

B Cell Antibodies for Immuno-Oncology

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AGM
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Developing B-cell based immuno-oncology therapies

- Mimotope Platform Technology: B cells to produce an antibody copy of the antibody you want to “mimic”
- HER-Vaxx: Completed a Phase 1 trial in patients with HER-2+/++ breast cancer
 - The Phase 1b/2 gastric cancer trial to begin this week (initiation starts this week)
- Technology originates from the Medical University of Vienna, one of Europe’s leading cancer institutes
- Technology identified in 2012 by Dr Axel Hoos (Sr. VP at GSK)
- Public listing on ASX in December 2013 via reverse merger into listed shell, Imugene Ltd - Axel Hoos joins the Board – his only Board worldwide

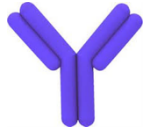


What is an Antibody?

A key defense of the immune system



Antibodies – look like the letter “Y” and are made of proteins. They are exquisitely made to attach themselves to one target only sitting on an invading organism which the body doesn’t like .



There are 2 ways to make antibodies

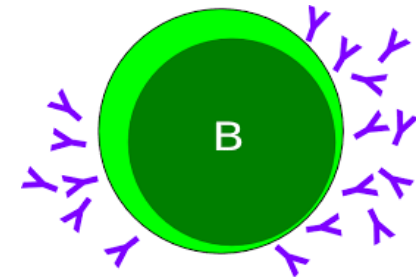
In a factory



For example,
Roche’s Herceptin
for breast cancer



Using B cells in your own body

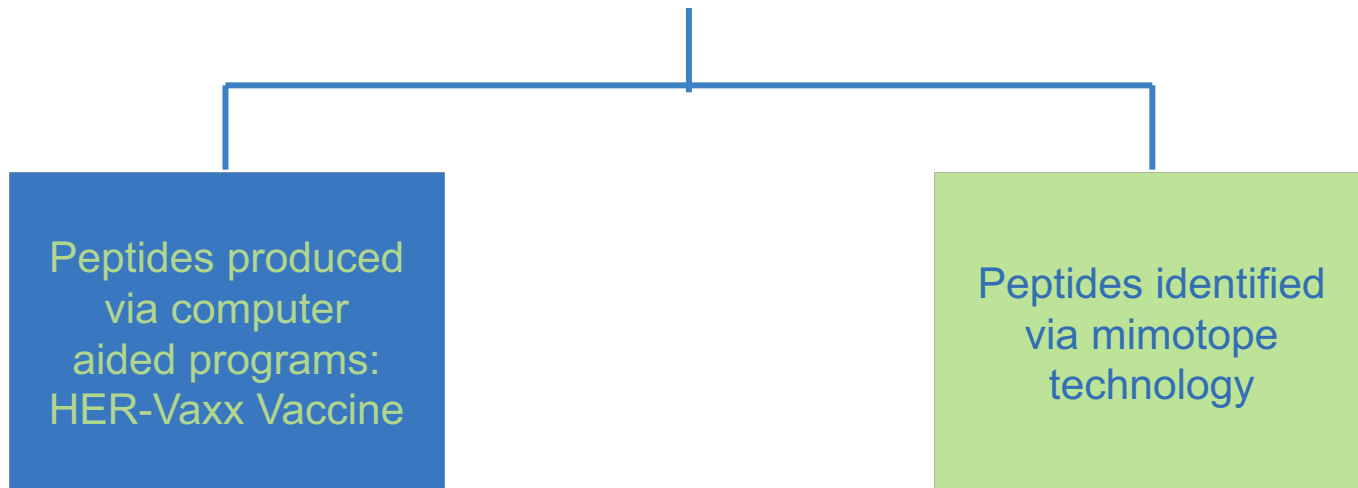


- **B Cells** – are like little antibody factories producing millions of antibodies to target “nasties” entering the body

Two Compelling Antibody Programs and Commercial Opportunities



Imugene's Pipeline B Cell Peptide technology



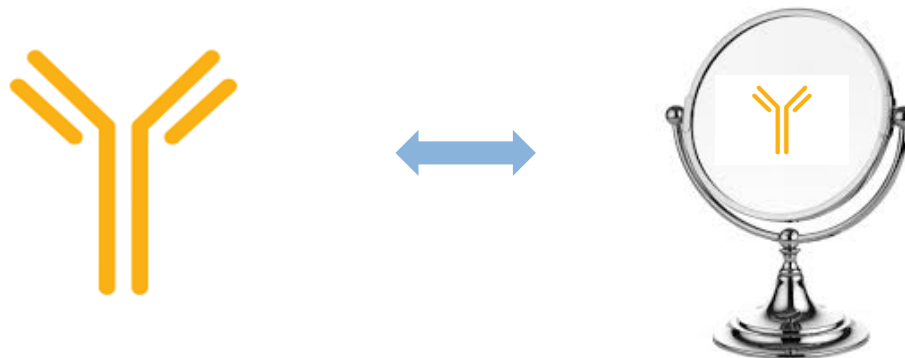
Building on the multi-levels of your own immune system

- Identification of cancer targets for variety of cancer indications
- Immune responses from conjugates and adjuvants
- B-Cell Peptide vaccines against checkpoint targets

A Mimotope Produces a Copy of an Antibody



- A mimotope is a small molecule, often a peptide, which mirrors the structure of an epitope, the specific target an antibody binds to. Because of this property it induces an antibody response similar to the one elicited by the epitope.
- A mimotope causes your B cells to produce an antibody copy of the antibody you want to “mimic”
- Mimotopes to be part of the next wave of the immuno-oncology revolution against cutting edge oncology targets
- Potential tool for selecting novel vaccine candidates against a variety of tumors
- Greatly extends IMU’s oncology franchise and pipeline.
- Monoclonal antibody market currently at US\$60bn pa



Advantages of Mimotopes Immunotherapy

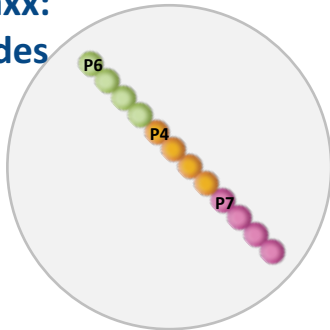


Issue	Mimotope Immunotherapy	Monoclonal Antibodies
Safety	<ul style="list-style-type: none">Stimulates the immune system to produce natural Abs, potentially safer, as demonstrated by HER-Vaxx	<ul style="list-style-type: none">Synthetic Ab, with side effects (including ventricular dysfunction, CHF, anaphylaxis, immune mediation)
Efficacy	<ul style="list-style-type: none">Polyclonal Ab response reduces risk of resistance and potentially increases efficacy	<ul style="list-style-type: none">Monoclonal Ab - single shot
Durability	<ul style="list-style-type: none">Antibodies continuously produced a lasting immune response to inhibit tumor recurrence	<ul style="list-style-type: none">Half life up to 12 days sometimes less
Usability	<ul style="list-style-type: none">Potentially low numbers of vaccinations required per year	<ul style="list-style-type: none">Requires regular infusion
Cost	<ul style="list-style-type: none">Low cost of production enables greater pricing flexibility facilitating combinations and opening up additional markets	<ul style="list-style-type: none">Expensive course of treatment >USD100K per year in the US

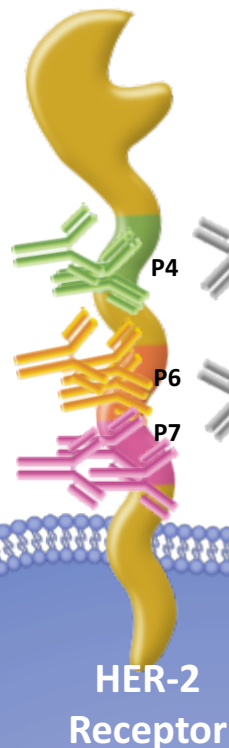
HER-Vaxx Attacks the Same Cancer Receptor the World's Largest Cancer Franchise



HER-Vaxx:
3 peptides



HER-Vaxx: x3
polyclonal
responses



Tumor cell

Binding site of



Binding site of



Monoclonal
response

Franchise sales annualising at
nearly \$8bn growing 13%*

Click to view [Mechanism
Of Action](#)

* \$USD Source: Roche H1 Report <http://www.roche.com/hy15e.pdf> p12

Phase Ib/2, in 2016 in Gastric Cancer



Trial to be done under a IND

Phase 1b lead-in

- Open label
- 15 patients, x 3 groups of 5 patients
- Combination with chemo
- Endpoints:
 - Recommended Phase 2 Dose of HER-Vaxx
 - Safety: any HER-Vaxx toxicity
 - Immunogenicity (anti-HER-2 antibody titres)
 - Test booster schedule (q 4 weeks or 8 weeks)

Phase 2

- Open label
- ~68 patients from sites in Asia
- Combination with chemo
- Randomized
- Primary Endpoints:
 - Overall Survival
 - Progression-Free Survival
- Secondary endpoint:
 - Immune response



Leadership – Extensive Drug Development Experience



Leslie Chong

Chief Operating Officer

- Over 19 years of oncology experience in Phase I - III of clinical program development
- Leadership role involvement in 2 marketed oncology products
- Previously Senior Clinical Program Lead at Genentech, Inc., in San Francisco



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**



Paul Hopper

Executive Chairman

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



Prof Ursula Wiedermann

Chief Scientific Officer

- Co-inventor of Her-Vaxx; inventor of mimotope platform technology
- Professor of Vaccinology at Medical University of Vienna



Dr Nick Ede

Chief Technology Officer

- 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



Dr Anthony Good

Clinical Program Manager

- Over 15 years oncology & immunology experience in global clinical development programs. Integral to the development of significant new medicines including Viagra, Revatio, Lipitor, Selzentry and Somavert.
- Ex Pfizer Global Research and Development, Covance Clinical and Periapproval Services and Western Sydney University

Strong News Flow in the next 12 months



Report Phase 2 results 2H 2019

Recruit for Phase 1b mimotope trial 2H 2018

US FDA IND allowed for mimotope 1H 2018

Recruit and run randomized controlled Phase 2 trial 2H 2017

Report Phase 1b trial results late 2H 2017

IND enabling GLP, Safety, Tox results of mimotope 2H 2017

Recruitment Progress and dose selection on Phase 1b 1H-2H 2017

Preclinical in vivo, in vitro results for 1st mimotope 1H 2017

Other Mimotopes Identified 1H 2017

1st mimotope candidate 1H 2017

First Patient In Phase 1b trial 2H 2016

Phase IB Study initiated/Started 2H 2016

Announce preclinical toxicology results (WIL) 2H 2016

Announce preclinical immunologic results (Charles River) 2H 2016

First regulatory and ethic board package submission 1H 2016

Appoint principal investigator 1H 2016

Her-Vaxx GMP clinical batch complete 1H 2016

■ mimotope

■ HER-Vaxx



Thank you



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