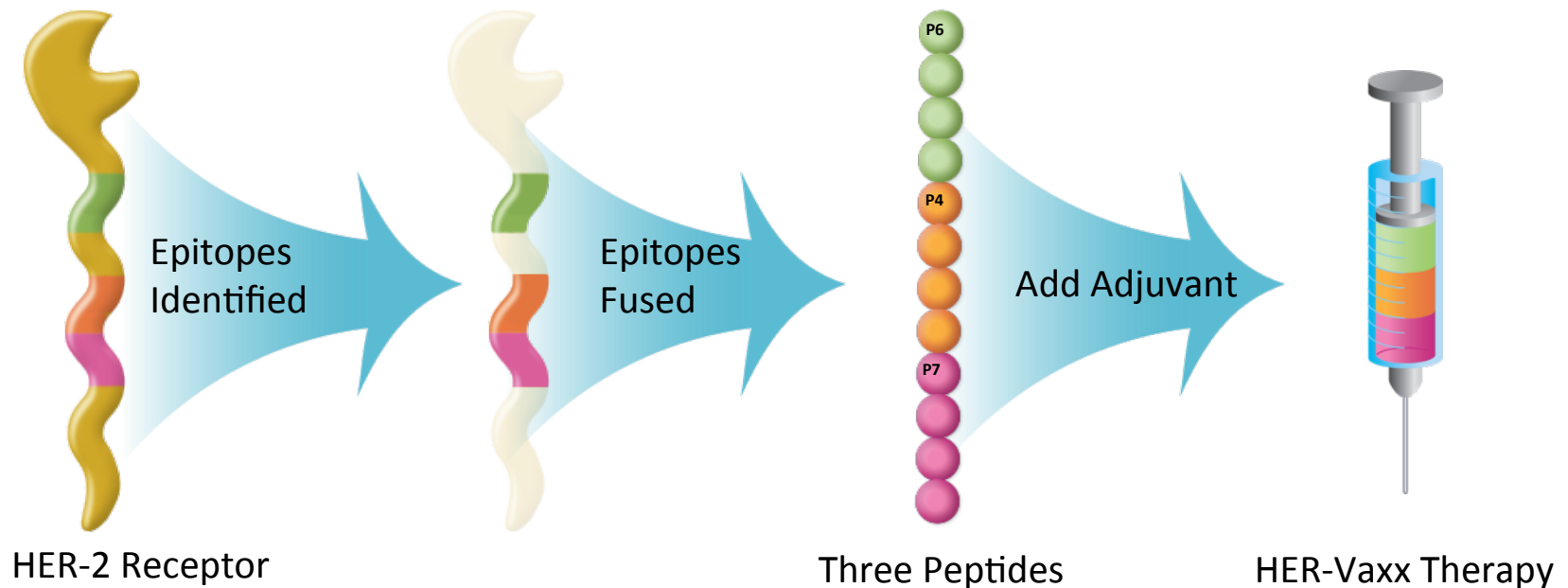


- ✓ GMP manufacturing complete – Dec 2015
- ✓ FDA IND allowed – Mar 2016
- ✓ Initiate Phase 1b clinical trial – Early 2016
- ✓ Phase 1b patient update – Q3 2016
- ✓ Phase 1b patient update – Q4 2016
- ✓ Complete Phase 1b trial – Dec 2016/Jan 2017
- ✓ Initiate randomized Phase 2 clinical trial – 1H 2017

# 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



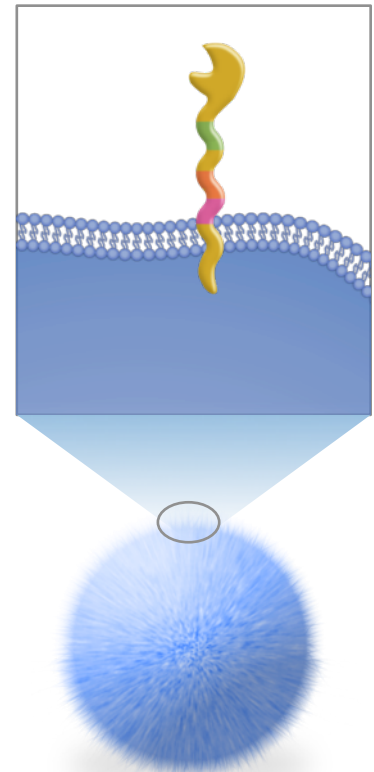
# What is HER-2?

## 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

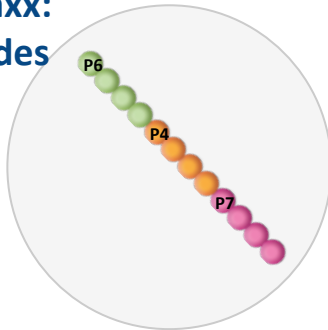
HER-2 Receptor



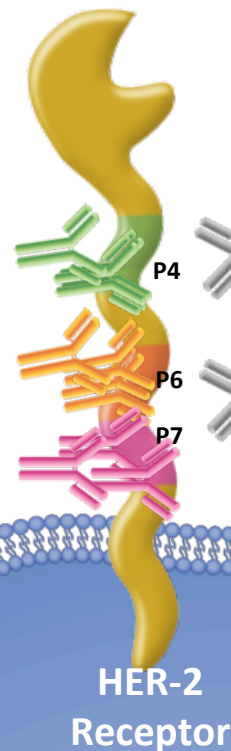
# HER-Vaxx Attacks the Same Cancer Receptor as 3<sup>rd</sup> Largest Cancer Drug Worldwide



HER-Vaxx:  
3 peptides



HER-Vaxx: x3  
polyclonal  
responses



Tumor cell

Binding site of



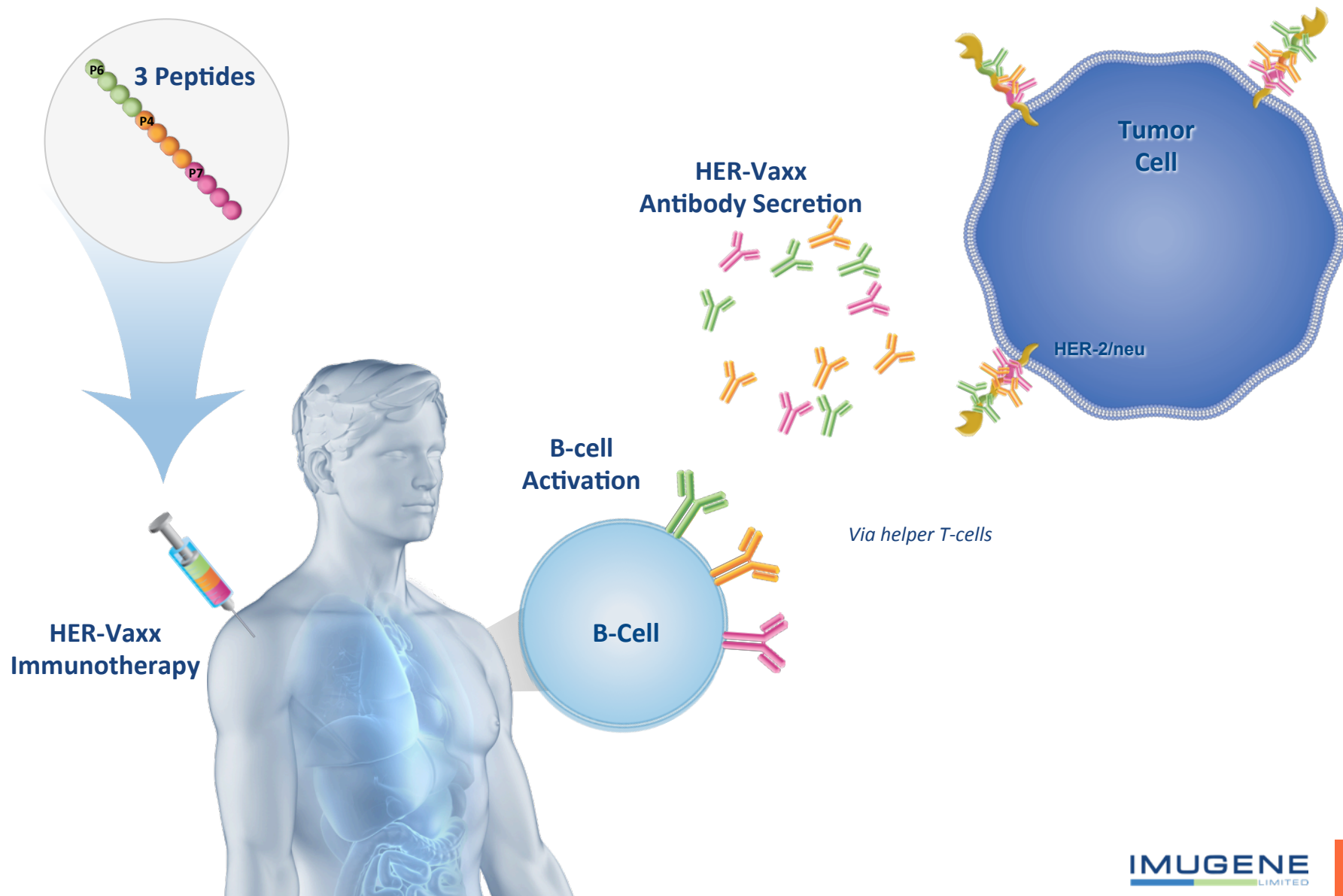
Binding site of



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 $\gamma$  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**

# Clinical Status:

## Phase I Breast Trial Completed



A blue-tinted illustration of a female torso. The breasts are highlighted with glowing, orange, flower-like patterns, representing breast cancer cells.

### Design

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

### Clinical Endpoints

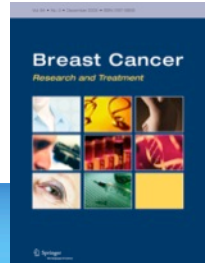
- 1 Safety and Tolerability
- 2 **Immunogenicity:** antibodies/humoral and cellular responses

# Clinical Status:

## Phase I Breast Trial Completed

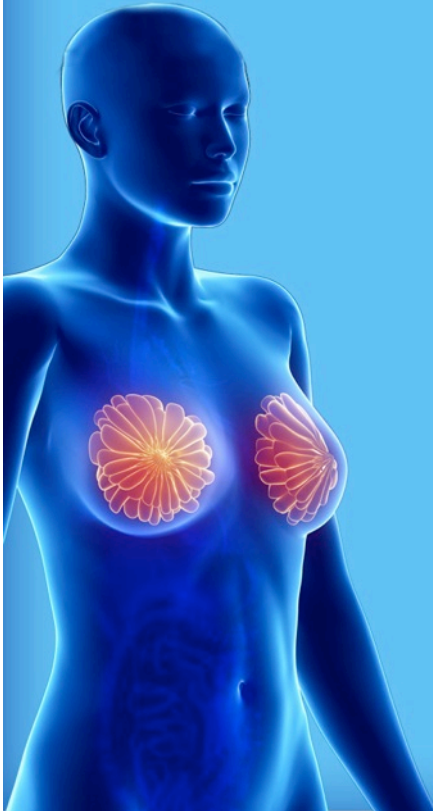


Wiedermann et al.,  
*Breast Cancer Res Treat*  
(2010)119:673 - 683



### Observations

- Patients developed anti-HER-2 antibodies
- Induction of cytokines (Th1 biased; IFN $\gamma$ )
- 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 the end stage of disease and not the primary target group



# Phase 1b/2 Trial Design Gastric Cancer



## Combined Phase 1b/2 clinical trial under IND

*CRO appointed*

**SIMBEC ORION**  
GROUP



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 Eastern Europe (2 arms by 34)
- Combination with chemo
- Efficacy, safety & immune response
- Randomised
- Endpoints:
  - Overall survival
  - Progression-free survival
- Secondary endpoint:
  - Immune response



# Huge Gastric Cancer 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 and Eastern Europe, chemotherapy such as capecitabine and 5-FU, is the standard of care, not Herceptin
- Asia has the largest incidence for gastric cancer globally and represents a large market opportunity



Chemotherapy



Monoclonal antibody



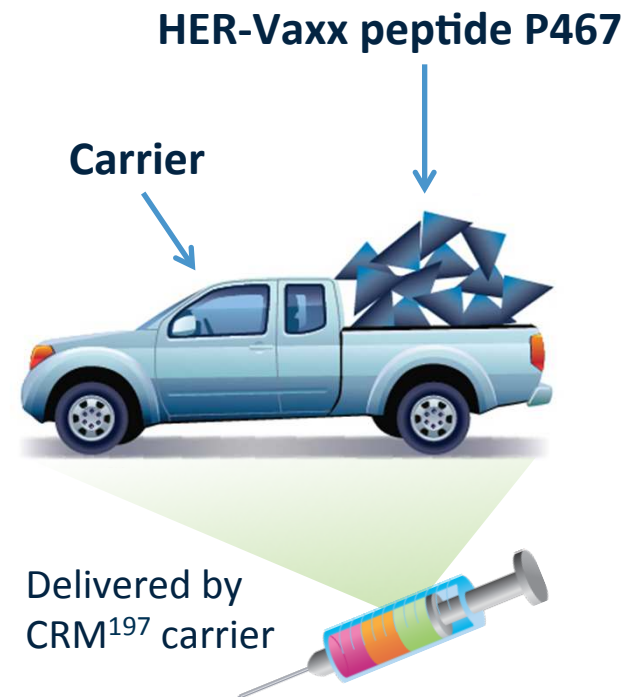
**HER-Vaxx is made up of two components – the peptide antigen P467 and the vaccine delivery/adjuvant platform CRM197**

*Manufacturing of new improved formulation on track and below budget (<A\$1Mil)*

## **Manufacturer**

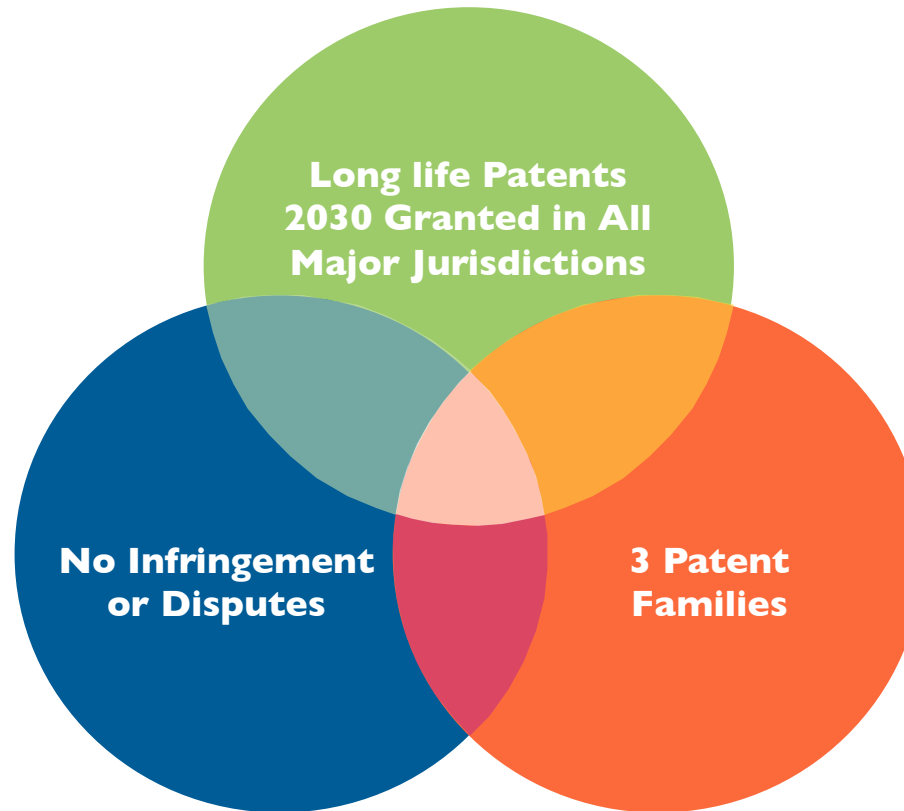
piCHEM GmbH - Graz, Austria

- Small focussed CMO with expertise in GMP peptide and CRM197 conjugate manufacture
  - Well priced and deliver on time (three successful R&D batches delivered in May, June and August)
  - Carrier clinically and commercially validated and fully approved by major regulatory agencies, eg CRM197 in Pneumococcal Conjugate Vaccine Prevnar13® (Pfizer \$4.3B sales p.a)
- GMP manufacture commenced in Aug 2015
- GMP clinical batch complete and released by Dec 2015



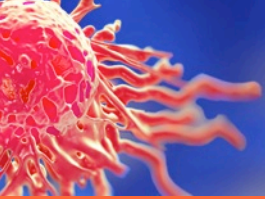
# Robust Intellectual Property Portfolio

## 100% Ownership



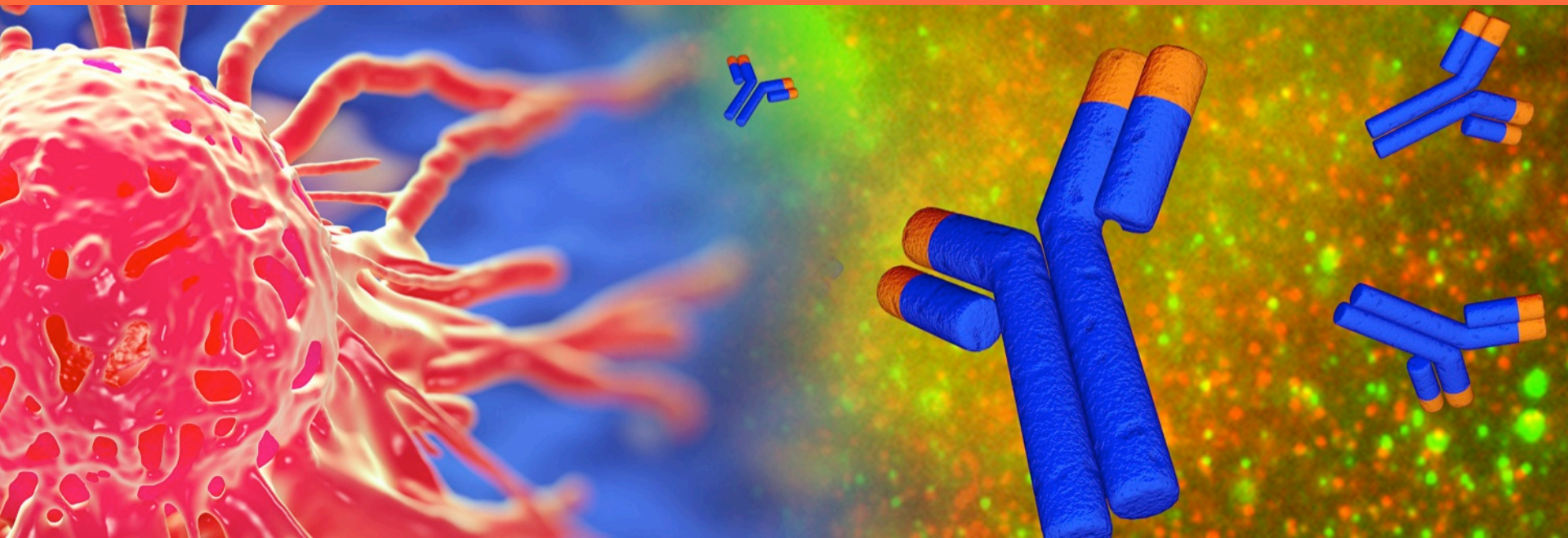
### Patent Families

- ✓ Vaccine against cancer diseases that are associated with the HER-2/NEU oncogene
- ✓ Manufacturing patent for multi-epitope vaccine
- ✓ New patent filed for CRM<sub>197</sub> formulations with potential for coverage to 2036



# News Flow & Milestones





## Paul Hopper

Executive Chairman

Imugene Limited

m: +61 406 671 515

e: [receptogen@earthlink.net](mailto:receptogen@earthlink.net)

w: [imugene.com](http://imugene.com)

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