IMUGENE
Developing Cancer Immunotherapies

ASX: IMU

IMUGENE

11 June 2021

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Introduction to Imugene

Imugene is a biotech company headquartered in Australia and publicly traded on the Australian Securities Exchange (ASX:IMU)

2013

Paul Hopper built Imugne around a technology that originated from the Medical University of Vienna

2015

Leslie Chong from Genentech joined Imugene

2017

HER-Vaxx, our HER-2 targeted B Cell Immunotherapy entered the clinic

2018

Licensed extensive B cell portfolio and platform from OSU and Mayo Clinic comprising of PD1, HER1, HER2, HER3, VEGF, IGF-1R, CD28

2019

Completed the acquisition of a prolific oncolytic virus from City of Hope invented by Dr Yuman Fong

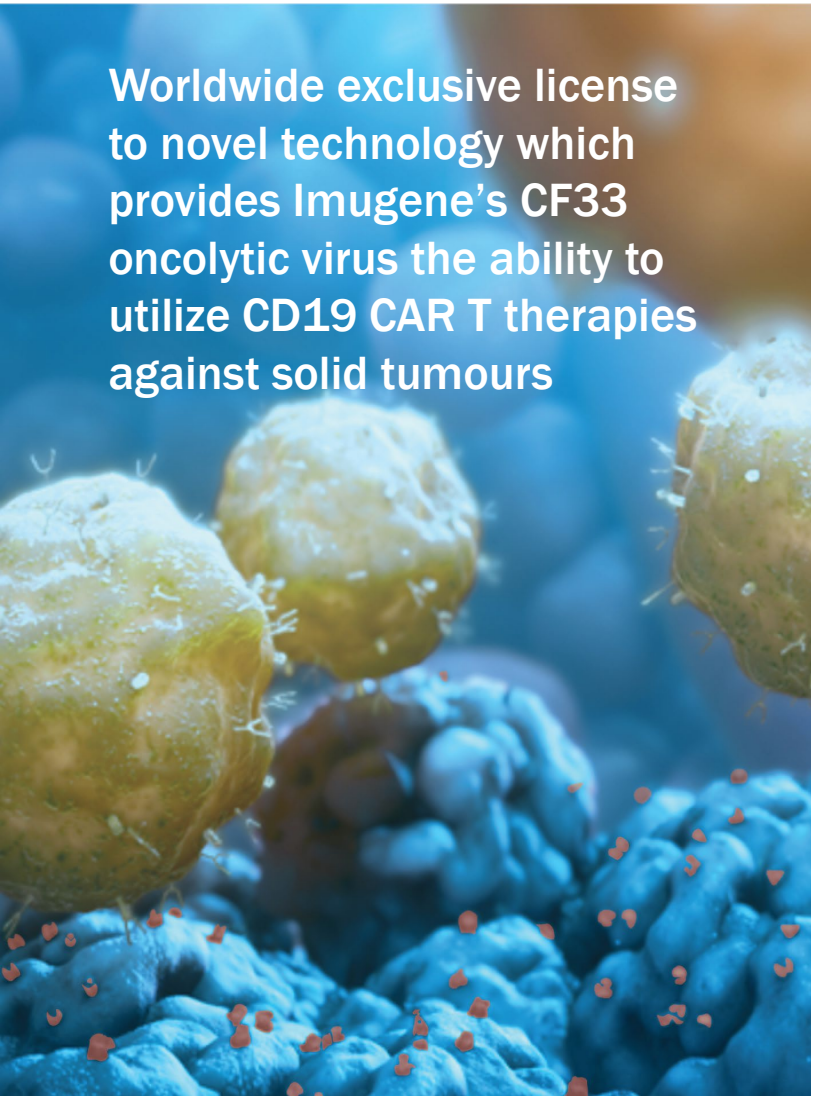
MAY 2021

Licensed onCARlytics from City of Hope invented by Dr Y Fong, Dr S Priceman & Dr A Park

Investment Highlights

- Three novel technology platforms: Oncolytic virotherapies, onCARIytics in cellular therapy and B-Cell activating immunotherapies
- B-Cell Technologies: HER-Vaxx Phase 2 in gastric cancer and PD1-Vaxx in NSCLC
- CF33 Oncolytic Virotherapies: 2 Phase 1 Clinical Trials
- OnCARIytics: Pre-clinical Toxicology Trials
- Highly experienced team in oncolytic virus and cellular therapies
- Significant news flow with multiple near & medium term valuation inflections

onCARIytics Acquisition



The four FDA approved CD19 CAR T drugs only work in blood cancers- solid tumours remain the holy grail

This technology makes the treatment of solid tumours by CAR T drugs viable

Offers Imugene numerous partnering or collaboration opportunities for both approved and in-development CAR Ts, bispecifics, ADC's etc

Enhancement of our scientific team to spearhead clinical development of onCARIytics

Compelling pre-clinical activity

in TNBC, colorectal, pancreatic, prostate, ovarian, head and neck and glioma cancers when combining onCARIytics (CF33-CD19) with CD19 CAR T

Phase 1 CF33 oncolytic virus studies, commencing shortly will accelerate development of onCARIytics

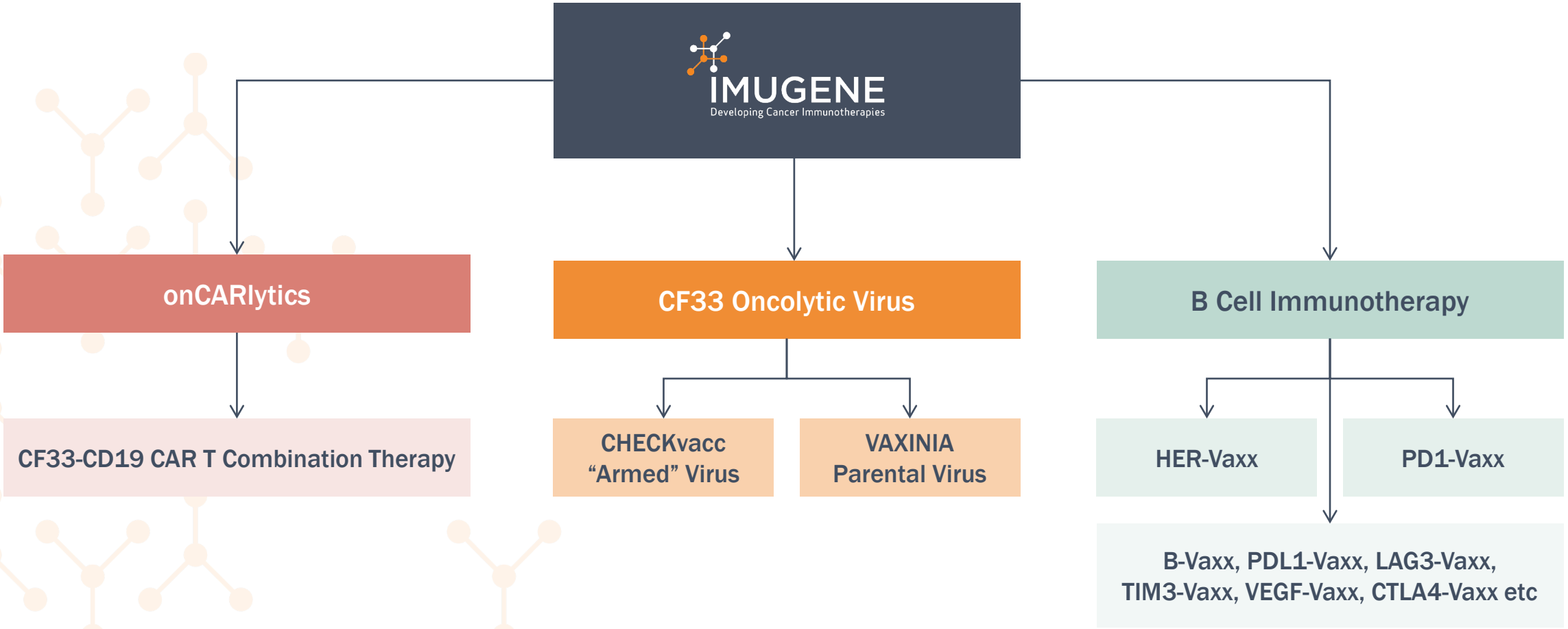
Attractive industry standard licensing terms and royalty rates

OnCARIytics Phase 1 study to commence in 2022

Robust intellectual property with long patent life

Four-year Sponsored Research Agreement with City of Hope Cancer Centre to further develop the technology

Three Novel Technology Platforms



Imugene's Deep Pipeline

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	Pre-clinical	Clinical development Phase 1	Clinical development Phase 2	Key Data / Results	Intellectual Property
onCARIytics (CF33-CD19)				• Compelling pre-clinical activity in multiple cancers when combining onCARIytics (CF33-CD19) with CD19 CAR T • Combination of onCARIytics and CD19 CAR T cells promotes endogenous memory T cell responses • No infection in normal cells	**Expiring 2038**
VAXINIA (CF33-hNIS)	Metastatic Advanced solid tumours			• CF33 has shown strong anti tumour responses in preclinical studies • Inhibition of tumour growth in nearly all NCI60 models in TNBC, Lung, Pancreatic etc. • Signs of increased tumour growth inhibition with CF33 + anti PD-L1	**Expiring 2037**
CHECKvacc (CF33-hNIS-aPD-L1)	Triple negative breast cancer			• Pre-clinical studies showed cancer growth inhibition was better than compared to Amgen or • Genelux oncolytic virus • Potentially solves the industry problem of additive toxicity of combined checkpoint inhibitors if safety of CF33 is maintained in combination	**Expiring 2037**
HER-Vaxx (HER-2)	Gastric			• Successful completion of Phase 1b trials, published in AACR, ASCO GI, ASCO, ESMO GI, ESMO, ESMO Asia 2019 • Strong trial results with no safety or toxicity issues, all patients had increased antibody response, 11/14 evaluable patients with encouraging clinical responses • Phase 2 Interim data: 0.418 HR (80% 2-sided CI: 0.186, 0.942); 14.2 months HER-Vaxx + chemo compared to 8.8 months chemo alone	**Expiring 2036**
PD1-Vaxx (PD-1)	Lung			• PD1-Vaxx has shown encouraging response in preclinical studies • Strong inhibition of tumour growth in mouse models of colorectal cancer (outperformed industry standard mouse PD-1 mAb) • Signs of increased tumour growth inhibition when co-administered with B-Vaxx • FDA IND approval • First NSCLC patient dosed December 2020	**Expiring 2037**

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B-Cell Immunotherapies

B Cell Based Antibodies Have Distinct Advantages To Existing Treatments

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B cell Vaccines offer a unique opportunity to intervene at multiple points in the immune system and create immune memory which enhances durability of response.

NATURAL B CELL DERIVED ANTIBODIES

MONOCLONAL ANTIBODIES

Safety	Stimulates the immune system to produce Abs, which may be potentially safer	Synthetic Ab, with side effects (including ventricular dysfunction, CHF, anaphylaxis, immune mediation)
Efficacy	Polyclonal Ab response reduces risk of resistance and potentially increases efficacy	Monoclonal Ab – may develop anti-drug antibodies
Durability	Antibodies continuously produced with lasting immune response to potentially inhibit tumor recurrence	Half life necessitates recurrent dosing
Usability	Potentially low numbers of vaccinations required per year	Requires regular infusion
Cost	Low cost of production enables greater pricing flexibility facilitating combination	Expensive course of treatment >US$100K per year

HER-Vaxx Phase 2 Recruitment Complete

Trial

- Phase 2
- Open label
- Asia
- Eastern Europe
- India

Patients

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

Study

Randomized
HER-Vaxx in combination with standard of care chemotherapy

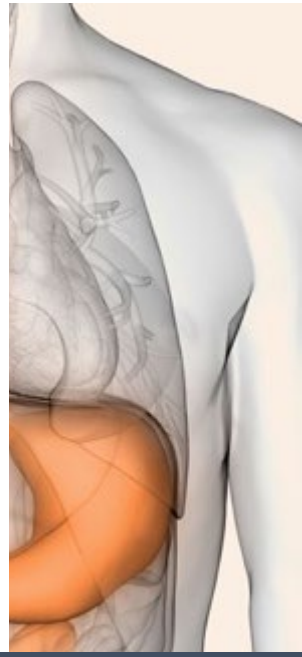
Or
Standard of care chemo: Cisplatin and 5FU or capecitabine or oxaliplatin

Primary Endpoints

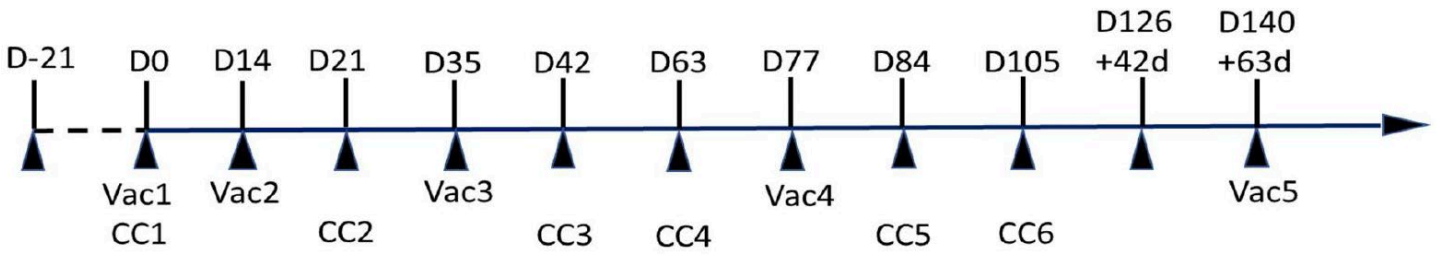
- Overall survival

Secondary Endpoints

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



First patient dosed March 2019/Last patient enrolled Jan 2021



Legend :
CC = Chemotherapy Cycle
Vac = IMU-131 administration

Max 6 cycles SOC chemo with progression assessment every 42 days

AACR 2021 Presentation Poster

Abstract No. CT107

A PHASE 1B/2 OPEN-LABEL STUDY WITH RANDOMIZATION IN PHASE 2 OF IMU-131 HER2/NEU PEPTIDE VACCINE PLUS STANDARD OF CARE CHEMOTHERAPY IN PATIENTS WITH HER2/NEU OVEREXPRESSING METASTATIC OR ADVANCED ADENOCARCINOMA OF THE STOMACH OR GASTROESOPHAGEAL JUNCTION

Interim Analysis Results

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INTRODUCTION

HER-Vaxx (IMU-131) is a B-cell activating immunotherapy consisting of three fused B-cell epitopes (p467) from the HER2/neu extracellular domain coupled to CRM197 and administered with the adjuvant Montanide.

The Phase 2 part of the study hypothesizes that active immunization with HER-Vaxx (IMU-131) will replicate or improve efficacy and safety of the approved monoclonal antibodies that target HER2 in patients with confirmed Her2+ advanced or metastatic Gastric Cancer. In the Phase 1b dose finding part of the study tumor response of patients who received 50ug dose strongly correlated with antibody levels with 50ug selected as the Phase 2 dose (Wiedermann et. al., Annals of Oncology (2019)).

BACKGROUND

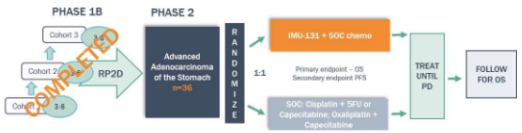

Figure 1: IMUACS.001 Study Design

In part 2 of study IMUACS.001, patients are randomized into two arms of either HER-Vaxx plus standard chemotherapy or standard chemotherapy alone.

The study is conducted in countries with limited access to trastuzumab in Asia and Eastern Europe.

The primary endpoint is overall survival, with progression-free survival and safety as secondary endpoints. Immune related endpoints include values and changes from randomization in humoral and cellular immunogenicity data.

METHODS

IMU-131 plus chemotherapy treated patients received 50ug dose of IMU-131 at Baseline/Day 0, Day 14, Day 35, Day 77 and then every 63 days until disease progression.

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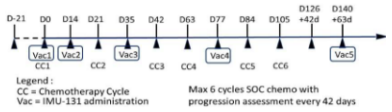


Figure 2: IMUACS.001 Phase 2 Treatment Schedule

RESULTS

Here we report the safety and efficacy results from the 1st interim analysis (OS and PFS) in a total of 27 patients after 15 progression events.

Within the ITT patient population, 8 of 27 patients have died on the control arm and 4 are deceased on the HER-Vaxx plus SOC chemotherapy arm. This translated into an overall survival HR of 0.418 (2 sided 80% CI: 0.186, 0.942) and a 1-sided p-value of 0.083. Progression free survival data of 27 patients was available, 9 patients progressed on the control arm and 6 patients on the HER-Vaxx plus SOC chemotherapy arm with a HR of 0.532 (2 sided 80% CI 0.267, 1.060) and a 1-sided p-value of 0.086.

Endpoint	Overall Survival Intent to Treat (Primary)		Progression Free Survival Intent to Treat (Secondary)	
Treatment	HERvaxx + Chemotherapy	Chemotherapy Only	HERvaxx + Chemotherapy	Chemotherapy Only
All Patients n=27	14	13	14	13
Events	4	8	6	9
HR	0.418		0.532	
2-sided 80%CI	(0.186,0.942)		(0.267,1.060)	
Log-rank Test (1-sided p-value) *	0.083*		0.086*	

*Pre-specified alpha at 0.10
* Statistically Significant

Table 1: IMUACS.001 Phase 2 Overall Survival & Progression Free Survival

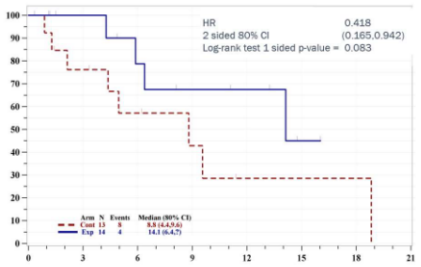


Figure 3 : IMUACS.001 KM-Curve Overall Survival Primary Endpoint

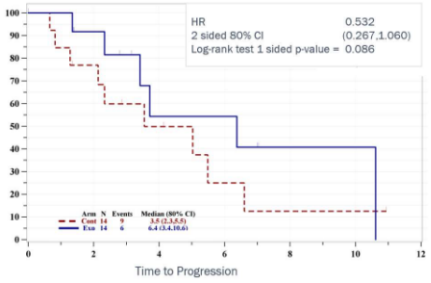


Figure 4: IMUACS.001 KM-Curve Progression Free Survival Secondary Endpoint

There was no difference in safety between the two treatment arms, suggesting HER-Vaxx does not add toxicity to SOC chemotherapy (Table 2). Incidence of Grade 3 and higher non-hematological (Table 3) and hematological adverse events (Table 4) were low and balanced between the treatment arms.

Two patients on each treatment arm had an asymptomatic LVEF drop, none of them below LVEF of 50.

Total (n=27)	HERvaxx + Chemotherapy n=14		Chemotherapy Only n=13	
	n	%	n	%
Patients with at least one TEAE	13	92.9%	12	92.3%
Grade 1	2	14.3%	3	23.1%
Grade 2	5	35.7%	2	15.4%
Grade 3	6	42.9%	4	30.8%
Grade 4	0		2	15.4%
Grade 5	0		1	7.7%

Table 2: IMUACS.001: Safety Overview of Treatment Emergent Adverse Events (TEAE)

Adverse Event ≥ Grade 3	HERvaxx + Chemotherapy n (grade)	Chemotherapy Only n (grade)
Gastrointestinal toxicity	0	1 (3)
Fatigue	2	0
Gamma-GT increased	2 (3+3)	0
Acute respiratory failure	1 (3)	1 (5)
Cachexia	0	1 (3)
Palmar-plantar erythrodysaesthesia syndrome	0	1 (3)
Pneumonia	0	1 (4)
Acute hepatic failure	0	1 (4)
Embolism	1 (3)	0
NOS (uncoded)	0	1 (3)
Total n	6	7

Table 3: IMUACS.001 Grade 3 and Higher Non-Hematological AE

Adverse Event	HERvaxx + Chemotherapy n	Chemotherapy Only n
Anemia:		
Grade 1+2	1	1
Grade 3	1	4
Febrile neutropenia:		
Grade 1	1	0
Neutrophil count decreased:		
Grade 2	1	0
Grade 3	1	0
Platelet count decreased:		
Grade 3	1	0
Grade 4	0	1
Total n	**6**	**6**

Table 4: IMUACS.001 Grade 3 and Higher Hematological AE

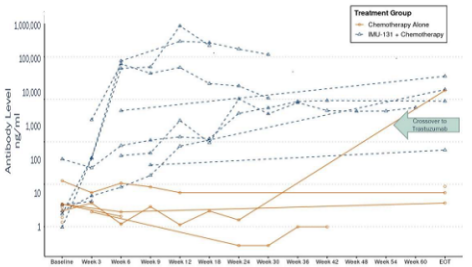


Figure 5: IMUACS.001 PHASE 2 - HER2 Specific Antibodies

By week 6 HER2-AB were developed by the patient's immune system as response to HER-Vaxx vaccinations and remained high during treatment with every 63 days maintenance vaccinations only. One patient on the chemo control arm progressed at week 24 and received trastuzumab containing treatment. The patient returned for one AB assessment that showed a similar level as HER-Vaxx (Figure 5).

Further data on response and biomarker is awaited.

CONCLUSIONS

These data demonstrate HER-Vaxx may provide treatment benefits consistent with traditional monoclonal antibodies with a corresponding adaptive immune response without toxicity.

A study (neoHERIZON) in perioperative HER2+GC with HER-Vaxx in combination with FLOT+/- anti-PD-L1 is in planning.

REFERENCES

Wiedermann et al: 2019, Annals of Oncology Volume 30 P495-496: Results of P1b study with a HER2/neu B-cell vaccine administered with chemotherapy in patients with HER2/neu overexpressing advanced gastric cancer

DISCLOSURES

Study is sponsored by Imugene Limited

B-cell peptide vaccine (IMU-131) was developed at the Medical University of Vienna

AACR 2021 Presentation Highlights

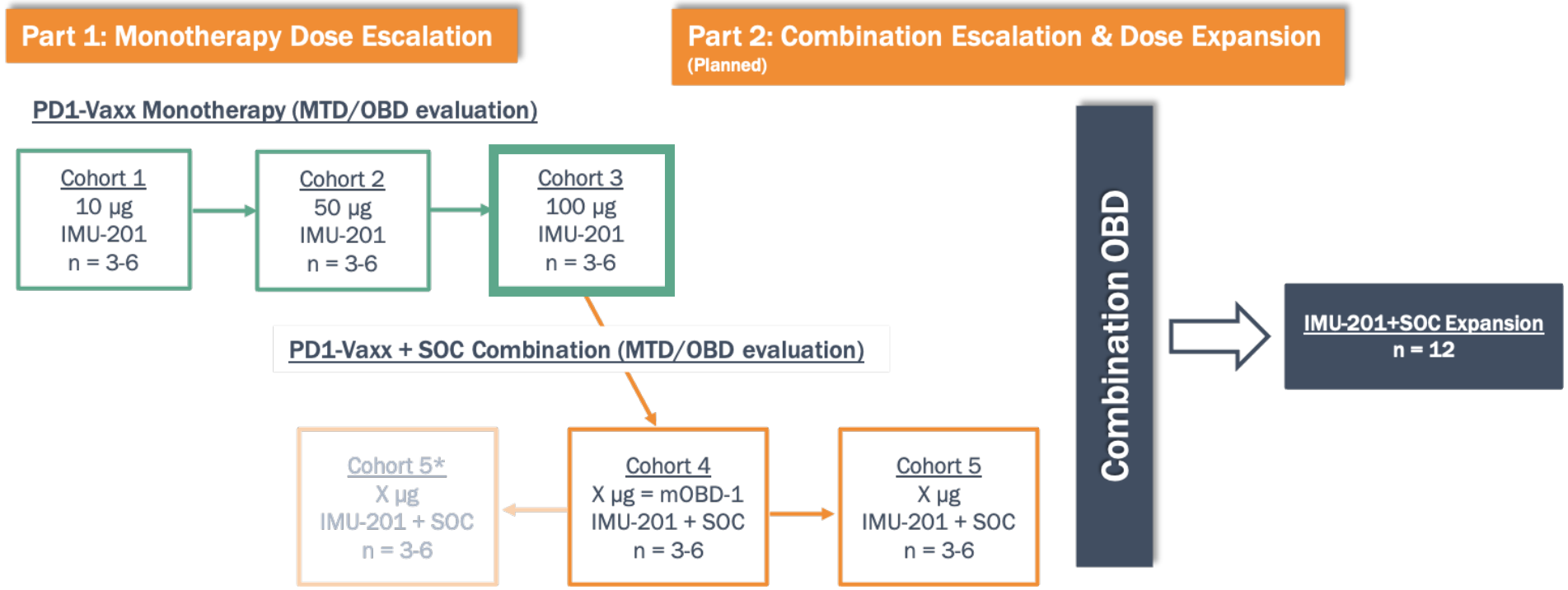
The AACR presentation highlights and presents the following new data:

- Treatment with HER-Vaxx clearly demonstrates that **all patients** develop **high levels** of HER2-specific **antibodies** early in the treatment protocol.
- Analysis of the antibody data reveals **high levels** are maintained during the treatment and maintenance phases, with only **minimal booster** injections of HER-Vaxx required to maintain the **high levels**.
- The constant and high HER2 antibody levels correlate with the **early separation** of the Kaplan Meier (KM) Curves for overall survival (OS) and progression free survival (PFS) clinical trial endpoints. The Kaplan Meier Curve provides a recognised statistical estimation of the survival function which visually represents the probability of an event occurring for each treatment arm at a respective time interval.
- Overall, this interim data is suggestive that the **treatment is effective** and **well tolerated** with an **overall survival benefit that is superior** to chemotherapy alone.

Final tumour response, correlation of antibodies with tumour response, and final PFS and OS data is expected to read out in 2021.

PFS Endpoint Events met on 21st April 2021; Top Line Data expected July 2021

PD1-Vaxx Phase 1 Study Design

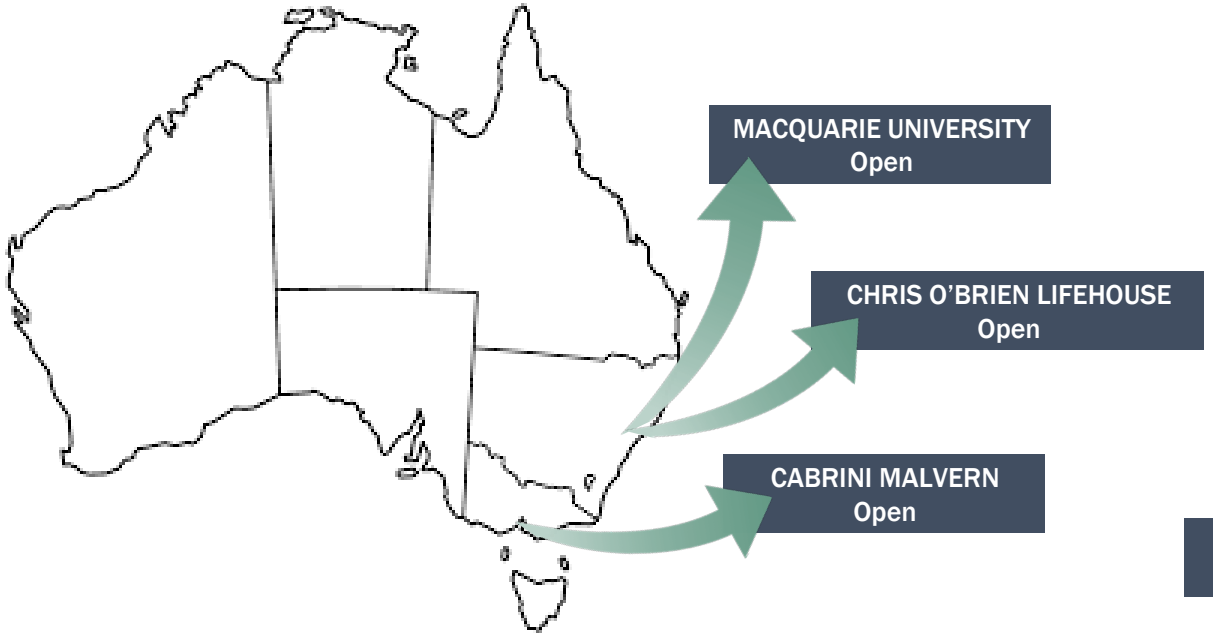


PHASE	MONOTHERAPY DOSE ESCALATION Part 1	COMBINATION ESCALATION & EXPANSION Part 2 (planned)
Indication	Non-small cell lung cancer expressing PD-L1	
Objectives	Safety & Tolerability, Immunogenicity, OBD Monotherapy	
# Patients	Approx. 12-22	Approx. 12-30
Site Location	Australia & USA	

PD1-Vaxx Phase 1 Study Design

Current Status

MILESTONES					
1st Patient Dosed Cohort 1 30 Nov 2020	Cohort 1 Cleared Jan 2021	1st Patient Dosed Cohort 2	Cohort 2 Cleared	1st Patient Dosed Cohort 3	Cohort 3 Cleared, RP2D & Expansion Opened



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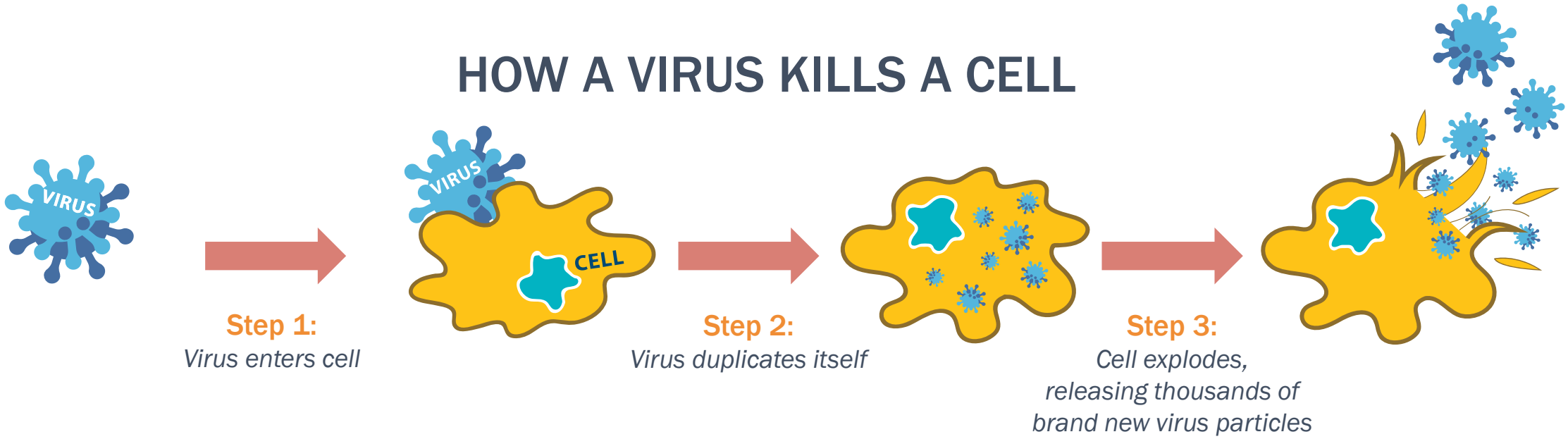
Oncolytic Virus CF33

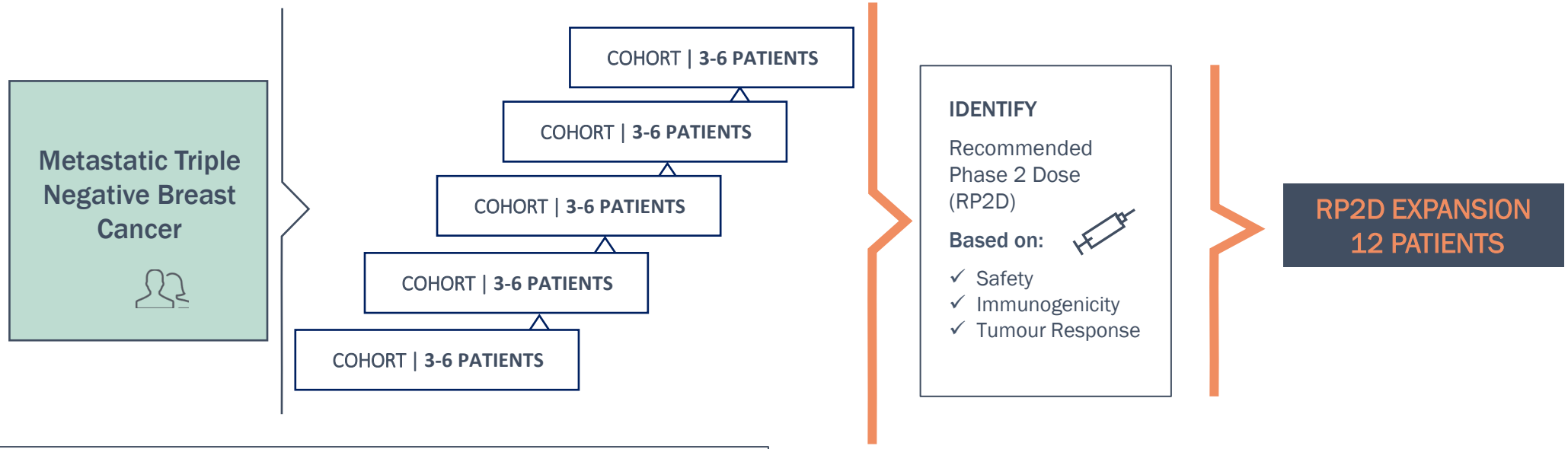
CF33 Mechanism of Action



- Direct infection, replication within and cancer cell killing
- Viral infection increases local check point targets (PD-1, PD-L1, CTLA4 etc)
- Cell death is immunogenic [surface expression of calreticulin, release of adenosine triphosphate (ATP) and release of high mobility group box 1 (HMGB1)]
- Local anti-PD-L1 expression may allow enhancement of anti-cancer immunotherapy
- Human sodium iodine symporter (hNIS) expression allows additional use of ^{131}Iodine or ^{188}Rhenium killing of infected cells and adjacent cells

CHECKvacc "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

IT Administration
Head & Neck, Advanced Melanoma, TNBC

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

Part 1: VAXINIA Monotherapy Dose Escalation

Dose Admin IT AND IV

COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS
COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS
COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS
COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS

IDENTIFY MONOTHERAPY

Maximum Feasible Does (MFD)

Based on:

- ✓ Safety
- ✓ Immunogenicity
- ✓ Tumour Response

Part 2: VAXINIA + SOC IO* Combination Dose Escalation

Dose Admin IT AND IV

COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS
COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS
COHORT | 3-6 PATIENTS	COHORT | 3-6 PATIENTS

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*

The CAR T Solid Tumour Challenge & Imugene's Solution

Chimeric Antigen Receptor (CAR) T cell therapy has had limited activity in solid tumours, largely due to a lack of selectively and highly expressed surface antigens, such as the blood B cell antigen CD19.

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NEW CONCEPT

Utilise OV's as a delivery vector to deliver CD19 antigen to solid tumour cells

Engineer Imugene's CF33 to infect solid tumour cells and insert CD19 transgene to enable presentation of CD19 over the tumour cells during tumour cell infection, onCARlytics (CF33-CD19)

Combination use of autologous or allogeneic CD19 CAR Ts (eg. Novartis KYMRIAH®) with onCARlytics (CF33-CD19) presents CD19 targets on solid tumours

Four FDA Approved CD19 CAR T's

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Approved and in-development autologous or allogeneic CD19 CAR Ts can be partnered with Imugene's onCARlylics for treating solid tumours:

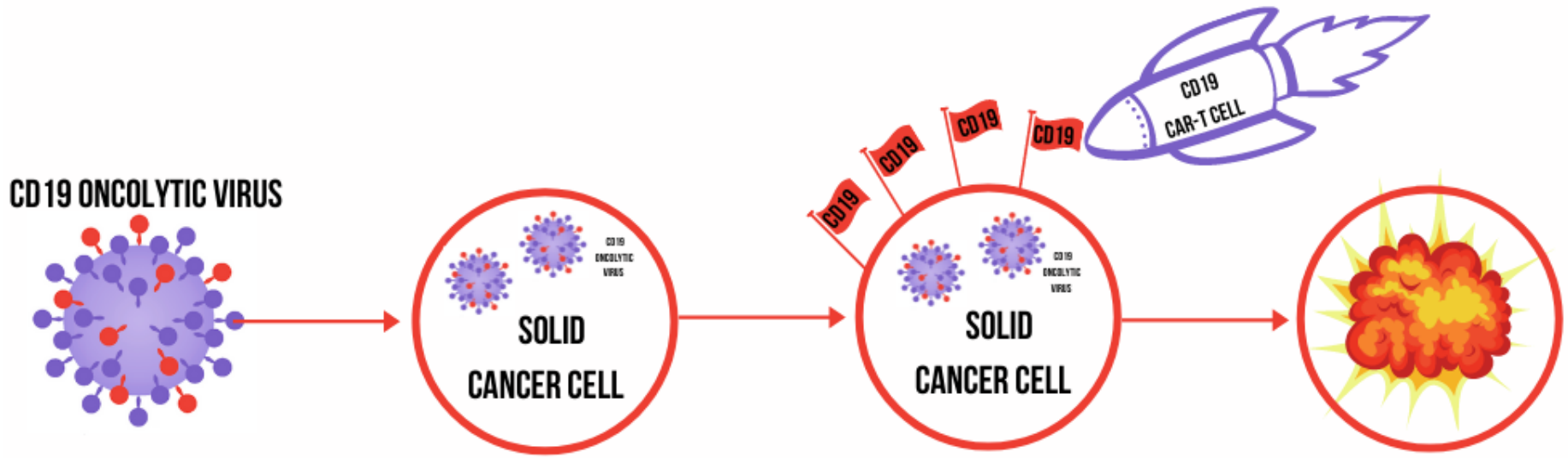
KYMRIAH® (tisagenlecleucel) Suspension for IV infusion
NOVARTIS

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion
GILEAD

TECARTUS™ (brexucabtagene autoleucel) Suspension for IV infusion
Kite

Breyanzi® (lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION
Bristol-Myers Squibb

HOW DOES THE CD 19 ONCOLYTIC VIRUS WORK?



1. CD19 ONCOLYTIC VIRUS INFECTS SOLID CANCER

2. CD19 ONCOLYTIC VIRUS CAUSES THE SOLID CANCER TO GROW "CD 19 FLAGS"

3. CD19 CAR-T CELL RECOGNISE THE CD19 FLAGS AND ATTACKS THE CANCER CELL

4. CANCER CELL DIES

Intellectual Property

FOUNDATION PATENT (2038)

PCT	US2019/033030
Title	Oncolytic virus expressing a CAR T cell target and uses thereof
Inventors	Fong, Priceman, Forman, Chen & Park
Assignee	City of Hope
Primary Date	11 August 2017
International Publication	14 February 2019
Expiration Date*	2038

PCT application filing date was 10/8/2018 and *estimated expiration date is in **late 2038**. The patent application includes both composition of matter and method of use. It is currently pending with the opportunity to secure worldwide rights. International search report was favorable for composition of matter.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 February 2019 (14.02.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/033030 A1

(51) International Patent Classification:
A61K 39/39 (2006.01) *C07K 16/28* (2006.01)
A61K 35/768 (2015.01) *C12N 7/00* (2006.01)
C07K 14/705 (2006.01) *C12N 7/02* (2006.01)
C07K 14/725 (2006.01) *C12N 15/863* (2006.01)

(21) International Application Number:
PCT/US2018/046313

(22) International Filing Date:
10 August 2018 (10.08.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/544,707 11 August 2017 (11.08.2017) US

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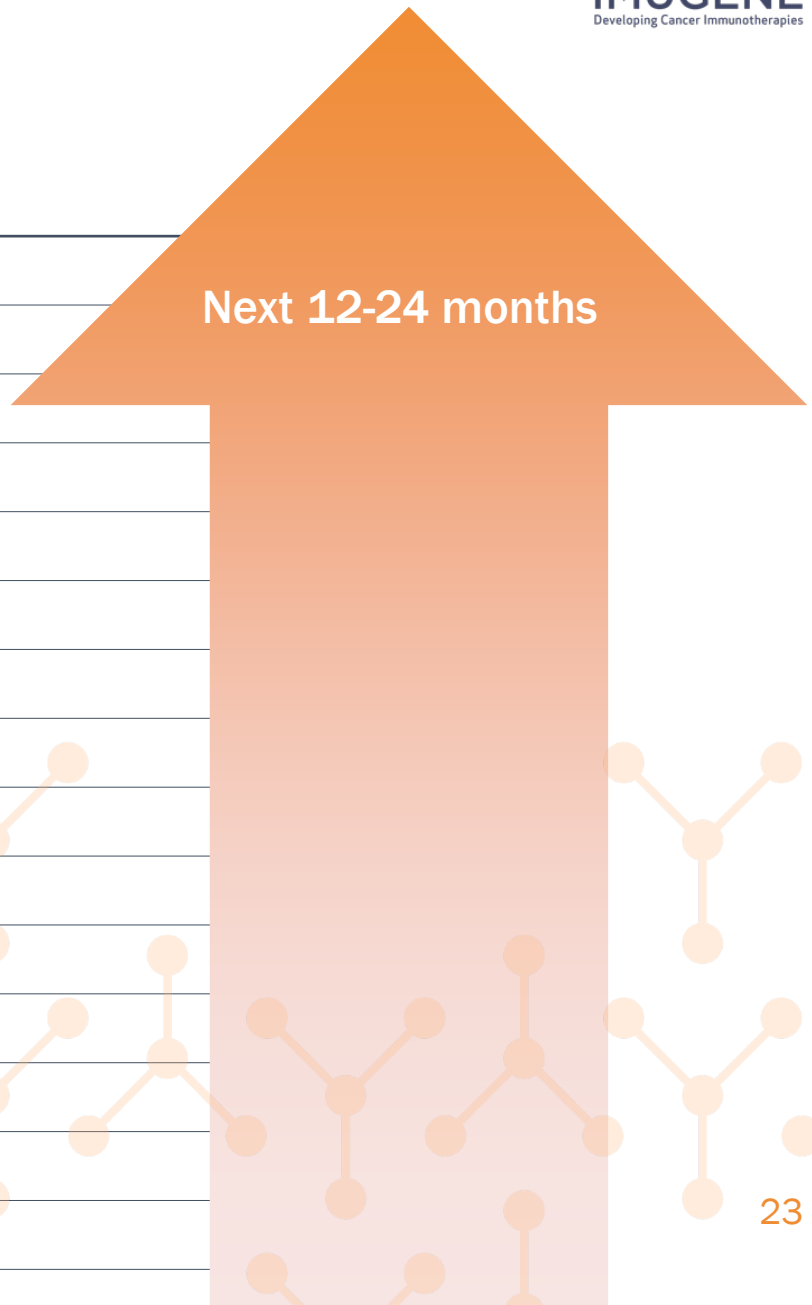
Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:
— *with international search report (Art. 21(3))*
— *with sequence listing part of description (Rule 5.2(a))*

Milestones

IMUGENE
Developing Cancer Immunotherapies



✓	Technology	Milestone
	onCARIytics	1st Patient Dosed Monotherapy
	onCARIytics	FDA IND Clearance
	PD1-Vaxx	Combination RP2D
	onCARIytics	GLP Toxicology Study
	VAXINIA	1st Patient Dosed
	PD1-Vaxx	Expansion combination study FPI
	HER-Vaxx	Phase 2 Final Analysis
	VAXINIA	FDA IND Clearance
	onCARIytics	FDA Pre-IND Meeting
	PD1-Vaxx	Maximum Feasible Dose Identified
	HER-Vaxx	OS Endpoint Met
	onCARIytics	GMP manufacturing for pre-clinical toxicology & Phase 1 study
	CHECKvacc	TNBC IST 1st Patient Dosed
	HER-Vaxx	PFS Top line Results
	CHECKvacc	FDA IND Clearance

Financial Summary

Public Market Overview

Share Price [1]	A$0.325
Market Capitalisation [2]	A$1.604B
Cash equivalents (31 Mar 21)	A$29.4M
Enterprise Value	A$1.575B

Top 5 Shareholders (as of May 2021)

Mann Family	5.93%
Paul Hopper	4.09%
Dr Nicholas Smith	2.40%
Ms Leslie Chong	1.56%
Private Portfolio Management	1.35%

Share Price Performance (last 6 months)

Note:
1. As of 26 May 2021
2. Market capitalization calculations based on ordinary shares (4.877 bn) only and excludes the dilutive impact of options outstanding (578m) as of 25 May 2021

IMUGENE
Developing Cancer Immunotherapies

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