

IMUGENE

ASX:IMU



# HARNESSING B-CELLS FOR CANCER IMMUNOTHERAPY

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Acquisition of OSU/Mayo assets and up to A\$20m capital raising

**Leslie Chong**

June 2018

Managing Director & Chief Executive Officer

*Not for release or distribution in the United States*

## NOTICE: FORWARD LOOKING STATEMENTS

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## EXECUTIVE SUMMARY

- **Synergistic technology acquisition from Ohio State University (OSU) and The Mayo Clinic (Mayo):** Full spectrum of indications and targets to choose from, including check point inhibitors and combination therapies
- **Funding:** Up to A\$20m capital raise to fund expanded clinical programs and acquisition
- **Experienced management & board:** Meeting milestones and successful M&A activity
- **Strengthened and broadened Imugene B-cell vaccine pipeline:** Broadened clinical programs globally, include U.S. and European centres
- **Additional IP Protection for Imugene platforms and technologies**

# CAPITAL RAISING SUMMARY

- Imugene is conducting an up to A\$20m capital raising to fully fund:
  - Acquisition of OSU and Mayo B-Cell Peptide IP and Clinical Portfolio;
  - Acceleration of combined Imugene Pipeline clinical programs;
  - Adaptive study for PD-1 vaccine candidate;
  - General working capital
- Offer Price represents a 12.0% discount to the weighted average closing price of Imugene over the past five trading days to 4 June 2018

## Capital raising structure

- Up to A\$12.0m Placement to Sophisticated and Professional investors in Australia and eligible institutional investors in US, UK, NZ and Hong Kong
- ~A\$8.1m 1 for 9.5 Entitlement Offer to existing eligible shareholders with registered addresses in Australia and New Zealand at the record date
- Participants will also receive 1 free option for every 3 Placement or Entitlement Offer share subscribed for
- Options will be listed on the ASX, with a Nov 2021 expiry and strike price of A\$0.040
- Shares issued under the Placement will not be eligible to participate in the Entitlement Offer.

## USE OF PROCEEDS

### Up to A\$20m Capital Raise (funding for up to 3 years):

- Acquisition of OSU B-Cell Peptide IP and Clinical Portfolio
- Acceleration of combined Imugene pipeline of HER2, PD-1 and combinations of B-cell vaccine clinical programs
  - Completion of Phase 2 Trial for OSU/Mayo Clinic HER-2 Vaccine
  - Adaptive study for PD-1 vaccine candidate
- Two new vaccine candidates through IND enabling studies
- R&D programs at OSU to advance four additional vaccine candidates
- GMP manufacturing and GLP-preclinical tox/SP for clinical candidates



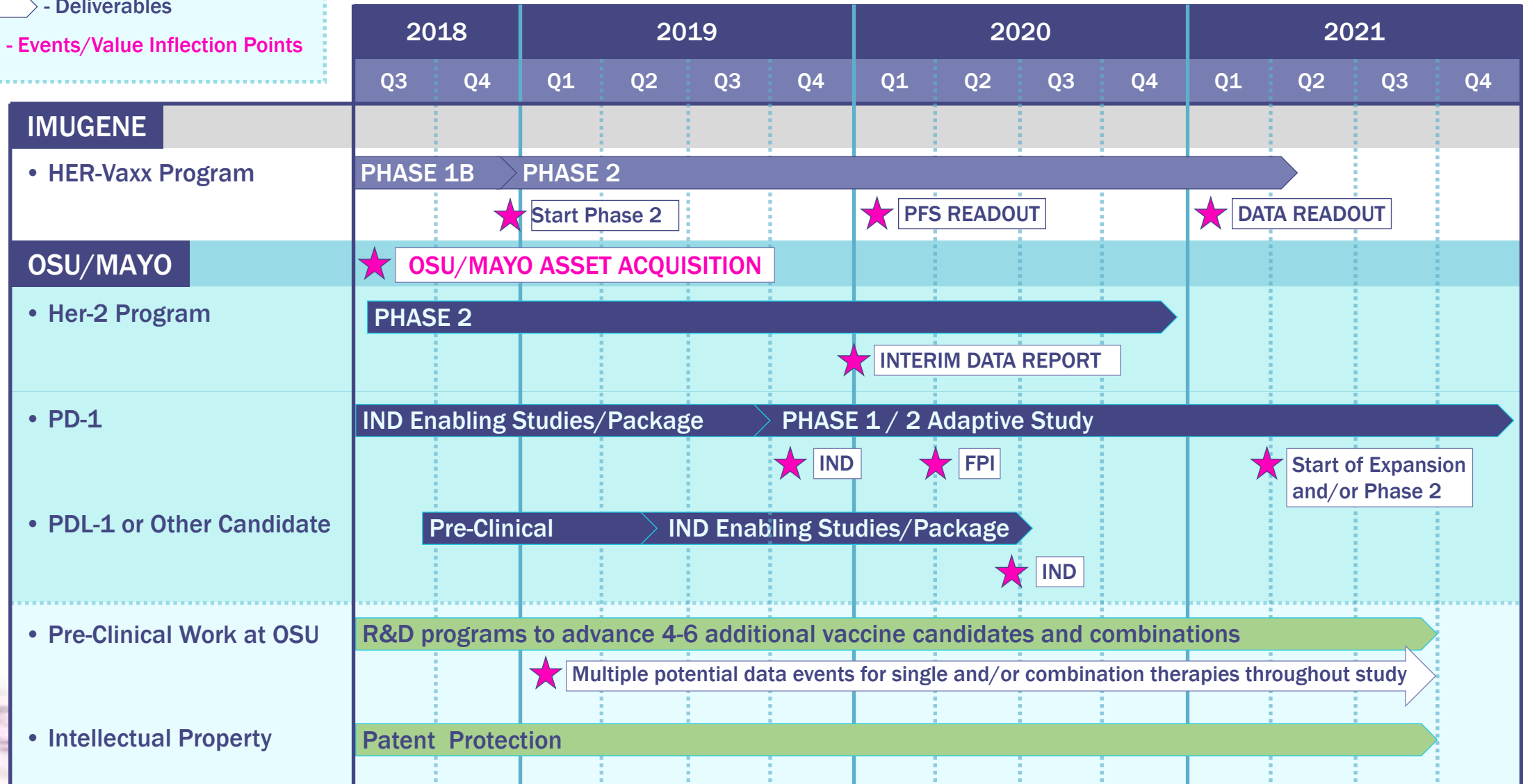
## Ohio State University and Mayo Clinic B-cell peptide vaccine portfolio

- Opportunity to create the pre-eminent, dominant position globally in B-cell peptide vaccines and therapeutics.
- Professor Kaumaya's work in the area of check-point inhibitors and tumor-associated antigens such as Her-2, is highly complementary to Imugene's existing platform and portfolio.
  - Six patent families including composition of matter and method of use patents covering PD-1, Her-1, Her-2, Her-3, VEGF, IGF-1R, CD28 peptide vaccines and therapeutics.
  - Commercially attractive upfront payment; royalty rate in low single digit royalty on sales; exclusive, world-wide and sub-licensable until expiry of the last patent.
- Broadens and accelerates key Imugene Research and Clinical programs
  - PD-1 and HER2 + PD-1 combination programs accelerate by 24+ months

# IMUGENE DELIVERABLES/MILESTONES: ESTIMATED TIMELINES

→ - Deliverables

★ - Events/Value Inflection Points



## FINANCIAL SUMMARY

ASX:IMU

<b>Market Cap (4 June 2018):</b>	<b>\$88.5M AUD, \$67M USD</b>
<b>Ordinary Shares:</b>	2.855 billion
<b>12 month price range:</b>	1.2 cents – 4.0 cents AUD
<b>Avg daily volume:</b>	23M shares (January-April 2018)
<b>Investment to Date:</b>	~\$22.4M (public) ~\$ 5.5M (VC)
<b>Cash &amp; Equivalents:</b>	\$10.45M (as at 31 March 2018)

## Options on issue (as at May 2018)

	No. of options	Exercise Price	Expiry
<b>Listed: (IMUOA)</b>	242.5M	\$0.026	30/11/2020
<b>Unlisted:</b>	64.5M	\$0.017*	
<b>Total:</b>	307M		

\* Average

## Top 5 shareholders (as at May 2018)

	No. of Shares	% Capital
<b>Platinum Asset Management (Australia Limited)</b>	158,898,254	5.57%
<b>Private Portfolio Managers</b>	125,201,351	4.39%
<b>Dr. Nicholas Smith</b>	80,000,000	2.80%
<b>Paul Hopper Executive Chairman</b>	71,196,875	2.49%
<b>Sarah Cameron</b>	60,000,000	2.10%



# A TEAM WITH TRACK RECORD IN DRUG DEVELOPMENT



**Leslie Chong (Sydney, Australia)**

**Managing Director & Chief Executive Officer**

- Over 20 years of oncology experience in Phase I – III of clinical program development
- Leadership role involvement in two marketed oncology products
- Previously Senior Clinical Program Lead at Genentech, Inc., in San Francisco



**Prof Ursula Wiedermann (Vienna, Austria)**

**Chief Scientific Officer**

- Co-inventor of HER-Vaxx
- Professor of Vaccinology at Medical University of Vienna



**Dr Axel Hoos (Philadelphia, U.S.A.)**

**Non-Executive Director**

- Senior Vice President and Head of Oncology at GSK
- Former Medical Lead for Yervoy, the first survival improving medicine in Immuno-Oncology
- Chairman of the BoD of the Sabin Vaccine Institute
- Co-Chair of the Cancer Immunotherapy Consortium Think-Tank



**Mr. Charles Walker (Brisbane, Australia)**

**Non-Executive Director**

- Experienced listed biotech CEO and CFO (ASX;ACL and ASX:IMU)
- Experienced in financial markets including executing 55 international tech corporate transactions
- Clinical experience includes managing pipeline of drugs in all stages from discovery, through to Phase III to launched products



**Paul Hopper (Sydney, Australia)**

**Executive Chairman**

- International & ASX biotech capital markets experience particularly in immuno-oncology & vaccines
- Chairman of Viralytics, Founder & Director of Prescient, Founder of Imugene & Polynoma LLC, former Director pSivida, Somnomed & Fibrocell Science



**Dr Nick Ede (Melbourne, Australia)**

**Chief Technology Officer**

- Over 25 years peptide vaccine and drug development
- Former CEO Adistem, CEO Mimotopes
- VP Chemistry Chiron (now Novartis), Research Fellow CRC Vaccine Technology

# Imugene Scientific Advisory Board



**Prof Christoph Zieliniski (Vienna, Austria)**

**Head of Scientific Advisory Board**

- Chairman of the Comprehensive Cancer Centre in Vienna
- Chairman of the Centre for Eastern EU Organisation for Research and the Treatment of Cancer (CEEORTC)
- Editor in Chief and European Society of Medical Oncology (ESMO) Open



**Prof Ursula Wiedermann (Vienna, Austria)**

**Chief Scientific Officer**

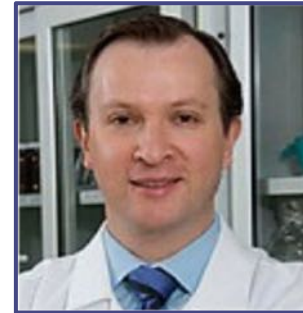
- Co-inventor of HER-Vaxx
- Professor of Vaccinology at Medical University of Vienna



**Dr Yelina Janjigian (MSKCC, U.S.A.)**

**Medical Oncologist**

- Expertise in esophageal and stomach (gastric) cancer
- Active in GI clinical trials testing combinations of Her-2 and checkpoint inhibitor therapies



**Dr Neil Segal (MSKCC, U.S.A.)**

**Medical Oncologist**

- Expertise in GI, Colon, Pancreatic cancers
- Active clinical immuno-oncology researcher
- Clinical lead in several trials using PD-L1 inhibitors



**Professor Peter Schmid (Barts Cancer Inst., London)**

**Chair of Cancer Medicine, Queen Mary Hospital London**

- Expertise in breast and lung cancer, cancer immunotherapy and early drug development
- Leads the Centre of Experimental Medicine at Barts Cancer Institute

# A BETTER WAY TO MAKE ANTIBODIES TO TREAT CANCER?

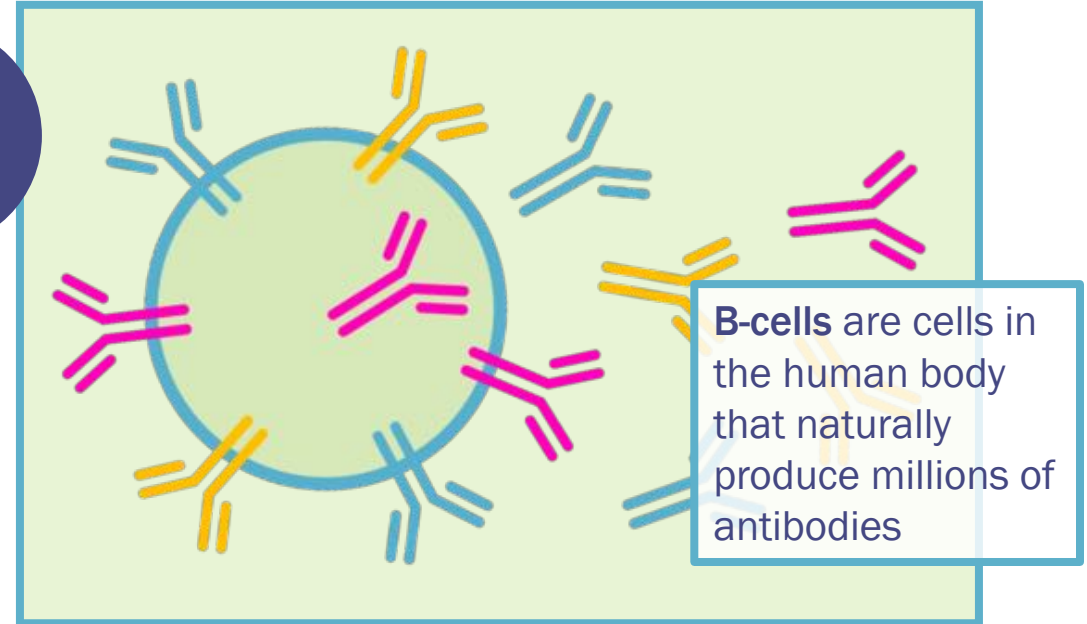
In a facility:



For example, Merck's Keytruda

VS

Using B-cells in your body



Teaching B-cells to make antibodies using peptide antigens



# B-CELL VACCINE PLATFORM TECHNOLOGY

The B-cell vaccine platform has the potential to be part of the next wave of immuno-oncology products. It makes multi-level therapies against a combination of targets achievable.

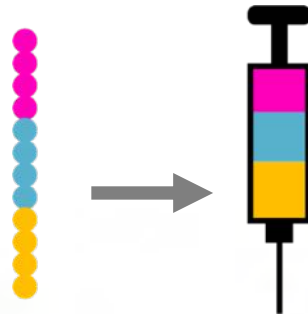
## SELECTION OF ANTIGENS

A library of peptides can be interrogated with any antibody to identify, with available published binding data, the antigens to which it binds



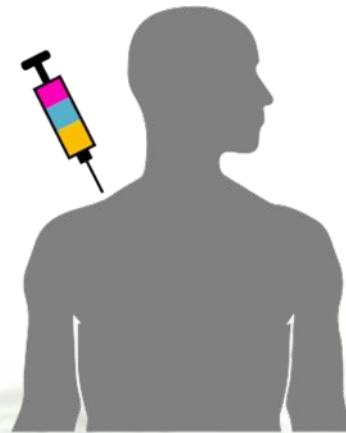
## CREATION OF A VACCINE

The selected peptide antigen(s) can be used in isolation or combination to create a B-cell peptide therapy with the appropriate carrier system and adjuvant.



## IMMUNIZATION

Immunization with the peptide vaccine will lead to the patient's B-cells producing functional antibodies



## ENDOGENOUS AB PRODUCTION

Successful delivery will result in endogenous Ab production with associated immune memory



# THE INVENTOR – PROFESSOR PRAVIN KAUMAYA



- Prof of Medicine Department of Obstetric Gynecology at Ohio State University Wexner Medical Center and The James Comprehensive Cancer Center
- Expert in the fields of vaccine research with emphasis on peptide vaccines for cancer
- Research focus in tumor immunology, mechanisms of tumor cell-immune cell interactions, and immune mechanisms
- Over 130 peer-reviewed articles in major scientific journals
- Fellow of the American Association for the Advancement of Science (AAAS), treasurer of American Peptide Society
- Conducted first NCI funded and FDA approved Phase 1 trial in Cancer Patients (Stage 4) with solid tumors in several indications at OSU James Cancer Hospital



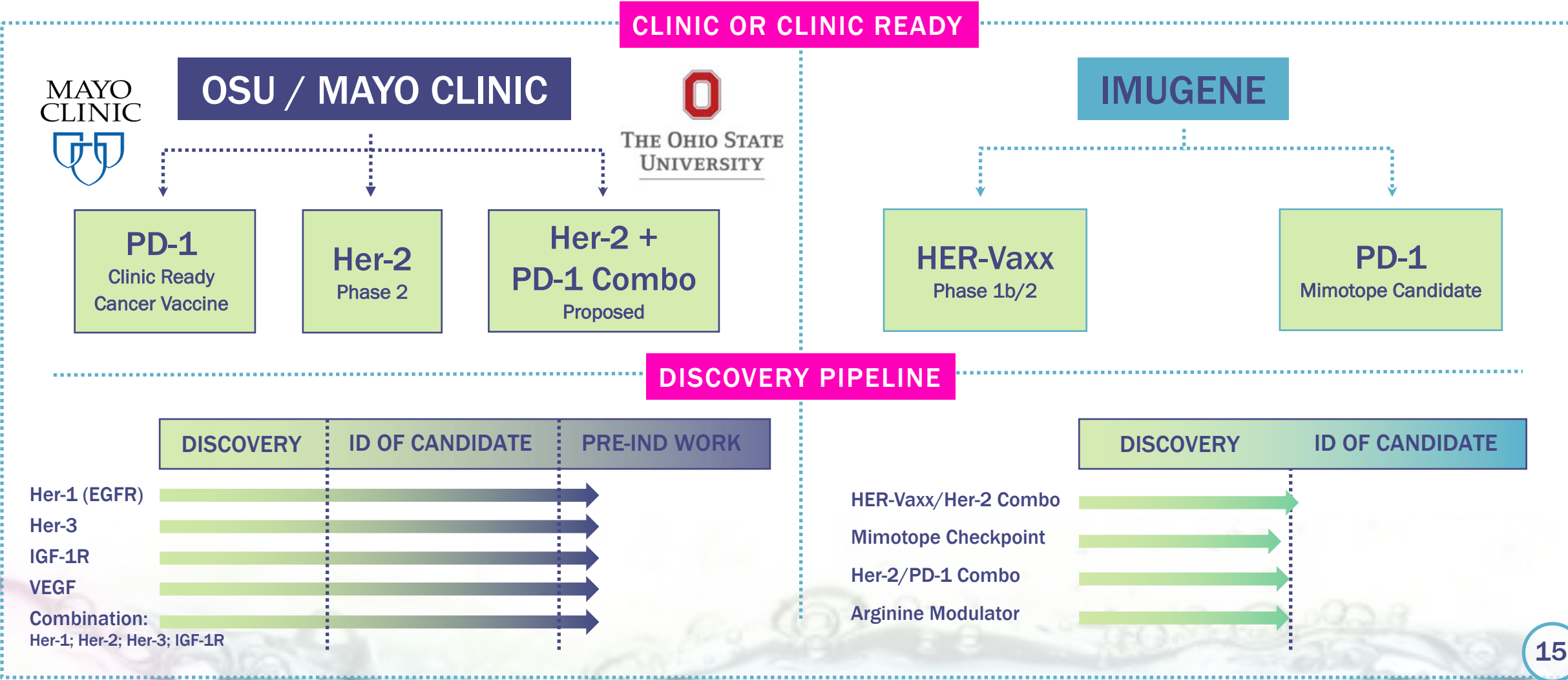
## PRINCIPAL INVESTIGATOR – DR. TANIOS BEKAI SAAB



- Professor of Medicine, Mayo Clinic College of Medicine; Science Co-Leader, Gastrointestinal Cancer Program, Mayo Clinic Cancer Center
- Medical Director, Cancer Clinical Research Office; Senior Associate Consultant Division of Hematology/Oncology Department of Internal Medicine, Mayo Clinic, Phoenix, Arizona, USA
- Focus is new therapeutic strategies with focus on molecular-targeted and immune therapies in gastrointestinal malignancies
- Principal investigator on numerous clinical trials. His work is funded by various sources, including the National Cancer Institute and multiple industry partners
- Member, American Society of Clinical Oncology, American Association for Cancer Research, and the American College of Physicians. Authored or co-authored 350 peer reviewed publications, abstracts, and book chapters

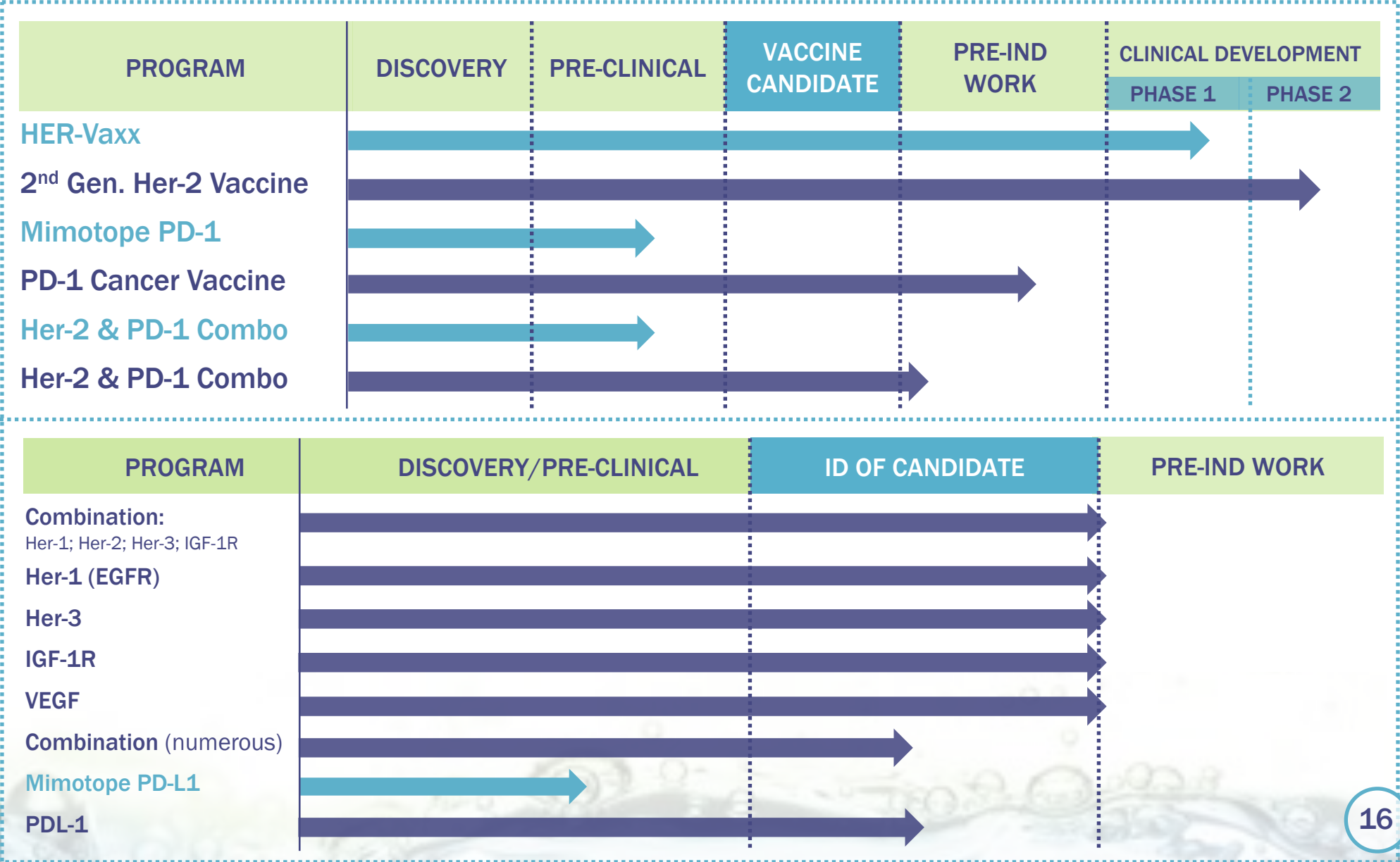
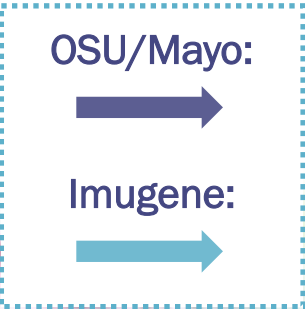
# EXPANDED IMUGENE B-CELL VACCINE PIPELINE

Strengthens and broadens Imugene's B-cell vaccine pipeline



# EXPANDED IMUGENE PIPELINE WITH OSU/MAYO ACQUISITION

Acquisition of clinic ready B-cell technology, with a full spectrum of indications and targets to choose from, to include check point inhibitors and combinations



## WHY SELECT AND TARGET PD-1 FOR B-CELL VACCINATION?

Monoclonal antibody immunotherapies  
Keytruda® (Merck) and  
Opdivo® (BMS) targeting PD-1 sold  
**USD\$3.8B and \$4.9B,**  
respectively, in 2017.

In industry-recognized mouse cancer  
models (colon cancer), the PD-1  
targeting B-cell vaccine is  
**more superior than the gold standard**  
**mouse PD-1 monoclonal antibody**  
(used in preclinical model testing for  
Keytruda and Opdivo).

Whilst acknowledging the rapid rise in  
clinical trials involving PD-1 and their  
combination with other treatments\*, a PD-1  
B-cell vaccination approach represents a  
**paradigm shift in cancer immunotherapy.**

*\* Tang et al. Comprehensive analysis of the clinical immuno-  
oncology landscape, Annals of Oncology, 2017*

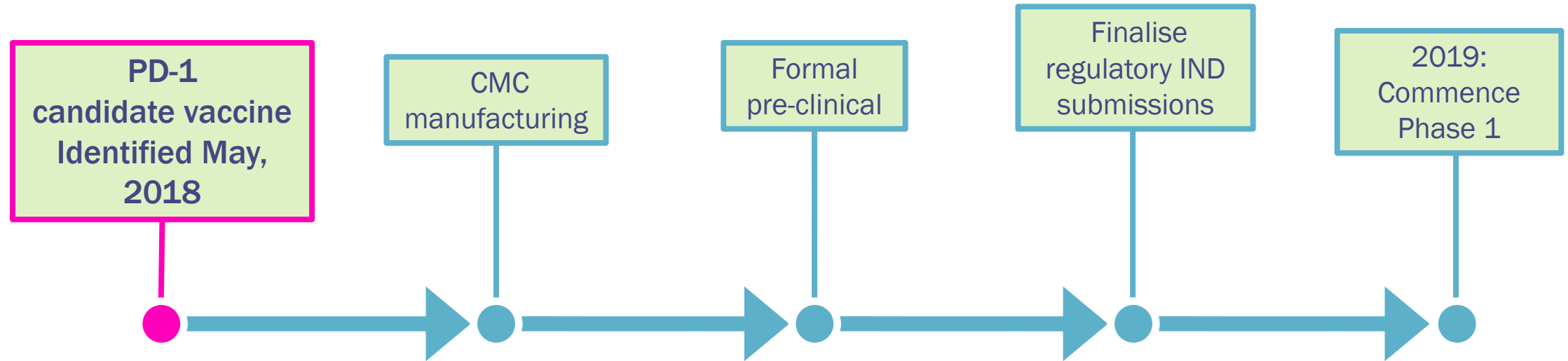
The combination of the PD-1 vaccine  
with the acquired Phase II Her-2 vaccine  
**significantly inhibits tumor growth**  
c/w mAb control in a Her-2+ model of  
colon cancer.

## PD-1 B-CELL VACCINE CANDIDATE IS CLINIC READY

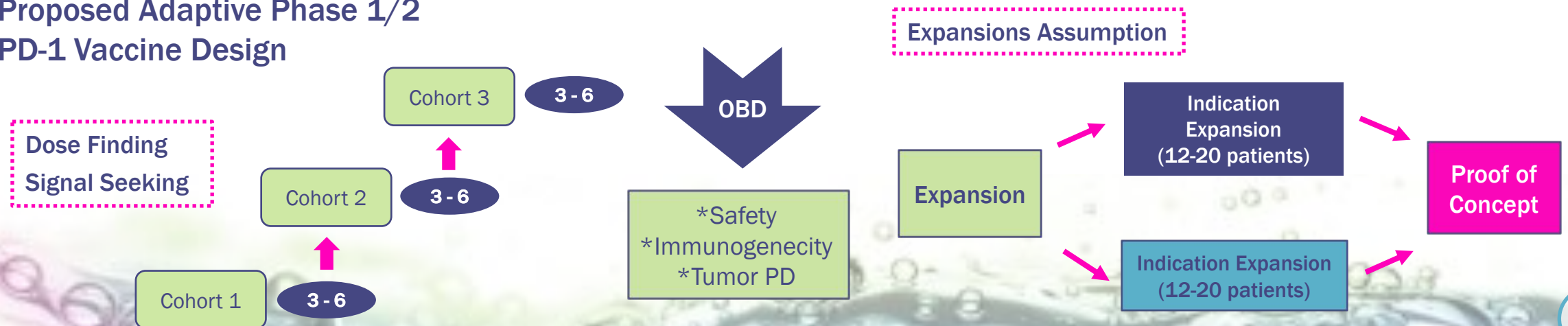
- Candidate PD-1 B-cell epitope antigen identified and characterized
- Actual vaccine candidate tested in preclinical immunogenicity and validated industry mouse models of cancer
- Encouraging data when combined with acquired Kaumaya Her-2 vaccine
- PD-1 B-cell vaccine individually or in combination with Her-2 vaccine outperforms gold-standard PD-1 monoclonal antibody in mouse model of colon cancer
- PD-1 vaccine candidate is ready for GMP manufacture and formal IND-enabling GLP preclinical tox and safety pharmacology studies
- PCT patent filed in March 2018
- Accelerates and advances Imugene PD-1 vaccine program by 24 months
- Brings the Imugene platform and technology into US and European focused clinical trial
- Budget: \$7 million (IND enabling studies, manufacturing and completion of Phase 1 trial)



# PD-1 VACCINE PHASE 1 DEVELOPMENT PATH 2018-2019



## Proposed Adaptive Phase 1/2 PD-1 Vaccine Design



# CURRENT OSU/MAYO PHASE 2 HER-2 STUDY (NO CHEMO)

Phase 1 (completed)	
<b>N=</b>	24 evaluable (49 dosed)
<b>Drug:</b>	2 Combination of two peptides MVF HER-2 (597-626) +MVF HER-2 (266-296)
<b>Patient Indications:</b>	All comers with solid tumour
<b>Type:</b>	IST (Investigator Sponsored Trial)
<b>Centres:</b>	OSU; James Cancer Centre &Solove Research Institute
<b>Endpoints:</b>	(OBD) Optimal Biological Active Dose; safety & tox
<b>Opened:</b>	Sept 2011
<b>Closed:</b>	2016
<b>Signals/ Efficacy</b>	10 out of 24 stable disease & 1 out of 24 partial response

Phase 2	
<b>Recruitment Target:</b>	48 (12 extension & 36 expansion)
<b>Current Enrollment:</b>	3
<b>Drug:</b>	Same as Phase 1
<b>Patient Indications:</b>	breast; GIST; colon; ovarian
<b>Type:</b>	IST
<b>Centres:</b>	OSU; James Cancer Centre &Solove Research Institute/ Mayo Clinic
<b>Endpoints:</b>	Efficacy Signals
<b>Opened:</b>	December 2016
<b>Interim data</b>	December 2019

See <https://clinicaltrials.gov/ct2/show/NCT01376505>

# INTELLECTUAL PROPERTY PORTFOLIO

- The IP estate comprises at least 6 patent families that comprise pending applications or issued patents:
  - a) compositions of matter and methods of use, of a large range of peptides and vaccines;
  - b) these peptides and vaccines comprise targets PD-1, Her-1, Her-2, Her-3, VEGF, IGF-1R, CD28
- The field of the license is for use of peptide vaccines and there is no restriction to any therapeutic indication.
- The license is exclusive, worldwide and sub-licensable through multiple layers of licensees.
- The term of the license is until expiry of the last patent. The PD-1 patent was filed in 2018.
- Since the patents claim biologics, there is also the prospect of obtaining data exclusivity for 10 years from marketing approval in the US.



# SUMMARY OF KEY RISKS

- IMU's clinical trials may prove unsuccessful;
- IMU currently has no material revenues. IMU intends to raise additional funds from Australian and international strategic investors mid 2018, which will have a dilutive effect on existing shareholders;
- IMU is dependent on the performance of its partners and the retention of key consultants and personnel for its specialized business;
- IMU's value may be impacted if its intellectual property is not able to be adequately protected;
- IMU may face competition from better resourced industry participants; and
- IMU may not obtain an industry partner and/or the regulatory approvals (such as the granting of FDA approval) that it requires for sale of its products or the reimbursement approvals required for sales growth, or such approvals may be subject to delay

# ACQUISITION SUMMARY

**Strengthens and broadens our B-cell cancer vaccine pipeline**

**Acquisition of clinic ready B-cell technology with full spectrum of indications and targets to choose from to include check point inhibitors and combination therapies**

**Clinical programs broaden to include US and EU centres**

**Expanded Imugene platforms and technologies fully patented**

- Funding: Capital raise to fund expanded clinical programs through key clinical data readouts and value inflection points
- Management team that has delivered on all critical milestones over the last three years and created value-inflections through strategic M&A activity
- Unique opportunity to secure the pre-eminent, dominant position globally in the R&D of B-cell peptide vaccines and complementary check-point inhibitor programs
- Synergistic technology acquisition from Ohio State University and The Mayo Clinic: expanded clinical stage pipeline (Tumour Associated Antigens) and PD-1/PD-L1 B-cell vaccines
- Leading clinical stage B-cell cancer vaccine company with multiple clinical candidates
  - Phase Ib/II HER-Vaxx combination with SOC chemo in gastric cancer
  - Phase II – Her-2 vaccine monotherapy in multiple solid tumours
  - Phase I adaptive study ready PD-1 B-cell vaccine



# Leslie Chong

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Managing Director

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