



IMUGENE
Developing Cancer Immunotherapies

ASX: IMU

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Investor Presentation

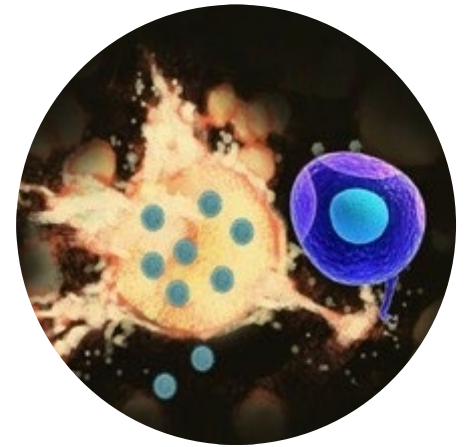
November 2020

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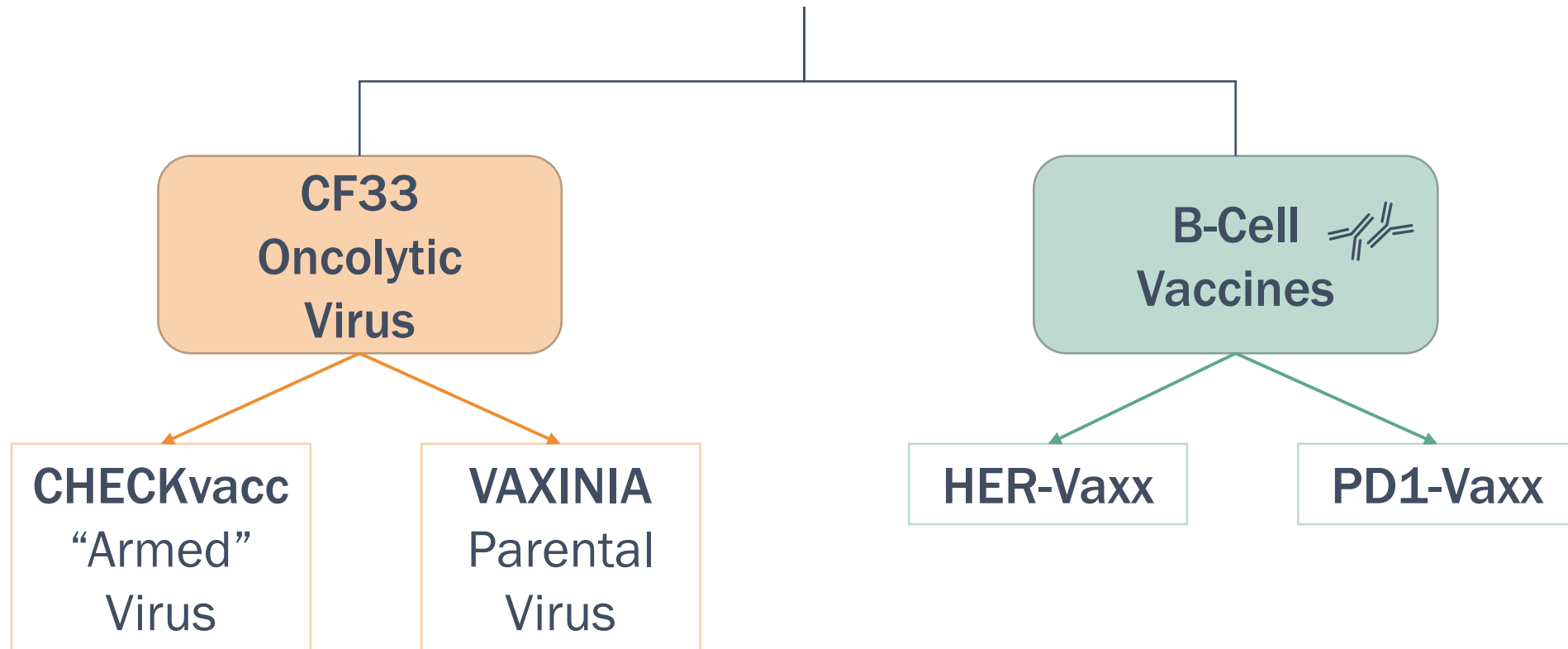
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INVESTMENT HIGHLIGHTS

- Two novel technologies: B-Cell activating immunotherapies and CF33 oncolytic virotherapy
- B-Cell Technologies: HER-Vaxx Positive Interim Data read out for Phase 2 trial in gastric cancer
- B-Cell Technologies: PD1-Vaxx screening patients in Phase 1 for NSCLC
- CF33 from City of Hope Cancer Centre in Los Angeles
- CF33 has demonstrated single agent & combination activity
- CF33 has prolific and compelling pre-clinical data
- CF33 GMP manufacturing complete for both trials
- Highly experienced CF33 team including CMO from ex OV biotech company and ex-Viralytics clinical development team
- Robust, long life IP portfolio over both technologies
- Significant news flow with multiple near & medium term valuation inflections



TWO NOVEL TECHNOLOGY PLATFORMS





**B-Cell
Immunotherapy**

HER-Vaxx PHASE 1B: DESIGN & RESULTS



Trial

- HER2 Gastric or GEJ cancer
- Phase 1b
- Open label
- Dose escalation
- 14 sites in Asia and Eastern Europe



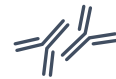
Patients

- Advanced stage IIIb or IV
- 7 HER2+++, 3 HER2++ (FISH positive), 4 HER2++ expressing tumors
- Age 57yo (21 - 79)
- ECOG 1(7) and 0(7)
- 9 Asian, 5 Caucasian
- 5 female, 9 male



Study

- 14 patients in 3 cohorts (10µg (3), 30µg (6) and 50µg (5))
- Dosed on D0, D14, D35
- IMU-131 in combination with chemo: cisplatin and 5FU or capecitabine



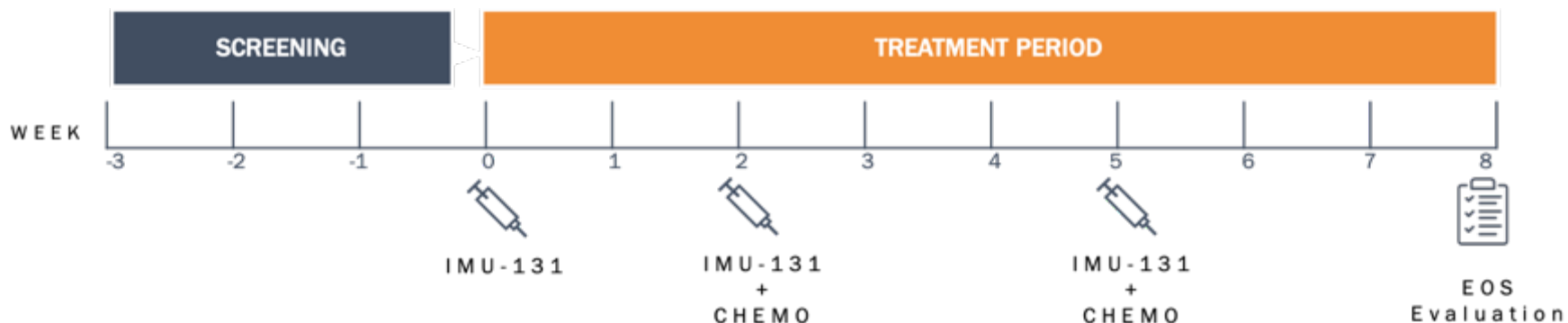
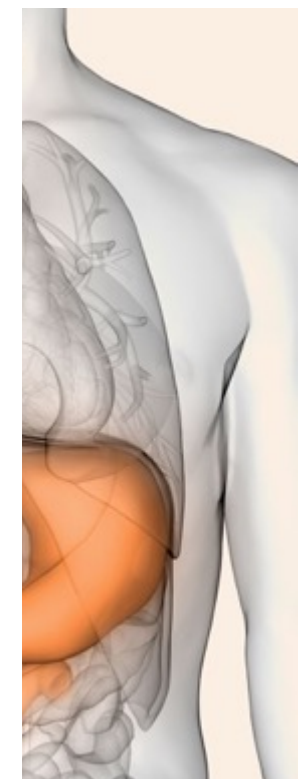
Endpoints

- Recommended Phase 2 Dose of IMU-131
- Safety and Toxicity
- Immunogenicity (anti-peptide (P467) and anti-HER-2 antibody titres)



Study Results

- No safety or toxicity issues
- All patients had increased antibody response
- 1 Complete Response
- 5 Partial Response
- 4 Stable Disease
- 1 Progressive Disease
- 50 µg selected as RP2D



HER-Vaxx PHASE 2: RECRUITING



Trial

- Phase 2
- Open label
- Eastern Europe
- India



Patients

- HER-2+++
- HER-2++ FISH/CISH +ve
- Advance or metastatic Gastric Cancer
- Stage IIIb/IV
- 68 patients in two arms



Study

Randomized

HER-Vaxx in combination with standard of care chemotherapy

Or

Standard of care chemo: Cisplatin and 5FU or capecitabine or oxaliplatin

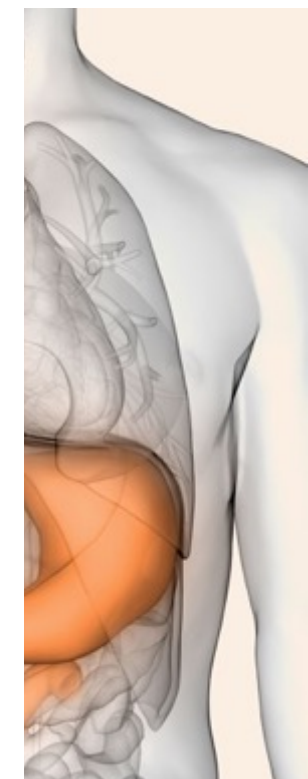


Primary Endpoints

- Overall survival

Secondary Endpoints

- Progression-free survival
- Safety and Tolerability
- Immune response



First patient dosed March 2019

HER-Vaxx PHASE 2: INTERIM ANALYSIS

Efficacy Outcome Overview

Endpoint	OS ITT * (Primary)	
	Chemo	Chemo+ HER-Vaxx
Treatment		
All Patients n=27 (at data cut off)	13	14
Events**	8	4
Hazard Ratio (HR)	0.418	
2-sided 80%CI	(0.186,0.942)	
Log-rank Test (1-sided p-value)***	.083 ⁺	

*Overall Survival Intent to Treat

**Death

***Pre-specified alpha at 0.10

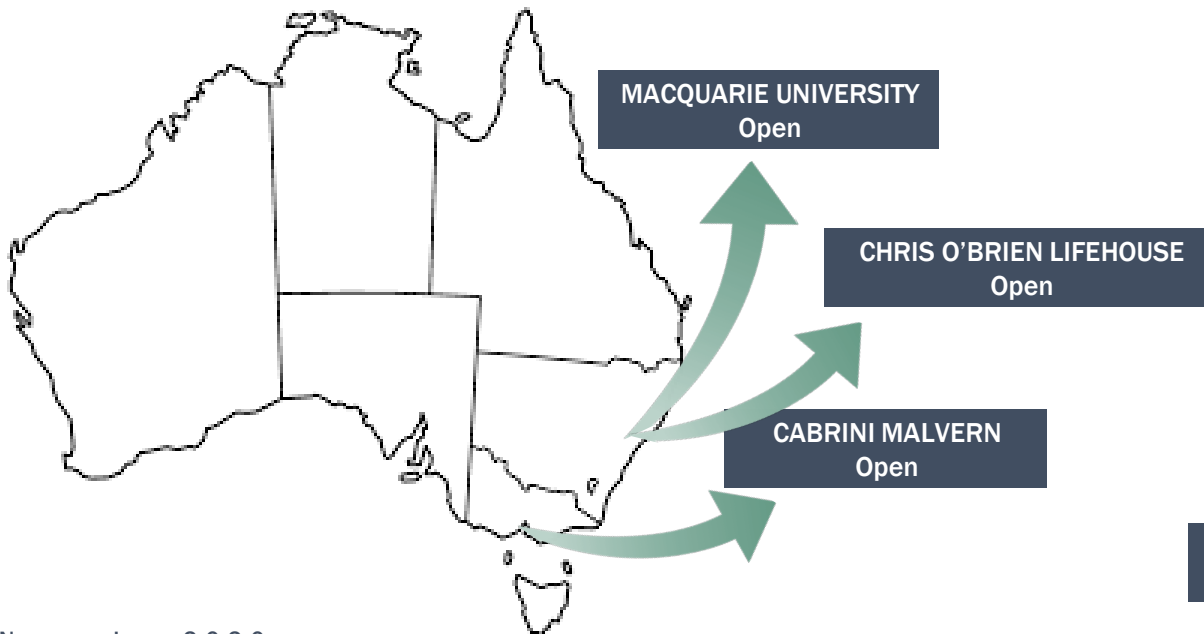
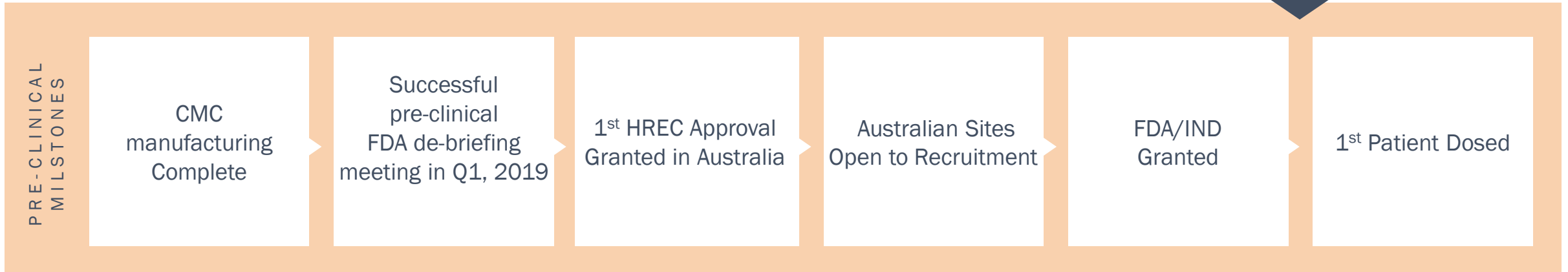
⁺ Statistically Significant

HER-Vaxx PHASE 2: INTERIM ANALYSIS

- ✓ Interim analysis showed statistically significant overall survival Hazard Ratio (HR) of **0.418** (80% 2-sided CI: 0.186, 0.942); HER-Vaxx showed a reduced risk of death of **58.2%** in the HER-Vaxx plus chemotherapy group as compared to chemotherapy alone.
- ✓ The median overall survival (OS) for patients receiving HER-Vaxx plus chemotherapy was **14.2 months**, compared to **8.8 months** in patients treated with chemotherapy alone.
- ✓ The Independent Data Monitoring Committee (**IDMC**) confirms a favourable survival outcome with no added toxicity for HER-Vaxx combined with SOC chemotherapy over chemotherapy alone and advised to **reduce the overall number of patients to ~34** and number of required events **given the strong signal** that it would be considered unethical to enroll 68 as originally planned.
- ✓ The IDMC agreed, that the safety of the study is favorable with **no added toxicity** for the combination of HER-Vaxx and SOC chemotherapy versus SOC chemotherapy alone.
- ✓ The IDMC agreed that the presented data is strongly encouraging to conclude that the combination of **HER-Vaxx and SOC Chemotherapy is safe**.
- ✓ The Phase 2 data represent a **clinical proof-of-concept signal for HER-Vaxx** when added to chemotherapy and indicate that B-cell activating immunotherapy vaccines can induce clinically active antibody responses.

PD1-Vaxx PHASE 1: RECRUITING

Current status

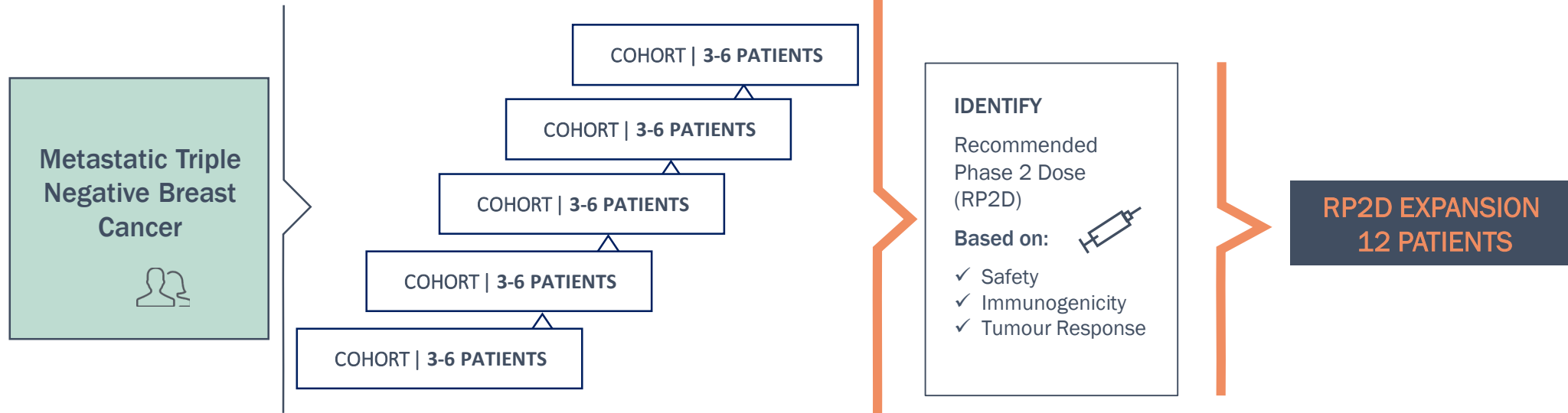







CF33: Oncolytic Virus

CHECKvacc: CF33+hNIS+aPD-L1 (“Armed” Virus)

Phase 1 Triple Negative Breast Cancer Study – GMP Manufacturing Complete

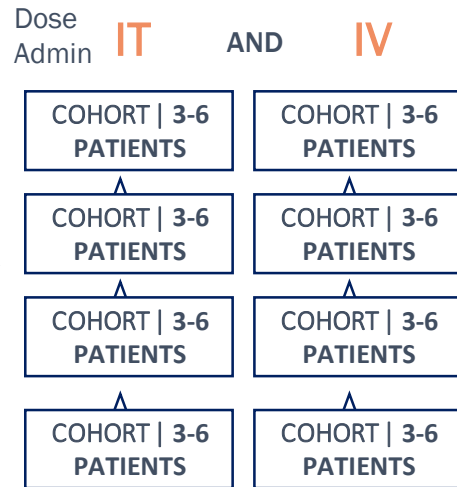


- ❑ Disease of need
 - 8-13 month survival for metastatic disease with few treatments
- ❑ Potential target for immunotherapy
 - Expresses PD1, PD-L1
- ❑ Treatment responses to Atezolizumab (JAMA Oncology, 5:74, 2019)
 - 1st line: 24%; 2nd line: 6%
 - Approved by FDA 8-March, 2019
- ❑ Potential for registration in well-designed, randomized P2 study

	Indication	TNBC
	FDA IND	CHECKvacc: CF33-hNIS-aPDL1
	N	Part 1=18-24 ; Part 2=12
	Location	Single Center: COH
	Admin Route	Intratumoral (IT)

VAXINIA PHASE 1 MAST STUDY (Metastatic Advanced Solid Tumours)

Part 1: VAXINIA Monotherapy Dose Escalation



IT Administration
Head & Neck,
Advanced
Melanoma, TNBC


IV Administration
Head & Neck,
Advanced
Melanoma, TNBC,
NSCLC, Bladder,
Gastric, Colorectal,
RCC

IDENTIFY MONOTHERAPY

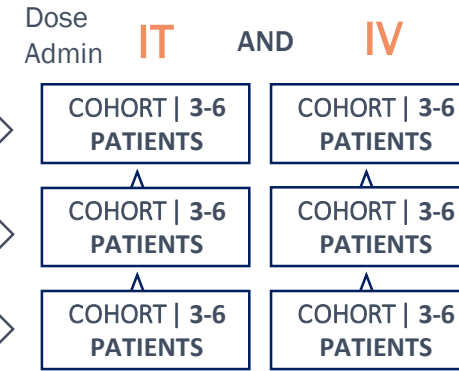
Maximum Feasible Does (MFD)

Based on:

- ✓ Safety
- ✓ Immunogenicity
- ✓ Tumour Response



Part 2: VAXINIA + SOC IO* Combination Dose Escalation



IDENTIFY COMBINATION

DLT* cleared VAXINIA monotherapy dose combined with IO* in dose escalation cohorts. Select IO* Combination for recommended phase 2 dose (RP2D) based on:

- ✓ Safety
- ✓ Immunogenicity
- ✓ Tumour PD and target Signals

Phase

Phase 1

Indication



IT: Head & Neck, Advanced Melanoma, TNBC
IV: Head & Neck, Advanced Melanoma, TNBC, NSCLC, Bladder, Gastric, Colorectal, RCC

Objectives

Safety & MFD

No. of Patients



Approx. 60-120

Site Location

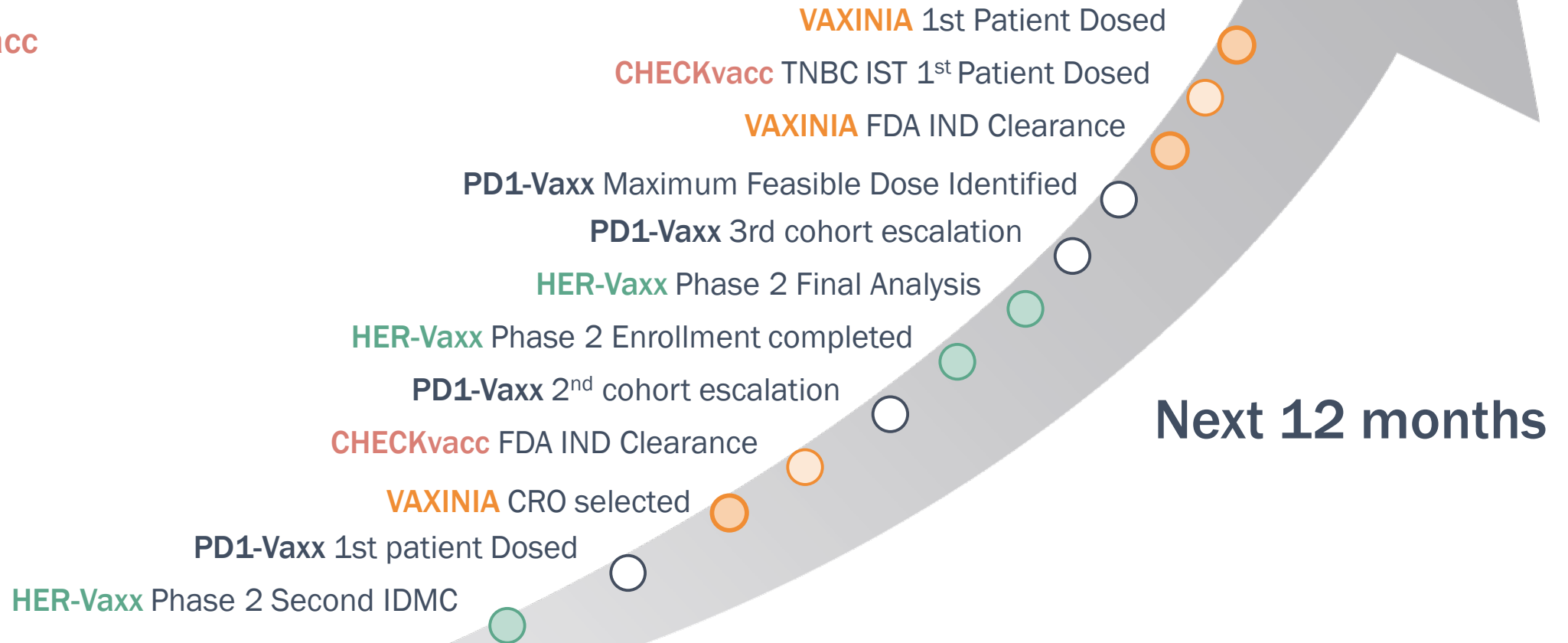
USA

*IO: Immunotherapy

*DLT: Dose Limiting Toxicity

MULTIPLE NEAR & MEDIUM TERM VALUE INFLECTION POINTS

- PD1-Vaxx
- VAXINIA
- HER-Vaxx
- CHECKvacc





Leslie Chong
Managing Director & CEO

leslie.chong@imugene.com
+61 458 040 433
