

# Initiation Report

IMUGENE LIMITED



## Imugene Limited – Therapeutic Cancer Vaccines and Oncolytic Virus Powered Immunotherapies Targeting Solid Tumors

Imugene Ltd. (ASX: IMU)

Share Price: A\$0.18

Valuation: A\$0.48



### Key Statistics

52 Week Range	A\$0.130 - A\$0.625
Avg. Volume (3 months)	22.38M
Shares Outstanding	6.27B
Market Capitalization	A\$1.13B
EV/Revenue	N/A
Cash Balance*	A\$175M
Analyst Coverage	5

\*Cash balance as of June 2022 (inclusive of institutional placement)

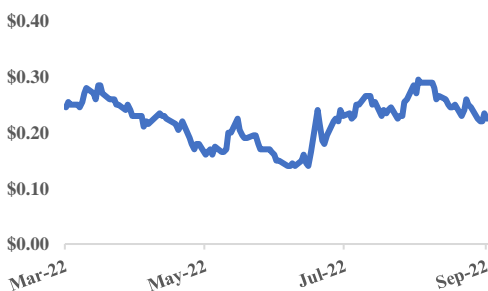
### Revenue (in A\$m)

June - FY	2022A	2023E	2024E
1Q	n/a	n/a	n/a
2Q	n/a	n/a	n/a
3Q	n/a	n/a	n/a
4Q	n/a	n/a	n/a
FY	n/a	n/a	n/a

### EPS (in A\$)

June - FY	2022A	2023E	2024E
1Q	n/a	n/a	n/a
2Q	n/a	n/a	n/a
3Q	n/a	n/a	n/a
4Q	n/a	n/a </td <td>n/a</td>	n/a
FY	(0.01)	(0.01)	(0.01)

### Stock Price Chart (in AS\$)



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### Investment Highlights

- Diversified Pipeline with Multiple Candidates in Clinical Trials** - In the past few years, the company has licensed multiple technologies, creating a diversified pipeline of five therapeutic products, four of which are in clinical trials. HER-Vaxx and PD-1 Vaxx have demonstrated robust safety and efficacy in the early stages of clinical trials. The ability of these underlying cancer vaccines to elicit active immunization at lower cost and dosage, and potentially deliver improved efficacy creates a more effective treatment modality than certain passive forms of immunotherapies such as monoclonal antibodies (mAbs). The company's oncolytic virus CF33, designed to infect, kill and replicate, has also shown effective cancer-killing phenomenon in a range of cancer cell lines. Both CHECKvacc (CF33-hNIS-antiPD-L1) and VAXINIA (CF33-hNIS) are currently being evaluated in phase 1 clinical trials. Leveraging the transgene delivery potential of OV, the company's fifth clinical candidate has the potential to supplement CD19-directed CAR-T therapy's ability to treat solid tumors. Imugene has adopted a basket approach, creating a diversified pipeline of multiple promising drug candidates, each of which has its own compelling medical and market case.
- Niche Therapeutic Candidates with Long Patent Life** - Instead of focusing on the much more crowded space of immunotherapies such as mAbs, Immune Checkpoint Inhibitors, and CAR-T cell therapy, Imugene is targeting the niche therapeutics segment of cancer vaccines and oncolytic virus therapy that tend to exert lower side effects in cancer patients than other systemic therapies. Additionally, all of its five pipeline candidates have long patent lives, with expiry for its lead candidate HER-Vaxx in 2036 and for others starting in 2037.
- Large Total Addressable Market** - With its five pipeline candidates, Imugene is targeting multiple solid tumor types with low survival rates and a lack of efficacious and safe treatment options. The targeted solid tumor types (HER2+ gastric cancer, NSCLC, TNBC, among others) represent an addressable market of over half a million patients globally and a multi-billion-dollar market.
- Valuation** - Imugene is well-capitalized with a cash reserve amounting to approximately A\$175 million as of June 30<sup>th</sup>, 2022, inclusive of recent institutional placement. The company's sound financial position reduces the financing and dilution risk over the short to medium term. We believe the company has strong fundamentals given the soundness of science exhibited through optimistic early-stage clinical results, a large total addressable market, and a management team with extensive experience in cancer therapies. Our valuation methodology is based on risk-adjusted DCF using a discount rate of 10.7%. We have forecasted revenue for four therapies currently in clinical trials and applied a probability of success factor based on their progress through the clinical trial. Our valuation methodology yielded a value of A\$2.98 billion or A\$0.48 per share, contingent on successful execution by the company.

### Company Description

Imugene Limited is an Australian clinical-stage immuno-oncology company developing a range of immunotherapies to activate the immune system of cancer patients to treat and eradicate tumors. The company is developing five unique assets based on three different platform technologies.

## Company Overview

Imugene Limited (ASX: IMU) is an Australia-based clinical-stage biotechnology company focusing on developing immunotherapies for the treatment of various cancers. The company has a diversified pipeline of 5 unique assets developed on a strong research base of 3 platform technologies. The company is targeting ten disease areas with high unmet needs and low survival rates. Imugene’s initial focus has been to advance its B-cell peptide vaccines technology, which stimulates the body’s immune system to produce antibodies against the normal self-proteins, such as HER2 and PD-1. The two lead therapies within the company’s pipeline include HER-Vaxx and PD1-Vaxx, aimed at treating Gastric and Non-Small Cell Lung Cancer, respectively. Expanding its purview, the company acquired the exclusive license to the CF33 Oncolytic Virus technology developed by Professor Yuman Fong at the City of Hope (COH) Cancer Centre in Los Angeles. CF33 is a novel, genetically engineered chimeric orthopoxvirus and has shown promising efficacy in a range of mouse models. Clinical development of CF33 oncolytic virus is being studied in two different constructs, CHECKvacc (CF33+hNIS+anti-PD-L1) and VAXINIA (CF33+hNIS). Both constructs are currently being pursued under phase 1 clinical trial. In addition to B-cell immunotherapy and CF33, Imugene, in May 2021, obtained the worldwide exclusive licenses to the patents covering CF33-CD19, also known as onCARlytics. The CF33-CD19 agent aid CD19-directed CAR T by labeling cancer cells for CAR T cell destruction. CD19 CAR T as a monotherapy faces key challenges in solid tumors largely due to a lack of selectively and highly expressed surface antigens.

*Imugene Limited (ASX: IMU) is an Australia-based clinical-stage biotechnology company focusing on developing immunotherapies for the treatment of various cancers*

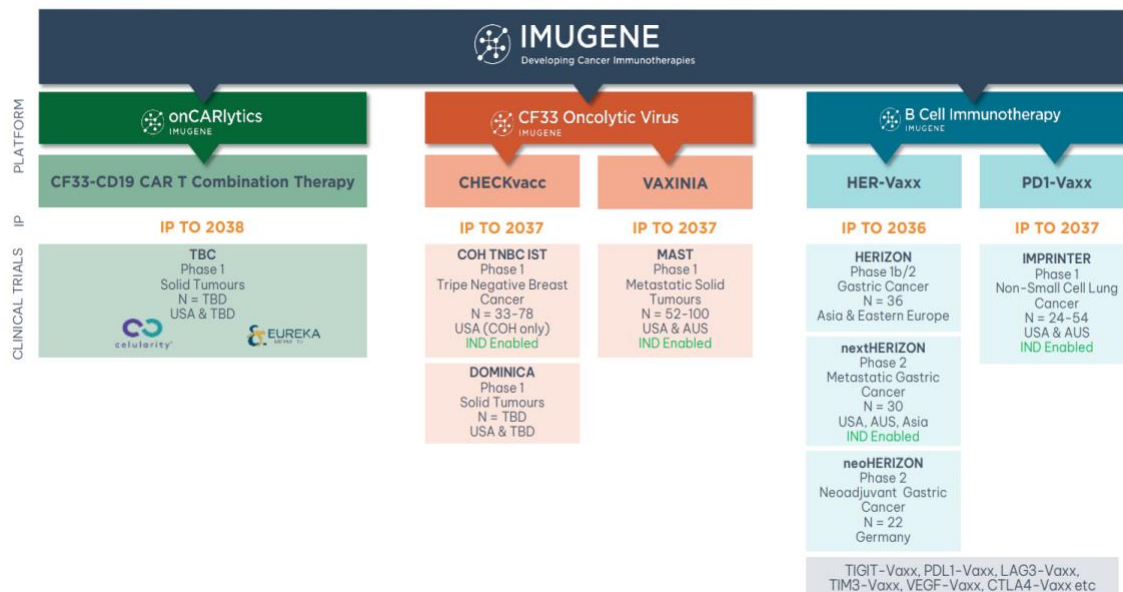


Exhibit 1: Imugene’s Three Technology Platforms and Five Unique Assets. Source: Imugene Limited

Imugene’s platform technology IP is protected by a set of patents, with a majority of the patent expiration starting post-2035. In order to advance its pipeline through different clinical stages and commercialization, the company has engaged in scientific collaboration with Celularity Inc. (NASDAQ: CELU), Eureka Therapeutics, Inc., and Arovella Therapeutics Ltd. (ASX: ALA). The company has also signed a clinical trial supply agreement with pharmaceutical giants Roche (SWX: ROG), Merck KGaA (ETR: MRK), and Pfizer (NYSE: PFE), adding further validation to its pipeline candidates. The company’s pipeline indication represents a multi-billion-dollar market opportunity targeting the highly valuable market of cancer immunotherapy.

## B-Cell Peptide Cancer Vaccines - An Effective Active Immunization Approach

In the past decade, there have been considerable advancements in cancer treatment, with targeted therapies and immunotherapies showing great promise for multiple types of cancer. Passive immunization, such as the use of humanized monoclonal antibodies, is proven to have promising therapeutic applications in the treatment of different forms of malignancies but comes with several caveats that limit the usage of these therapies in numerous cases. Toxicity problems and resistance, high costs, sophisticated therapeutic regimen, and long half-life are a few of the significant shortcomings that have raised the need for an efficacious and long-lasting active immunization approach. One such approach that Imugene believes can cause a paradigm shift in cancer research is the advancement of B-cell epitope vaccines. Cancer vaccines based on B-cell peptides are generally composed of an adjuvant and an immunogenic protein containing a B-cell epitope peptide that can induce B cells to create polyclonal antibodies that bind to different parts of the vaccine antigens. The resulting construct of polyclonal antibodies yields a powerful antitumor effect that is long-lasting and inhibits tumor recurrence. Even though humanized mAbs have a somewhat similar mechanism of action, the use of synthetic bodies to treat cancer has been fraught with several concerns. Poor penetration across tissues, large quantities of hmAbs resulting in toxicity, expensive treatment (average cost: [US\\$150,000](#) per year), and long and frequent infusions. Despite these challenges, hmAbs therapy has become a multi-billion-dollar business.

*The use of B-cell immunotherapies to stimulate the patient's immune system to produce polyclonal antibodies may have advantages over synthetic antibodies*

Therapeutic cancer vaccines, on the other hand, provide an attractive alternative solution due to their potential safety, specificity, lower cost of production, improved efficacy, and long-lasting response—perhaps even cures—due to stimulation of immune memory. Cancer vaccines are believed to hold even greater market potential given the apparent advantages over mAbs contingent on successful FDA approvals. Even though there has been advancement in the development of cancer vaccines, unfortunately, many cancer vaccine programs haven't been able to yield the required results. Lessons learned from these failed attempts are now allowing cancer vaccine research to turn the corner and begin to achieve some promising clinical results. The key lessons driving this progress emanate from three areas: the need for multiple immunogenic antigens; the importance of highly potent vaccine vectors; and a growing understanding of how to quell tumor-mediated immunosuppression.<sup>1</sup>

*In addition to HER2 and PD-1 cancer vaccines, Imugene has also licensed a number of other B-cell cancer vaccines targeting PDL-1, LAG-3, EGFR, VEGF, and CTLA-4*

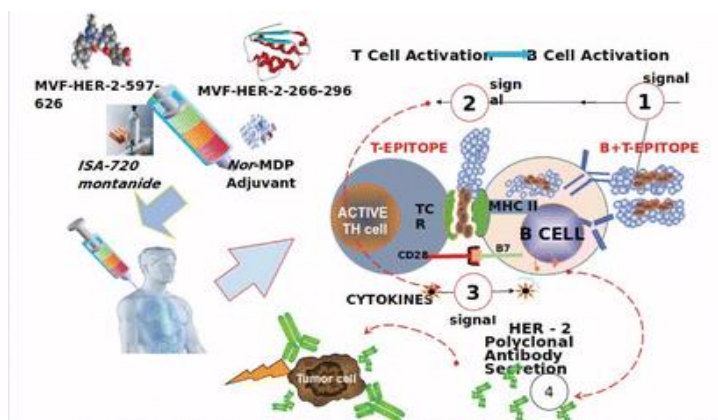


Exhibit 2: B-Cell Epitope Peptide Vaccine Mechanism of Action. Source: Kaumaya et al.

<sup>1</sup> Hollingsworth, R.E., Jansen, K. Turning the corner on therapeutic cancer vaccines. npj Vaccines

## HER-Vaxx – Cancer Vaccine for Gastric Cancer

HER-Vaxx is B-cell immunotherapy that is designed to treat cancers that overexpresses HER2 protein. Different types of solid tumors such as breast cancer, gastric cancer, ovary, endometrium, bladder, head, and neck cancer have been found with over-expression of the HER2 protein. The amplification/over-expression is often associated with poor prognosis and low survival rates. HER-Vaxx is a B-cell peptide vaccine composed of 3 fused epitopes (p467) derived from the extracellular domain of HER2/neu coupled to CRM197 and adjuvanted with Montanide.<sup>2</sup> The resultant vaccine formulation induces a potent polyclonal antibody response that targets cells with overexpressing HER-2 receptors on their surface. Pre-clinical studies have shown strong anti-tumor activity in-vitro and in-vivo and better growth inhibition of breast cancer cells or HER2 signaling pathway compared with single-agent mAb trastuzumab.

The current vaccine formulation is an enhanced version that replaces virosomes used in previous formulations of HER-Vaxx. The company had previously examined the virosomal formulation in phase 1 clinical trial in end-stage breast cancer patients. While the study showed good immunogenicity as well as an excellent safety profile, several drawbacks of the virosomal formulations, including solubility and limited stability after coupling all the single peptides together to virosomes, were the reasons to reconstruct and improve the multi-peptide vaccine with respect to specificity and clinical applicability. The enhanced formulation has been shown to have a faster production of antibodies and a more rapid immune response.

### HER-Vaxx - Herizon (Phase1b/2) Trial Design and Clinical Trial Results

The reformulation/enhanced formulation was administered to Asian and Eastern European patients with HER2/neu-positive gastric cancer. 14 patients with 10 HER2+ over-expression and 4 HER2++ expressing tumors were enrolled in the phase 1b dose escalation study. Three doses were administered at dose levels of 10, 30, and 50 µg. 11 patients received all three doses, and three patients received only two doses due to disease progression. The primary endpoints include assessment of safety, tolerability, immunogenicity, and identification of RP2D of HER-Vaxx. The secondary outcome measures included Progression Free Survival (PFS), Disease Control Rate (DCR), and Time to progression (TTP), among others.

The patient population was divided into three cohorts, each including 3-5 patients. HER-Vaxx was found to be well tolerated with no significant local or systemic reactions. Of the 14 patients that received the treatment, 11 were evaluable for tumor progression and vaccine-specific response at day 56 and later. All patients in cohort 3 (50µg/dose) exhibited higher levels of HER-2/neu specific immunoglobulin G (IgG) antibodies post-administration. In contrast, cohort 2 (30 µg/dose) and cohort 1 (10 µg/dose) displayed moderate to little increase in antibody titers. Along similar lines, cohort 3 displayed a strong clinical response/change in tumor size, exhibiting a strong correlation with anti-body levels. A decrease in tumor size from the baseline was observed in all treatment groups. Additionally, no dose-limiting toxicities (DLTs) or serious adverse events (SAEs) were observed during the course of the study.

*HER-Vaxx has been shown to stimulate a potent polyclonal anti-body response to HER-2/neu, a well-known and validated cancer target*

<sup>2</sup> Future Oncology 2020 16:23, 1767-1791

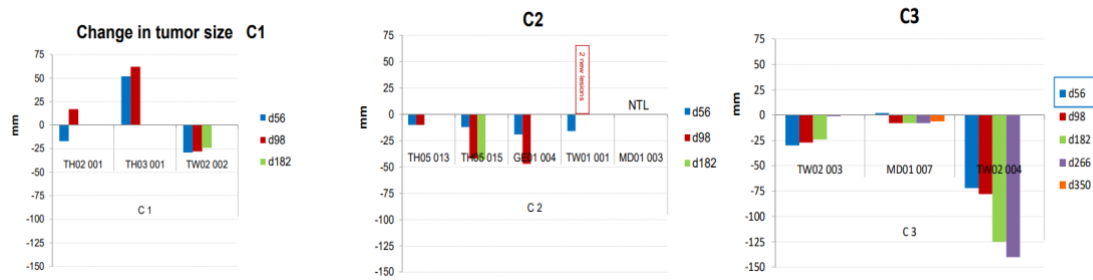


Exhibit 3: Change in Tumor Size (in mm) from Day 0 to Day 56, 98, 182, 266, and Day 350 in C1, C2, and C3. Source: ESMO Asia 2019 Presentation

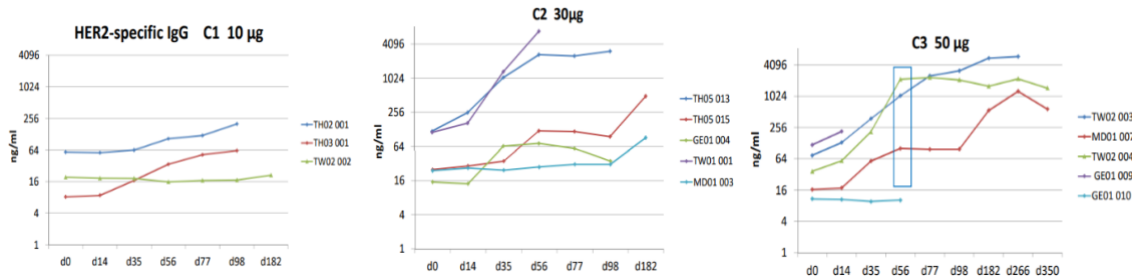


Exhibit 4: HER2-specific IgG Abs in Cohorts 1, 2, and 3 Measured in Sera Obtained at Days 0, 56, and 98. Source: ESMO Asia 2019 Presentation

Of the 11 patients that were evaluable at day 56, one showed complete response, five patients showed partial response, and 4 showed stable disease. The vaccine was tolerated among the patient population, and patients treated with the 50µg dose produced the most consistent P467 and HER-2 specific antibodies compared to those treated with 10 and 30 µg doses. The preliminary response data also demonstrated that 50 µg of HER-Vaxx was associated with tumor size reduction. Further, a dose of 50µg was recommended for phase 2 clinical trials.

Best Overall Response	IMU-131 10 µg (n=3)	IMU-131 30 µg (n=6)	IMU-131 50 µg (n=5)
Complete Response (CR)	1 ( 33.3%)	0 (0.0%)	0 (0.0%)
Partial Response (PR)	0 (0.0%)	2 (33.3%)	3 ( 60.0%)
Stable Disease (SD)	2 (66.7%)	2 (33.3%)	0 (0.0%)
Progressive Disease (PD)	0 (0.0%)	1 (16.7%)	0 (0.0%)
Not Evaluable (NE)	0 (0.0%)	0 (0.0%)	1 (20.0%)
Not Applicable (NA)	0 (0.0%)	1 (16.7%)	1 (20.0%)
Objective Response (CR+PR)	1 (33.3%)	2 (33.3%)	3 (60.0%) *
Disease Control Rate (CR+PR+SD)	3 (100.0%)	4 (66.7%)	3 (60.0%)

Table 2: Best overall response

\* In cohort 3, the 3 patients evaluated at Day 98 after completed IMU-131 vaccinations showed 100% objective response (CR+PR), while 2 patients dropped out early due to incorrect enrolment or SAE (non-vaccine related).

Exhibit 5: Response Data in Accordance with RECIST Source: ESMO Asia 2019 Presentation

### Phase 2 Portion of Herizon Clinical Trial Design and Trial Result

The Phase 2 trial portion of Phase 1b/2 clinical trial is a randomized two-arm study of HER-Vaxx plus standard of care chemotherapy (SOC) and standard of care (SOC) chemotherapy alone. The phase 2 trial hypothesizes that treatment with HER-Vaxx will meet or improve the efficacy and safety standards set by the approved mAbs HER2+ metastatic gastric cancer treatment in the

market. The study has enrolled patients from countries in Asia and Eastern Europe with limited access to trastuzumab. The patients enrolled in the trial received standard of care (SOC) chemotherapy for a maximum of six cycles. Additionally, the HER-Vaxx plus SOC arm also received a 50µg dose of IMU-131 at Baseline/Day 0, Day 14, Day 35, Day 77, and then every 63 days until disease progression. The primary endpoint of the trial includes overall survival, with progression-free survival (PFS) and safety as a secondary endpoint. Initially, 68 patients were planned to be included in the trial, which then was reduced to 36 in accordance with guidance from IDMC owing to robust interim safety and efficacy data.

**HER-VAXX PHASE 2:  
SAFETY**



TREATMENT EMERGENT ADVERSE EVENTS

	HER-VAXX + CHEMOTHERAPY ( N =1 9 )	CHEMOTHERAPY ONLY ( N =1 7 )
	n (%)	n (%)
Patients with at least one TEAE	18 (94.7%)	16 (94.1%)
Grade 1 / 2	10 (52.6%)	9 (52.9%)
Grade ≥ 3	8 (42.1%)	7 (41.2%)
Serious AE*	2 (10.5%)	5 (29.4%)
Fatal AE	1 (5.3%)	1 (5.9%)

*The company has been granted patents for HER-Vaxx across all the major geographies including USA, Europe, China, South Korea and Japan protecting its IP to 2036*

**HER-VAXX PHASE 2:  
OVERALL SURVIVAL**



END POINT	OVERALL SURVIVAL Interim Analysis		OVERALL SURVIVAL Final OS Readout	
	HER-Vaxx + Chemotherapy	Chemotherapy Only	HER-Vaxx + Chemotherapy	Chemotherapy Only
Treatment				
Sample Size	14	13	19	17
Events	4	8	15	17
Median OS (2-sided 80% CI)	14.2 months (6.4, NA)	8.8 months (4.4, 9.6)	13.9 months (7.5, 14.3)	8.3 months (6.0, 9.6)
Median Duration of Response	-	-	30 weeks	19 weeks
HR	0.418		0.585	
2-sided 80%CI	(0.186, 0.942)		(0.368, 0.930)	
Log-rank Test (1-sided p-value)*	0.083*		0.066*	

\* Pre-specified alpha of 0.10  
\* Statistically significant

Exhibit 6: Herizon Final OS Readout. Source: Imugene Limited

The company recently announced the results of the randomized phase 2 trial in HER2/neu overexpressing advanced gastric cancer. The study exhibited a 41.5% overall survival rate in favor of patients treated with HER-Vaxx and SOC chemotherapy compared to SOC chemotherapy alone. The median overall survival was 13.9 months for HER-Vaxx and Chemotherapy versus 8.3 months for the controlled arm. This translated into an overall survival Hazard Ratio (HR) of 0.585 (80% 2-sided CI: 0.368, 0.930) with a statistically significant p-value of 0.066. Both the treatment arms were well tolerated without any difference in their safety profiles, indicating that HER-Vaxx does not add toxicity to SOC chemotherapy. The final result indicates comparable superiority of

HER-Vaxx over Herceptin, which exhibited an overall survival HR of 0.65 for the analysis of the same patient population in a study examining the effect of Herceptin plus chemotherapy versus chemotherapy alone in advanced gastric cancer. We believe the previous reduction in patient population size in the clinical trial based on the robust interim results (n=27) also showed confidence in HER-Vaxx’s safety and efficacy profile. Additionally, the longest HER-Vaxx treated patients remained alive 2.5 years after starting the therapy, and notably, HER-Vaxx elicited the strongest anti-Her-2 antibody levels in these patients.

### Progressing Towards Combination Clinical Studies

Even though HER-Vaxx as a monotherapy demonstrated superior efficacy and safety when compared to SOC chemotherapy, the company believes the combination of already approved immunotherapies and HER-Vaxx might support better outcomes for patients. The majority of clinical trials support the concept of synergy that combination therapy of vaccines and ICIs holds maximized potential to improve clinical outcomes.<sup>3</sup> Importantly, the combination has acceptable safety and minimal additional toxicity compared with single-agent vaccines or ICIs.<sup>3</sup> Imugene has begun the dual combination studies evaluating HER-Vaxx in combination with pembrolizumab (KEYTRUDA®) and avelumab (BAVENCIO®)

nextHerizon phase 2 clinical trial (IND enabled) - nextHerizon is an open-label, multi-center (Australia, USA, and Asia), dual-arm clinical trial to assess the safety and efficacy of HER-Vaxx in combination with SOC chemotherapy (arm 1) and pembrolizumab (arm 2) in patients with HER2/new over-expressing metastatic gastric cancer after progression on trastuzumab. Currently, in the recruitment phase, the clinical study is expected to enroll 30 patients. Based on the safety and efficacy profile of the Herizon clinical trial, the Cohort Review Committee (CRC) has confirmed a new higher dose of HER-Vaxx (100µg). The primary endpoint includes objective response rate (ORR) and safety, and the secondary endpoints are overall survival (OS), progression-free survival (PFS), and duration of response (DOR).

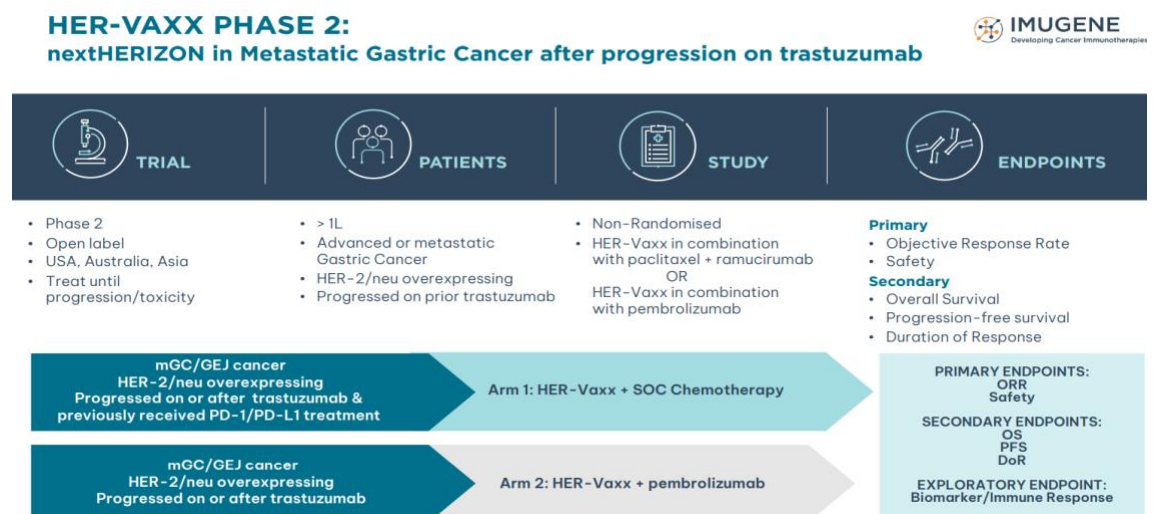


Exhibit 7: nextHerizon Clinical Trial Design. Source: Imugene Limited

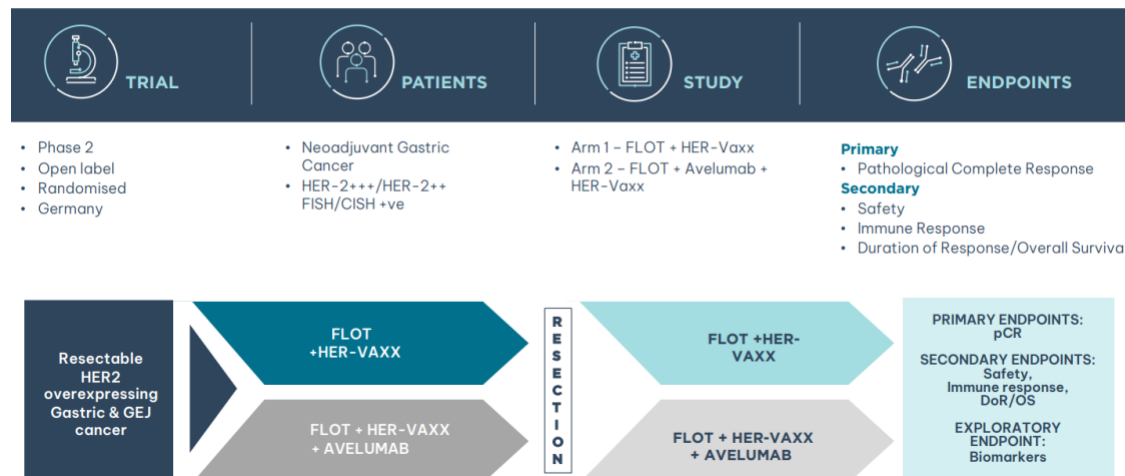
neoHerizon phase 2 clinical trial - neoHerizon is an open-label, randomized dual-arm clinical trial in patients with resectable HER2+ overexpressing gastric cancer. The trial will assess the safety

<sup>3</sup> Front Pharmacol. 2019 Oct 11;10:1184.



and efficacy of perioperative HER-Vaxx in combination with chemotherapy and with or without avelumab. The study's primary endpoint includes pathological complete response. The secondary endpoint includes safety, immune response, and overall survival.

**HER-Vaxx PHASE 2:  
neoHERIZON in Resectable Gastric Cancer**



*Imugene has entered into a clinical trial supply agreement with Merck KGaA and Pfizer to provide Avelumab (BAVENCIO®) for its phase 2 neoHERIZON study in resectable gastric cancer*

Exhibit 8: neoHerizon Clinical Trial Design. Source: Imugene Limited

Additionally, the company has announced that it has procured a large-scale batch of HER-Vaxx, allowing it to complete all of its planned HER-2 positive gastric cancer trials (nextHerizon and neoHerizon).

**Gastric Cancer Epidemiology**

Gastric Cancer remains one of the deadly and fourth most common forms of malignancies diagnosed with 1,089,103 annual incidences worldwide. It also remains the third most common form of cancer death (769,793 deaths) of all malignancies worldwide. Gastric cancer is more prevalent in males, with an age-standardized annual incidence of 17.4 per 100,000 compared to 7.1 for women. The incidence widely varies across the globe, with the majority of cases found in eastern Asian and European countries. In east Asia, the age-standardized incidence is 32.5 per 100,000, whereas central and eastern European countries have an ASR of 17.4 per 100,000. North American countries have a lower incidence and account for approximately 2.7% of the worldwide cases diagnosed each year. This year, an estimated 26,380 (15,900 men and 10,480 women) in the United States will be diagnosed with stomach cancer.

	Incidence						Mortality					
	Both sexes		Males		Females		Both sexes		Males		Females	
	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)
Eastern Africa	9 961	0.53	4 919	0.58	5 042	0.49	8 715	0.47	4 261	0.51	4 454	0.43
Middle Africa	3 345	0.49	1 731	0.53	1 614	0.44	2 972	0.43	1 535	0.48	1 437	0.39
Northern Africa	9 397	0.49	5 414	0.61	3 983	0.38	7 727	0.40	4 489	0.50	3 238	0.30
Southern Africa	1 850	0.37	1 096	0.52	754	0.26	1 575	0.31	954	0.45	621	0.21
Western Africa	7 849	0.47	4 340	0.56	3 509	0.40	6 956	0.42	3 860	0.50	3 096	0.36
Caribbean	4 245	0.78	2 549	1.03	1 696	0.56	3 394	0.59	2 091	0.82	1 303	0.40
Central America	13 825	0.81	7 470	0.98	6 355	0.67	10 833	0.62	6 019	0.77	4 814	0.49
South America	49 547	0.98	30 520	1.37	19 027	0.65	39 165	0.74	24 449	1.06	14 716	0.47
Northern America	29 772	0.48	18 175	0.63	11 597	0.35	13 391	0.19	8 090	0.25	5 301	0.13
Eastern Asia	656 349	2.63	452 324	3.80	204 025	1.49	435 211	1.70	295 349	2.45	139 862	0.98
South-Eastern Asia	39 763	0.62	24 142	0.83	15 621	0.44	32 814	0.51	20 106	0.69	12 708	0.35
South-Central Asia	102 676	0.64	67 701	0.87	34 975	0.42	89 595	0.56	59 832	0.77	29 763	0.36
Western Asia	21 156	0.99	13 235	1.33	7 921	0.68	17 586	0.82	11 157	1.14	6 429	0.54
Central and Eastern Europe	65 516	1.39	39 925	2.17	25 591	0.84	50 018	1.01	30 443	1.61	19 575	0.58
Western Europe	28 490	0.66	17 900	0.93	10 590	0.42	17 755	0.35	11 039	0.51	6 716	0.21
Southern Europe	30 555	0.85	18 628	1.18	11 927	0.55	21 456	0.53	13 143	0.74	8 313	0.33
Northern Europe	11 477	0.52	7 263	0.70	4 214	0.34	7 768	0.31	4 830	0.42	2 938	0.20
Australia and New Zealand	2 676	0.52	1 799	0.75	877	0.31	1 355	0.22	839	0.29	516	0.15
Melanesia	559	0.88	333	1.16	226	0.64	435	0.72	260	0.95	175	0.50
Polynesia	62	1.01	38	1.17	24	0.85	49	0.80	28	0.86	21	0.75
Micronesia	33	0.67	21	0.86	12	0.48	23	0.42	14	0.49	9	0.35
Low HDI	22 229	0.52	12 195	0.62	10 034	0.44	19 640	0.47	10 784	0.55	8 856	0.39
Medium HDI	122 015	0.68	77 748	0.91	44 267	0.46	105 352	0.59	67 794	0.80	37 558	0.40
High HDI	586 903	1.76	397 829	2.54	189 074	1.03	461 234	1.36	310 756	1.97	150 478	0.80
Very high HDI	357 688	1.24	231 586	1.80	126 102	0.73	182 375	0.54	113 335	0.79	69 040	0.33
World	1 089 103	1.31	719 523	1.87	369 580	0.79	768 793	0.90	502 788	1.29	266 005	0.55

Exhibit 9: Gastric Cancer Global Incidence and Mortality. Source: Globocan 2020 Data

The global five-year survival rate is only 5-10% if the disease has been found to metastasize. Human epidermal growth receptor 2 (HER2) overexpression of HER2 gene amplification is present in 20% of gastric cancers and defines a subset amenable to HER2-directed therapeutics. The overexpression of HER2 is often associated with a poor prognosis.

### Competitive Overview

Imugene’s lead drug candidate HER-Vaxx faces competition from already approved HER2-directed gastric cancer mAbs and PD-1 binding immune checkpoint inhibitors. Multiple targeted therapies and immunotherapies are currently under clinical trial for advanced or metastatic gastric cancer, indicating fierce competition in this particular disease area. Trastuzumab (Herceptin) and fam-trastuzumab deruxtecan-nxki (Enhertu) are major HER-2-directed therapeutics that are FDA-approved. Even though HER-Vaxx exhibited robust efficacy and safety in the early stages of clinical development, the company’s ability to fend off competition depends on its superior safety and comparative efficacy profile at a reasonable cost.

Drug	Patent expiry	Annual Revenue (2021)	Pricing
Trastuzumab	off-patent	\$2,694 million	\$76,500
nivolumab	2028	\$7,523 million	\$187,728
fam-trastuzumab deruxtecan-nxki	2024	\$426 million	\$164,000

Exhibit 10: Major FDA-approved Gastric Cancer Drugs. Source: Diamond Equity Research, Company Filings

## PD1 – Vaxx – Therapeutic Vaccine for NSCLC

Immune Checkpoint Inhibitors as potent immunotherapy has already reached consensus, with numerous FDA approvals for several cancer types recording billions of dollars in sales worldwide. Thousands of immunotherapies are currently being tested in clinical trials for different types of malignancies. Even though PD-1/PD-L1 signaling inhibitors have shown great clinical success, the development of primary and secondary resistance has contributed to just a small subset of patients (10–15%) responding to the monotherapy.<sup>4</sup>

PD-1 Vaxx is potentially a cost-effective, potent, and novel approach toward inhibiting the PD1/PD-L1 signaling pathway, thus triggering anti-cancer effects similar to those observed in ICI mAbs such as Keytruda® and Opdivo®. Based on the B-cell epitope peptide vaccine platform technology, PD-1 B-cell peptide epitope vaccine (PD-1 Vaxx) is derived from extracellular amino acids 92-110 of PD-1 linked to a measles virus fusion peptide (MVF) amino acid 288-302 via a four amino acid residue (GPSL). The resulting formulation, when injected, elicits a B-cell antibody response, inducing the body to produce polyclonal antibodies. These antibodies block the PD-1 signaling pathway that is crucial for tumor growth and simultaneously promotes T-cell recognition of cancer cell leading to targeted killing. Activation of both T-cell and B-cell functioning encourages immunological response providing a formidable cancer immunotherapy candidate.

*Constructed from a single B cell epitope derived from extracellular domain of PD-1, PD-1 Vaxx has shown great potential in pre-clinical and early-stage clinical trials*

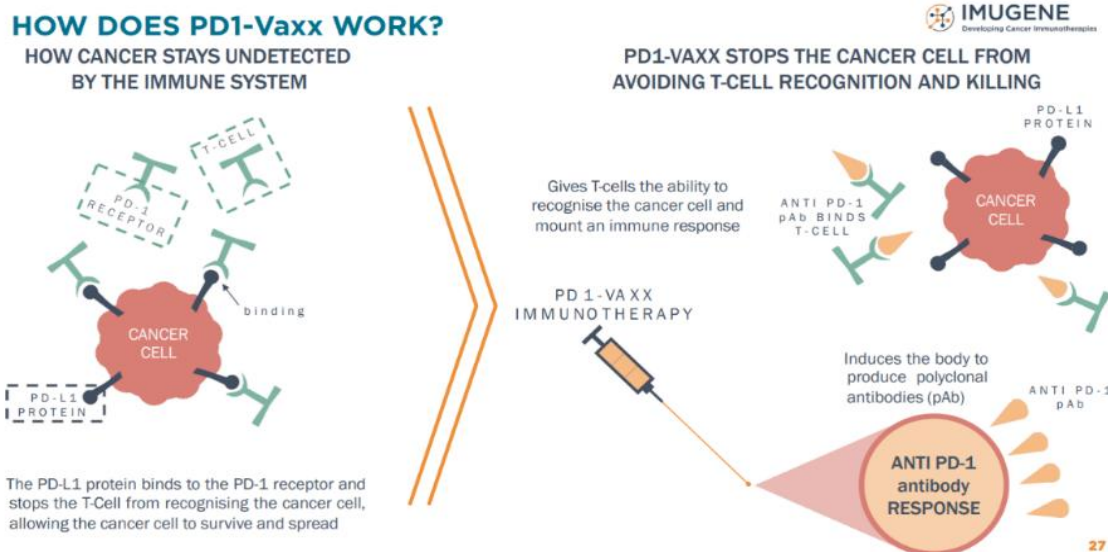


Exhibit 11: PD-1 Vaxx Mechanism of Action. Source: Imugene Limited

In order to test the concept of PD-1 Vaxx, the company carried out pre-clinical studies in well-established murine colon carcinoma cell line CT26 tumor model in syngeneic BALB/c mice evaluating the effects of vaccination of four potential PD-1 vaccines developed using different novel peptide sequences. Female BALB/c mice aged 6 to 8 weeks were immunized three times at 3-week intervals with different vaccine formulations. Two weeks post the third immunization, mice were challenged subcutaneously with CT26/HER-2 tumor cells. Mice treated with mPD-1 mAb served as a positive control, and the PBS-treated mice as a negative control. Tumor growth was measured daily and two times a week for up to 3 weeks.

<sup>4</sup> British Journal of Cancer (2021) 125:152–154

The preclinical study results showed one PD-1 epitope sequence 92-110 epitope that significantly reduced tumor growth. Additionally, all vaccinated mice showed high immunogenicity developing high antibody titers. Triple vaccinated, and mAb treated mice showed significantly less tumor burden than the PBS group. Another similar BALB/c mice study was undertaken in order to verify the efficacy of the PD1-Vaxx (PD-1 (92-110) vaccine epitope) versus that of mAb 29F.1A12. Vaccination with PD-1 Vaxx was found to have better tumor control ability compared to anti-mouse PD-1 mAb. Mice vaccinated with PD1-Vaxx showed no toxicity and autoimmunity.

The PD-1 vaccine showed high immunogenicity and antigenicity to human PD-1 and induced tumor inhibition in vivo in a syngeneic BALB/c colon carcinoma CT26 tumor model. Furthermore, the CT26/HER-2 model demonstrated enhanced immunogenicity and inhibition of tumor growth in the triple combination (combo HER-2 + PD-1) versus the single PD-1 vaccine or the combo HER-2 vaccine.<sup>5</sup> Mice vaccinated with PD1-Vaxx showed no toxicity and autoimmunity. No significant lesions were noted in any of the organs submitted for histologic evaluation.

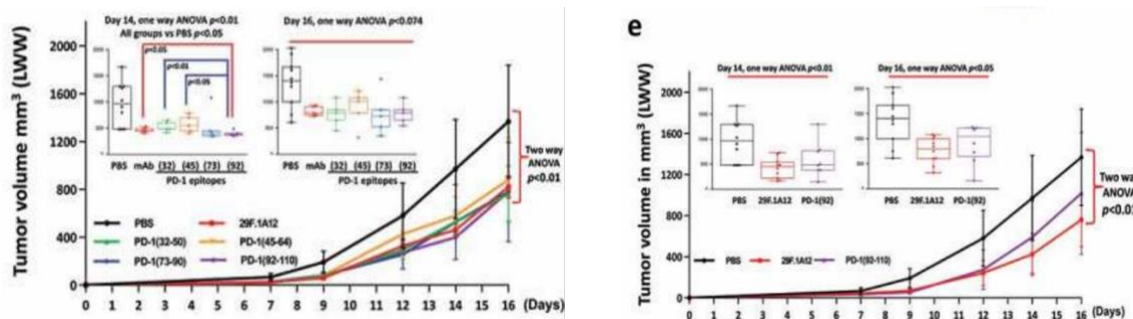


Exhibit 12: Tumour Volume Plot - Comparison of PBS and Treated Mice (left), Comparison of Vaccinated and mAb Treated Mice (right). Source: [Kaumaya et al.](#)

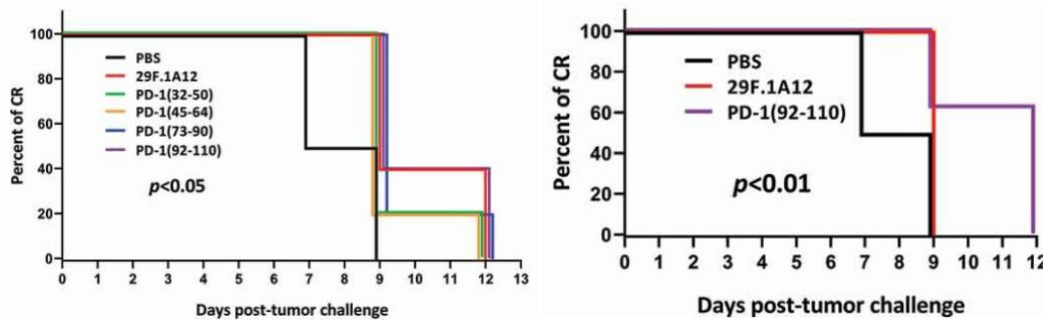


Exhibit 13: Percent of Complete Response (CR) - Comparison of PBS and treated mice (left), Comparison of vaccinated and mAb treated mice (right) Source: [Kaumaya et al.](#)

*Imugene has also entered into a clinical trial supply agreement with Roche for a period of up to five years for the supply of atezolizumab for its Phase 1b (IMPRINTER) trial*

### PD-1 Vaxx - IMPRINTER Phase 1 Trial Design and Results

PD-1 Vaxx is evaluated in IMPRINTER phase 1 open-label dose escalation clinical study as a monotherapy (phase 1a) and in combination with Atezolizumab (phase 1b) in adults with Non-Small Cell Lung Cancer (NSCLC) expressing PD-L1. Patients enrolled in the study must have been previously treated with immune checkpoint inhibitors (ICIs) and experienced disease progression. The primary outcome includes the evaluation of the safety and tolerability of PD-1

<sup>5</sup> OncoImmunology, 9:1, DOI: 10.1080/2162402X.2020.1818437

Vaxx and obtaining the optimal biological dosage (OBD). The secondary objective includes Overall response rate (ORR), progression-free survival (PFS), and Overall Survival (OS).

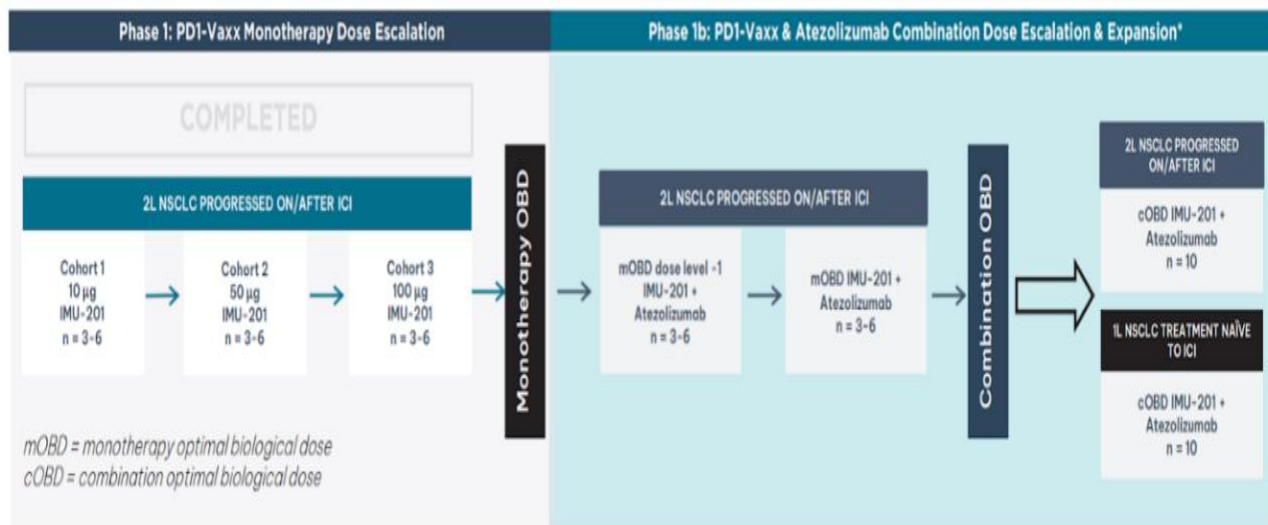


Exhibit 14: Phase 1 Trial Design. Source: Imugene Limited

14 patients were enrolled in Phase 1 of the IMPRINTER study, with 4 in cohort 1 (dosage level: 10µg), six in cohort 2 (dosage: 50µg), and 4 in cohort 3 (dosage: 100µg). PD1-Vaxx was administered on Days 1, 15, 29, 64, and every 63 days subsequently until the end of treatment. The treatment was well-tolerated with no dose-limiting toxicities. Most of the adverse events were low grade, mild and manageable except for two instances (50µg and 100µg) of Immune-mediated pneumonitis. By week 6, PD1-Vaxx was found to induce pAb generation, which was sustained at high titers at a dosage of 100µg/dose. Biomarker data showed that PD1-Vaxx is immunogenic and stimulates a sustained antibody response. Encouraging tumor response data included one patient achieving CR in a low dose (10µg) cohort, two patients achieving SD in the 50µg dose cohort, and among the four patients in the 100µg cohort, one achieved PR, and two patients achieved SD. The preliminary efficacy and safety data allow Imugene to progress towards Phase 1b in treatment-naïve NSCLC patients, where in PD1-Vaxx is expected to be assessed in combination with atezolizumab.

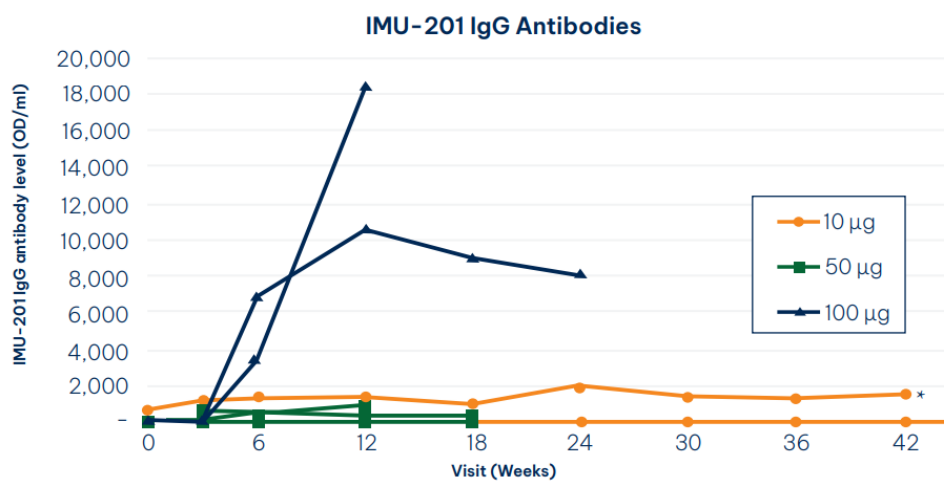


Exhibit 15: Antibody Level. Source: [Boyer et al. Phase 1](#)

## NSCLC Epidemiology

Lung cancer remains the second most common form of malignancy, with 2,206,771 cases diagnosed across the globe in 2020. It remains a major health problem. The 5-year survival rate was found to be only 10% - 20% in most countries among those diagnosed from 2010 through 2014. Being a major health problem, it is the leading cause of cancer death across of globe, claiming 1,796,144 lives in 2020 (refer to exhibit 16). In general, about 13% of all lung cancers are small cell lung cancer (SCLC), and 84% are non-small cell lung cancer (NSCLC). The highest incidence rates are observed in Micronesia/Polynesia, Eastern and Southern Europe, Eastern Asia, and Western Asia. Developed nations, including North America and Western European nations, have an incidence rate higher than world age-standardized rates (ASR).

	Incidence						Mortality					
	Both sexes		Males		Females		Both sexes		Males		Females	
	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)
Eastern Africa	7 419	0.42	3 970	0.49	3 449	0.36	6 758	0.39	3 611	0.45	3 147	0.33
Middle Africa	2 037	0.29	1 270	0.41	767	0.18	1 897	0.27	1 184	0.38	713	0.17
Northern Africa	23 179	1.32	19 310	2.29	3 869	0.40	20 728	1.19	17 295	2.06	3 433	0.36
Southern Africa	9 178	2.05	6 283	3.24	2 895	1.13	7 939	1.80	5 408	2.83	2 531	1.01
Western Africa	4 175	0.26	2 449	0.32	1 726	0.21	3 849	0.25	2 262	0.30	1 587	0.20
Caribbean	11 058	2.10	6 670	2.73	4 388	1.54	10 079	1.89	6 230	2.54	3 849	1.32
Central America	9 934	0.61	5 798	0.79	4 136	0.46	9 236	0.56	5 499	0.74	3 737	0.41
South America	76 609	1.64	44 878	2.12	31 731	1.23	67 312	1.42	39 106	1.80	28 206	1.08
Northern America	253 537	3.99	129 086	4.32	124 451	3.70	159 641	2.29	83 945	2.61	75 696	1.99
Eastern Asia	1 012 021	4.14	670 827	5.66	341 194	2.65	841 174	3.38	558 235	4.67	282 939	2.12
South-Eastern Asia	123 309	2.02	85 795	3.06	37 514	1.10	109 520	1.81	76 521	2.76	32 999	0.97
South-Central Asia	121 369	0.80	88 130	1.17	33 239	0.42	109 356	0.72	79 920	1.06	29 436	0.37
Western Asia	58 437	2.93	47 146	4.99	11 291	1.01	52 467	2.71	42 542	4.69	9 925	0.87
Central and Eastern Europe	151 632	3.49	111 986	6.26	39 646	1.46	130 596	2.97	96 769	5.39	33 827	1.20
Western Europe	146 460	4.07	89 646	5.05	56 814	3.15	113 524	2.91	72 486	3.80	41 038	2.09
Southern Europe	104 391	3.61	74 009	5.38	30 382	2.00	85 635	2.71	61 692	4.10	23 943	1.44
Northern Europe	75 051	3.63	39 413	3.96	35 638	3.33	54 421	2.39	29 072	2.67	25 349	2.13
Australia and New Zealand	15 587	3.06	8 372	3.33	7 215	2.80	10 791	1.89	6 104	2.14	4 687	1.65
Melanesia	918	1.63	588	2.22	330	1.09	798	1.41	515	1.93	283	0.93
Polynesia	268	4.90	188	6.91	80	2.87	229	4.16	157	5.76	72	2.56
Micronesia	202	4.38	129	5.96	73	2.92	194	4.20	126	5.86	68	2.66
Low HDI	16 418	0.40	9 713	0.51	6 705	0.31	15 108	0.37	8 987	0.48	6 121	0.28
Medium HDI	165 943	0.96	116 316	1.39	49 627	0.55	149 887	0.87	106 011	1.27	43 876	0.48
High HDI	1 047 707	3.21	697 411	4.51	350 296	1.99	918 661	2.81	610 626	3.95	308 035	1.74
Very high HDI	975 665	3.68	611 867	4.96	363 798	2.54	711 630	2.49	462 513	3.54	249 117	1.55
World	2 206 771	2.74	1 435 943	3.78	770 828	1.77	1 796 144	2.18	1 188 679	3.08	607 465	1.34

Exhibit 16: Gastric Cancer Global Incidence and Mortality. Source: Globocan 2020 Data

Programmed death ligand 1 (PD-L1), also known as CD274, is an immune checkpoint that is responsible for tumor cell proliferation by weakening the host immune response to tumor cells. PD-L1 expression is observed in approximately 32% of the cases and is linked with increased tumor proliferation, increased aggressiveness, and lower survival rates.

## Competitive Overview

EGFR inhibitors and ICI mAbs have cornered a large portion of the NSCLC market in dollar terms. Erlotinib (Tarceva), Osimertinib (Tagrisso), Atezolizumab (Tecentriq), Nivolumab (Opdivo), and Pembrolizumab (Keytruda) are a few of the major approved therapeutics for NSCLC. Additionally, thousands of clinical trials are currently underway utilizing different therapeutic approaches for the treatment of NSCLC. By the time PD-1 Vaxx gets FDA approval and is commercialized (estimated: 2028), most of the above-stated drugs would have lost their exclusivity or would be on the verge of losing their exclusivity, leading to the entrance of low-cost biosimilars. A clearer insight into Imugene's competitive positioning within the NSCLC market would be based on its progress in clinical trials, thus providing an idea of its efficacy and safety when compared to other therapeutics in the market. The pricing of PD-1 Vaxx will also play a major role in its ability to capture increased market share.

HER-Vaxx and PD-1 Vaxx have been evaluated as monotherapy in pre-clinical and clinical settings exhibiting anti-tumor properties with tolerable safety profiles. Historically cancer vaccines and immune checkpoint blockades have been limited by low clinical efficacy and development of resistance, respectively. The company's approach to using both in a combination therapy setting in further clinical trials could be a way to improve overall therapeutic outcomes (enhancing the immune response by overcoming the immunosuppressive tumor micro-environment with limited toxicity and resistance). Both these therapies are targeting a sizeable yet competitive market.

## Oncolytic Virus - An Emerging Frontier in Cancer Immunotherapy

A virus is an infectious agent that utilizes the host's genetic material to replicate itself, thereby spreading to healthy cells. One such substrate of naturally occurring or genetically modified viruses that act as a potent therapeutic agent and have the ability to infect and kill cancer cells are commonly called Oncolytic viruses. Cancer cells have impaired anti-viral defenses and are susceptible to infections. Modification in Oncolytic viruses through genetic engineering enhances their ability to deliver therapeutic payload and diminishes the possibility of widespread resistance.

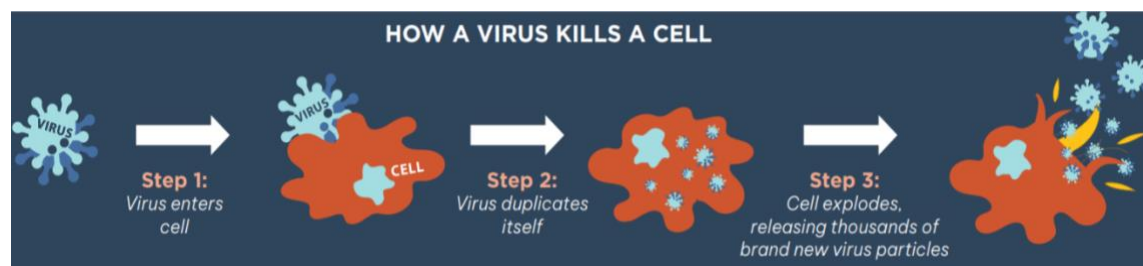


Exhibit 17: Oncolytic Virus Mechanism of Action. Source: Imugene Limited

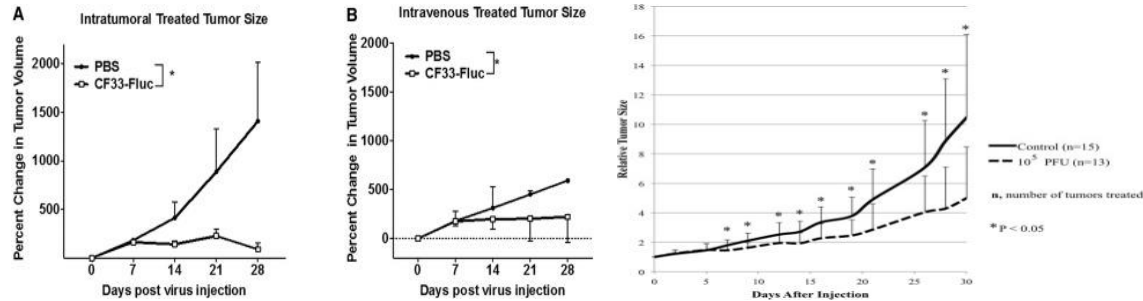
Although oncolytic viruses are potentially powerful therapeutic agents for cancer treatment, a single type of oncolytic virus is not enough to destroy all the cancer cells due to the heterogeneity of cancer tissues and the complexity of cancer cells. Determining the virus and delivery method are two of the most challenging and crucial parts of the underlying therapy.

Developed at the City of Hope Cancer Center in Los Angeles, California, CF33 is a chimeric vaccinia virus derived from genomic sequencing of multiple strains of vaccinia virus, thus generating a safer and more potent virus that is also immunostimulatory. Nine different "parental" virus strains of orthopoxvirus (cowpox virus, rabbitpox virus, raccoon pox virus) were introduced, grown, and titered in CV-1 cell lines leading to the creation of 100 chimeric orthopoxviruses. These "daughter" virus strains contained different combinations of genes from the parental virus, which were then tested for potency by screening them against the NCI-60 panel. CF33 proved to be the most potent and is chosen further for in vivo and clinical development.

### Proving the Effectiveness of CF33 in Multiple Pre-clinical Models

CF33 Oncolytic virus has been tested in multiple cell lines and xenograft mouse models in pancreatic cancer, colorectal cancer, lung cancer, and Triple-negative breast cancer (TNBC). CF33 and imaging-capable derivative CF33-Fluc (firefly luciferase) have shown to demonstrate anti-tumor properties both in vitro and in vivo. Chimeric CF33 was found to kill multiple colorectal cancer cells in multiple cell lines in vitro. It also proved effective in two different TNBC xenografted mouse models demonstrating a significant reduction in tumor size. In addition to

safety and efficacy, CF-33 also demonstrated abscopal effects at a single low dosage in pancreatic cancer xenografts. Even though the trial reported encouraging results indicating virus replication and spread to non-injected distant tumors and causing tumor shrinkage, it should be noted that the in vivo studies were conducted in immunodeficient mice, which makes it easier for the virus to spread when compared to subjects with normal immune systems. Increased infiltration of CD8 T cells was observed in both injected and distant tumors. Furthermore, the multiple clinical trials indicated that CF33 and its derivatives had exhibited tolerable safety profiles, in vivo and in vitro.



*Oncolytic Viruses are considered as promising tools in cancer treatment due to their multi-mechanistic anti-tumor effects*

Exhibit 18: Anti-tumor activity in HCT116 Xenograft model (left) and in MDA-MB-231 Xenografts (right) Source: Molecular Therapy – Oncolytics

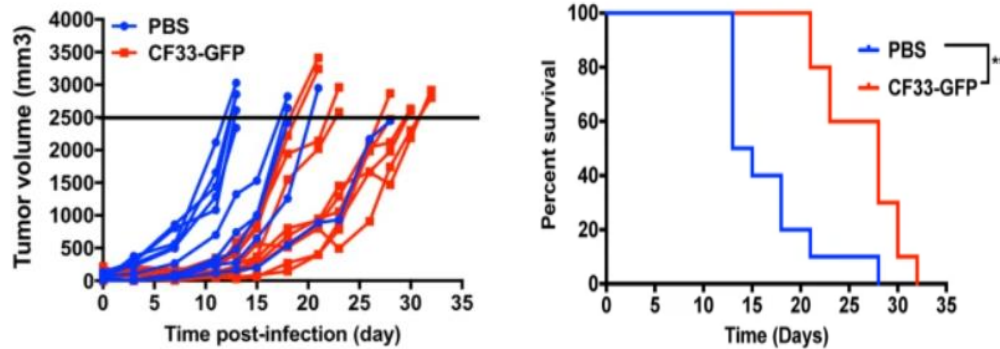
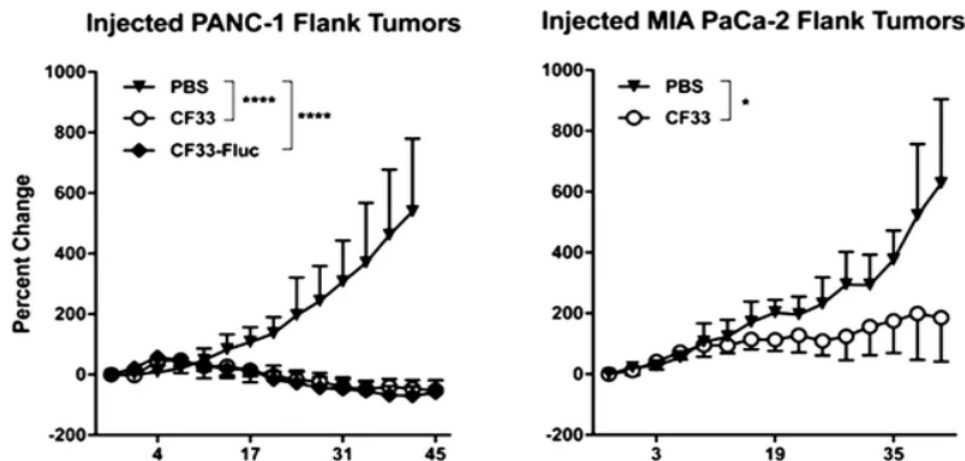


Exhibit 19: Anti-tumor Efficacy in a Syngeneic Mouse Model of Lung Cancer. Source: Yuman Fong Et al.



*CF33 Oncolytic Virus has demonstrated safety in a number of pre-clinical trials with evidence for both a local and systemic anti-tumor response*

Exhibit 20: CF33 is safe in mice and causes regression of both injected and non-injected distant tumors at a low dose in PANC-1 and MIA PaCa-2 xenograft models. Source: [Fong et al.](#)

Female immunodeficient mice were implanted with either PANC-1 or MIA PaCa-2 and a single injection of 10<sup>3</sup> PFU of CF33 for PANC-1 and 10<sup>5</sup> PFU for MIA PaCa-2 were administered intratumorally in the left tumor. Tumor growth inhibition and a decrease in tumor size was observed in xenografts injected with intratumoral CF33 at 10<sup>3</sup> PFU in PANC-1 and 10<sup>5</sup> PFU in



MIA PaCa-2 when compared to PBS, injected control. No toxicity was noted in the PANC-1 group injected with a dose of  $10^3$  PFU of CF33 when compared to the PBS-injected group.<sup>6</sup>

Additionally, the efficacy of CF33 was also compared to that of GLV-1h68 and T-VEC (FDA approved) in Xenograft mouse models and pancreatic cancer cell lines. CF33 was found to be more potent in both in vivo and in vitro models. CF33 OV showed lower survival of cancer cells when compared to GLV-1h68 and T-VEC. In a mouse model of lung cancer, CF33 exhibited comparatively lower tumor volume than what was observed in GLV-1h68 and T-VEC and substantially lower when compared to PBS at day 30.

Novel chimeric orthopoxvirus CF33 has been developed in different constructs currently under phase 1 clinical trials: VAXINIA (CF33-hNIS) and CHECKvacc (CF33-hNIS-anti PD-L1).

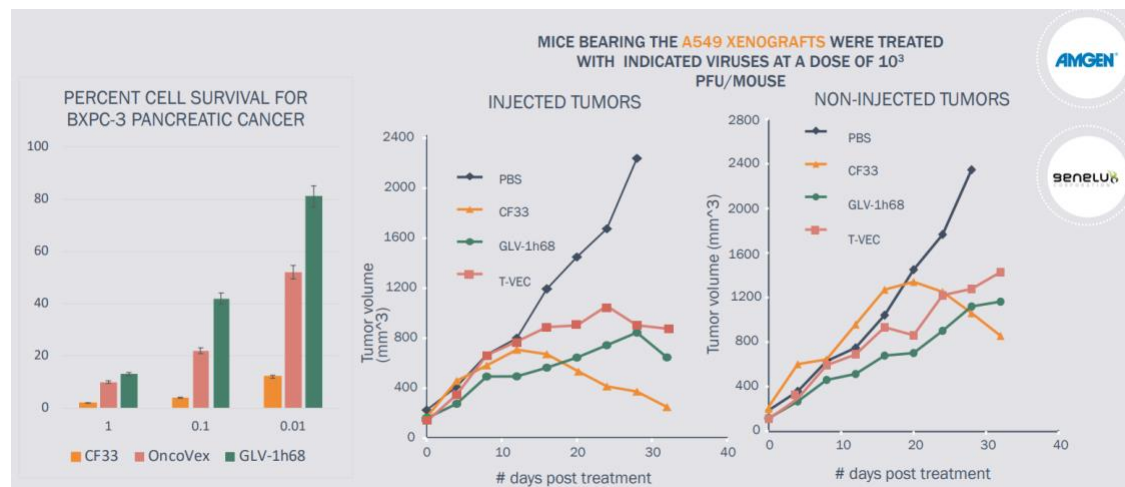


Exhibit 21: CF33 Efficacy Comparison with T-VEC and GLV-1h68. Source: Imugene Limited

### VAXINIA (CF33 + hNIS)

CF33 with Human Sodium-Iodide Symporter (hNIS) gene is currently being evaluated in the phase 1 Mixed Advanced Solid Tumors (MAST) study. Encoding of hNIS gene enables reliable non-imaging of viral replication using positron emission tomography mediating targeted radiotherapy. CF33 encoded hNIS gene has been previously studied in colon cancer xenograft mouse model, demonstrating the synergy of oncolytic viral therapy with radioablation in vivo. The cancer cell lines induced xenografts were implanted into athymic nude female mice and were administered with either intratumoral PBS or CF33-hNIS injections. CF33-hNIS-induced tumor growth abrogation and regression were observed in animals with HCT116-derived xenografts. Abrogation and regression of tumor growth were also observed in HT29-derived tumors in some mice, but the results were not statistically significant. Additionally, the treatment was found synergistic with I-131 Radioisotope, exhibiting an effective and sustained tumor growth inhibition when compared to monotherapy treatment with PBS, CF33-hNIS, or I-131. The use of a more targeted approach (CF33 + hNIS + I-131) would decrease toxicity and enhance efficacy at a lower dosage and cost.

<sup>6</sup> *J Transl Med* 16, 110 (2018). <https://doi.org/10.1186/s12967-018-1483-x>

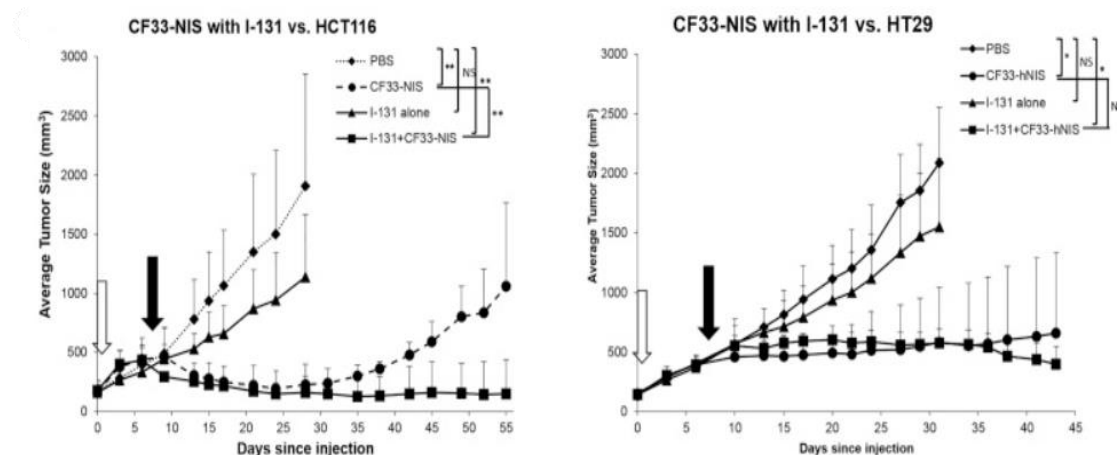


Exhibit 22: I-131 Intravenous Synergy with CF33-hNIS. Source: Molecular Therapy – Oncolytics

### Phase 1 Trial Design

The phase 1 trial is an open-label, dose escalation study multi-centre phase 1 study evaluating CF33 + hNIS as a monotherapy and in combination with pembrolizumab in patients with metastatic or advanced solid tumors. The treatment will be delivered via two routes of administration, intratumoral (IT) or intravenous (IV), and only to those who had been treated with two prior lines of SOC treatment. With an estimated enrollment of 100 participants, the study is anticipated to run for approximately 24 months. The primary outcome includes frequency and severity of adverse events and RP2D. The secondary outcome measures include PFS, ORR, OR, DOS, and DCR, among others.

### VAXINIA Phase 1 Mast Study (Metastatic Advanced Solid Tumours)

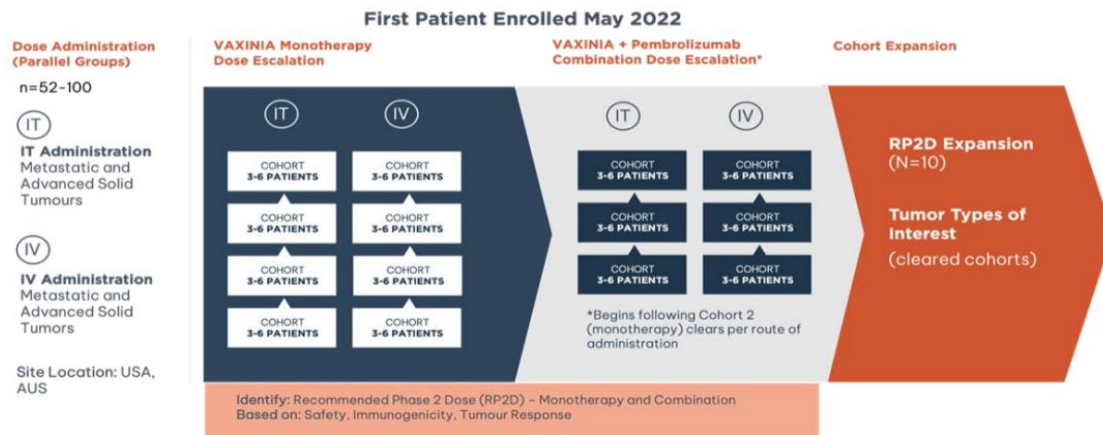


Exhibit 23: VAXINIA Clinical Trial Design. Source: Imugene Limited

### CHECKvacc (CF33 + hNIS + aPD-L1)

The VAXINIA therapy is armed with an immune checkpoint inhibitor, anti-PD-L1 protein eliciting local immune changes consistent with changes in the tumor, enabling the enhancement of anti-cancer immunotherapy. Preliminary pre-clinical studies demonstrated that CHECKvacc-infected tumor cells successfully secreted functional hNIS and anti-PD-L1 protein. The therapy was safe and well tolerated inducing anti-cancer activity.

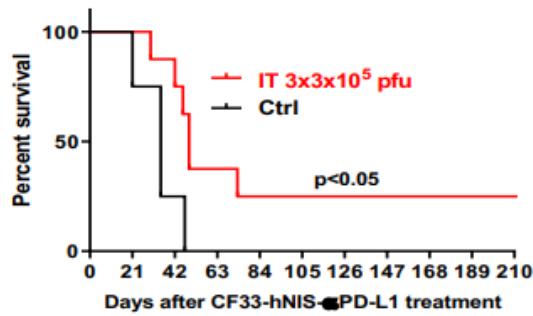


Exhibit 24: Anti-tumor Activity in Mouse Models of Human PDAC. Source: AACR 2021

CHECKvacc phase 1 clinical trial is an open-label, dose-escalation study in patients with metastatic triple-negative breast cancer (TNBC). The primary objective of the study is to evaluate and determine the safety and tolerability of CHECKvacc. The secondary objective includes determining optimal biological dosage (OBD), RP2D, and tumor response rates by RECIST. The estimated targeted enrolments are 33 patients (minimum) to 78 patients (maximum).

**CHECKvacc PHASE 1 TNBC STUDY**  
CF33+hNIS+aPD-L1 (“Armed” Virus)

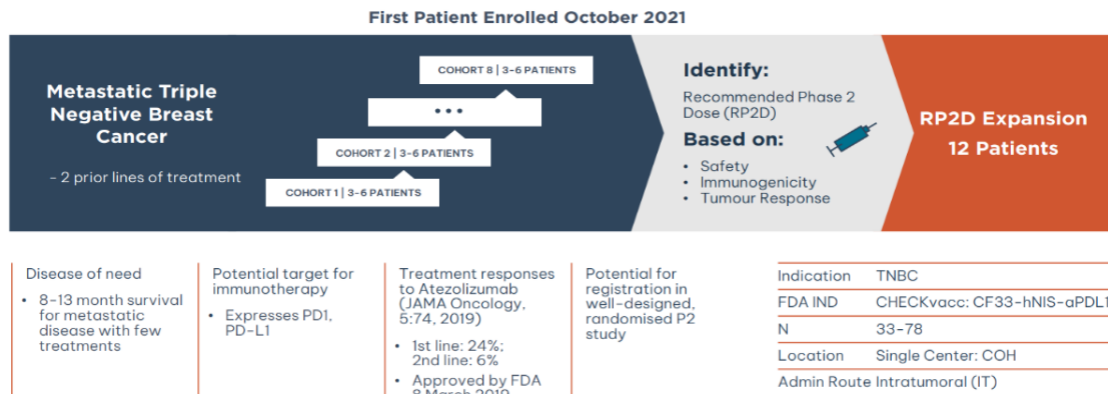


Exhibit 25: CHECKvacc Clinical Trial Design. Source: Imugene Limited

**Triple Negative Breast Cancer (TNBC) Epidemiology**

Breast Cancer is the most common forms of malignancy with an annual global incidence of 2,261,419, representing 11.7% of total cancer cases diagnosed in 2020. It is also the fifth leading cause of cancer death, claiming 684,996 lives, in 2020. 15%-20% of all breast cancer cases are triple negative with a 5-year survival rate of 8% to 16% lower than hormone receptor-positive disease. Due to the lack of prognostic biomarkers and therapeutic targets, TNBC is one of the most challenging breast cancer types to treat. In the US, TNBC accounts for 12% of total breast cancer cases diagnosed; in the UK and Europe, TNBC’s share of total breast cancer cases is 15% and 20%, respectively.

**Oncolytic Virus Market and Competitive Overview**

Oncolytic virus as a treatment modality has gained a lot of attention after positive results from many clinical trials. The ability to infect cancer cells selectively while allowing for additional genetic modification and stimulating the innate immune system to fight cancer cells offers a novel approach to cancer immunotherapy. The most notable shift in the OV field has been from its

application as a direct lytic agent to its development as a multimodal agent involving cell lysis, immune stimulation, and gene therapy, which further established OV as a strong candidate for cancer therapy.<sup>7</sup>

Name	Virus Type	Year Approved	Country Approved	Indication	Background
Rigvir (ECHO-7)	Picornavirus	2004	Latvia	Melanoma	Unmodified
Oncorine (H101)	Adenovirus Serotype 5	2005	China	Head and Neck Cancer	Deleted for Viral E1B-55K and with Four Deletions in Viral E3
T-VEC (Imlygic)	HSV-1	2015	The United States and Europe	Metastatic Melanoma	Deletion of ICP34.5 and ICP47; Encoding Two Copies of Human GMCSF
DELYTACT (Tesperaturev/G 47Δ)	HSV-1	2021	Japan	Malignant Glioma or any Primary Brain Cancer	Triple Mutation (Deletion of ICP34.5, ICP6, and α47 Genes)

Exhibit 26: List of Approved Oncolytic Viruses. Source: Diamond Equity Research, [Cancers 2021](#)

There are 162 Oncolytic virus therapy currently under active development as of June 2022, of which only four have successfully navigated through clinical development and received regulatory approval. 63% or 103 therapies are in the early stages and haven't even progressed through clinical trials. Of the four OV therapies that have been approved, Imlygic (talimogene laherparepvec) is the most noteworthy, being studied across 50 clinical trials. It was approved for the treatment of melanoma in 2015 by the FDA and EMA. Other OV therapy approval relates to comparatively smaller pharmaceutical markets.

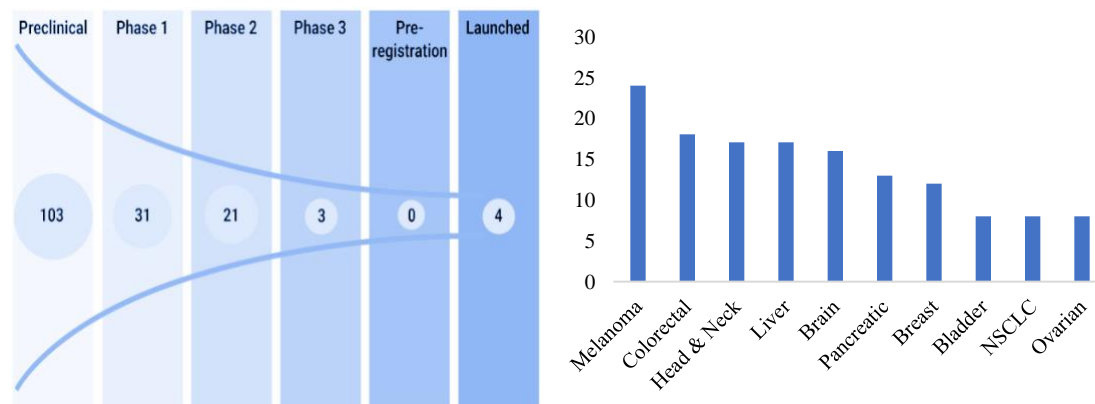


Exhibit 27: Oncolytic Virus Therapies in Different Phases of Development and Top Cancer Types Being Invested by Oncolytic Virus Therapies as of June 2022. Source: Diamond Equity Research, Informa Pharma Intelligence

Of the 55 therapies in clinical development, three are in late-stage development. CG-0070, developed by CG Therapeutics, is based on a modified common cold adenovirus that contains a cancer-specific promoter and a GM-CSF transgene. The novel OV therapy is currently being

<sup>7</sup> Cancers 2021, 13(21), 5452; <https://doi.org/10.3390/cancers13215452>

evaluated in phase 3 trials as monotherapy for the treatment of BCG-unresponsive, Non-Muscle Invasive Bladder Cancer (NMIBC). DB-107 by Denovo Biopharma was evaluated in a phase 3 trial in patients with glioma. Although the Phase 3 trial results were negative overall, there were patients identified who demonstrated a significant survival benefit in pre-planned subgroup analyses. Another OV therapy, BDB201, developed by The Shanghai-based Seven and Eight Biopharmaceuticals Inc., is in stage development for the treatment of melanoma. Genelix Corporation recently advanced its Olvi-Vec OV monotherapy candidate into phase 3 trial. The therapy is being evaluated in women diagnosed with platinum-resistant/refractory ovarian cancer.

Cancer Type	Top Encoded Genes
Bladder	GM-CSF, Mtor, STAT
Bladder	GM-CSF, mTOR, STAT
Brain	IL13, PVR, thymidylate synthetase
Breast	GM-CSF, CTLA-4, PVR, FLT3L
Colorectal	GM-CSF, CTLA-4, PD1, PVR
Head and Neck	GM-CSF, CTLA-4, STAT, mTOR
Liver	GM-CSF, TNF4
NSCLC	IFN-beta
Melanoma	GM-CSF, CTLA-4, IL2, PD1, PVR, TNF
Ovarian	IL2, TNF
Pancreatic	mTOR, STAT

Exhibit 28: Top Encoded Genes in Oncolytic Virus Therapies. Source: Diamond Equity Research, Informa Pharma Intelligence

More than 100 pharmaceutical companies are developing OV therapies, with the majority of them being small biopharmaceutical companies. PsiOxus Therapeutics and Replimune Therapeutics have 3 OV therapeutics candidates currently under clinical trials, while Transgene has two candidates currently in phase 2 trial. Astellas Pharma, Inc. and Merck & Co., Inc. are the only two large pharmaceutical companies with a notable presence in the pipeline gained through acquiring the specialist biotech companies KaliVir Immunotherapeutics, LLC and Viralytics Limited, respectively.<sup>8</sup> Melanoma, Colorectal, and Head & Neck cancer represent the top 3 targeted diseases within the OV therapy research landscape.

Date	Source	Buyer	Deal Type	Up-front	Note
Dec 2021	VCN Biosciences, S.L.	Synthetic Biologics	Acquisition	\$4.7 million	Lead Drug Candidate VCN-01
Dec 2020	KaliVir Immunotherapeutics	Astellas Pharma Inc	Licensing	\$56 million	VET2-L2 and the Second Product
May 2019	Transgene	AstraZeneca	Licensing	\$10 million	Five Research Candidates
Sep 2018	Viratherapeutics	Boehringer Ingelheim	Acquisition	\$245 million	VSV-GP Project, Preclinical
Feb 2018	Viralytics	Merck & Co	Acquisition	\$394 million	Cavatak, Phase II Asset

<sup>8</sup> <https://invivo.pharmaintelligence.informa.com/IV146684/A-Promising-Future-For-Oncolytic-Viruses-As-Cancer-Immunotherapies>

Nov 2017	Oncolytics	Adlai Norte	Licensing	\$5 million	Far East Development of Reolysin
Nov 2016	Virttu Biologics	Sorrento	Acquisition	\$25 million	Seprehvir, Phase II Asset
Jun 2016	Psioxus	Bristol-Myers Squibb	Licensing	\$10 million	Enadenotucirev, Phase I Collaboration
Jan 2011	Biovex	Amgen	Acquisition	\$424 million	Imlygic, Approved for Melanoma in 2015

Exhibit 29: Major Deals in Oncolytic Virus Therapy Segment. Source: Diamond Equity Research, Company Announcements

Oncolytic Virus Therapy is steadily moving from niche treatment modality to mainstream. Even though several aspects of OV's have improved pertaining to safety, efficacy, and delivery methods in the past few decades, OV's still face certain challenges (unknown host, antiviral pathways, adaptive immune responses limiting viral functions indirectly, and an immunosuppressive tumor microenvironment) that limit its use as monotherapy. This has also led to OV's being researched as combinational strategies with immunotherapies and cell therapies. For example, armed OV's with enhanced tumor-specific replication ability and stimulating a potent anti-tumor immune response can be combined with immune checkpoint inhibitors and cell therapies for cancer that develops resistance against current therapies because of rapid mutations and heterogeneous cell populations.<sup>7</sup>

### onCARlytics - 'Mark and Kill' Approach

Expanding the Immuno-oncology portfolio, the company licensed the CD19 Oncolytic virus from City of Hope, enabling CD19 CAR-T against solid tumors. CD19-directed CAR T as monotherapy has shown remarkable success in hematological malignancies, but its applicability in solid tumors is accompanied by various challenges which have led to poor outcomes in pre-clinical and clinical studies. Antigen escape, toxicity related to CAR-T cells, antigen heterogeneity, the trafficking of CAR-T cells and tumor infiltration, poor stability, and immunosuppressive microenvironment are among the limitations that impede the ability of CAR-T cell therapy to produce sustained response in patients with solid malignancies (accounts for 90% of all cancer cases worldwide).

CAR-T Therapy	Company	Targeted Disease	2021 Sales
Kymriah® (Tisagenlecleucel)	Novartis	B-cell acute lymphoblastic leukemia, follicular Lymphoma, and diffuse large B-cell lymphoma	<a href="#">\$587 million</a>
Yescarta® (axicabtagene ciloleucel)	Gilead	large B-cell lymphoma and follicular lymphoma	<a href="#">\$695 million</a>
Tecartus® (brexucabtagene autoleucel)	Gilead	mantle cell lymphoma or acute lymphoblastic leukemia	<a href="#">\$176 million</a>
Breyanzi® (lisocabtagene maraleucel)	Bristol Myers Squibb	Diffuse large B cell lymphoma, primary mediastinal large B-cell lymphoma, and Follicular lymphoma	<a href="#">\$87 million</a>

Exhibit 30: CD-19 CAR-T FDA-approved Therapies. Source: Diamond Equity Research, Company Sources

Higher generation CAR-T therapy has been shown to have superior ant-tumor activity when compared to first and second generations therapies. However, even with the use of a high later generation of CAR T-cells products, objective responses for trials in solid tumors have been mostly disappointing. Many studies are focusing on enhancing the applicability and usefulness of CAR-T therapies by combining it with other adjuvant therapies. One such combination therapy where Imugene believes that the combination can yield promising results is the use of Oncolytic virotherapy with CD19-directed CAR-T therapy. OV's ability to selectively replicate themselves while developing adaptive anti-tumor immunity has gained a lot of attention since the FDA approval of T-VEC. OVs can also be engineered in such a way that forces the expression of certain genes in the tumor milieu, that is, activating the targeted transgenic delivery potential, thus augmenting the oncolytic viral treatment.

*The company aims to enhance the use case of CD19 CAR-T cell therapy targeting solid tumors by utilising OVs as a delivery vector to deliver CD19 antigen to solid tumor cells*

The company is leveraging the transgenic delivery mechanism of Oncolytic Viruses such as CF33 to infect cancer cells and encourage the selective expression of a CAR-targetable tumor antigen, a truncated non-signalling variant of CD19 (CD19t). These underlying mechanisms of OVs allow endogenous production of T-cells and CAR T-cell infiltration into tumors, eventually exhibiting cancer-killing activities. Imugene obtained the worldwide licenses of the patents covering the cell therapy technology, which includes CF33-CD19, known as onCARlytics™, developed at City of Hope.

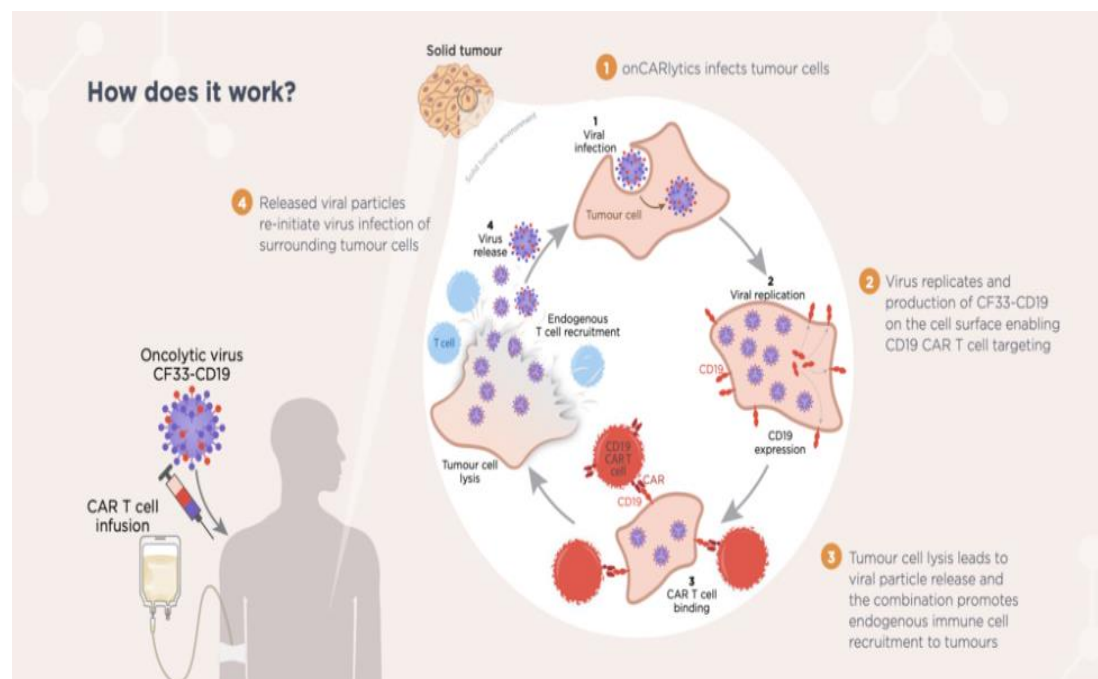


Exhibit 31: onCARlytics and CD19 CAR-T Combination Therapy Mechanism of Action. Source: Imugene Limited

**Pre-Clinical trial efficacy and safety**

CF33-CD19 in combination with CAR-T cell therapy has been evaluated in multiple pre-clinical studies in vivo and in vitro. Oncolytic chimeric orthopoxvirus CF33 carrying the CD19t encoded gene was administered and demonstrated robust cell surface CD19 expression on tumor cells, which promoted activation and tumor killing by CD19-specific CAR T cells.

Human triple-negative breast cancer cell lines MDA-MB-468 were infected with OV19t (OV carrying the CD19t gene) at various multiplicities of infection (MOI). CF33-CD19 and CD19

*onCARlytics in combination with CD19-CAR T cell therapy have shown to promote tumor regression in xenograft model of triple negative breast cancer (TNBC)*

expressions were observed on the cell surface in an MOI-dependent manner. The percentage of tumor cells positive for CD19t and CF33-CD19 was nearly 100% after 24 hours at an MOI of 1. Similar results pertaining to infection efficiency, CD19 positivity, and virus-mediated killing were observed across multiple tumor types, including pancreatic cancer, prostate cancer, ovarian cancer, gliomas, and head and neck cancer.

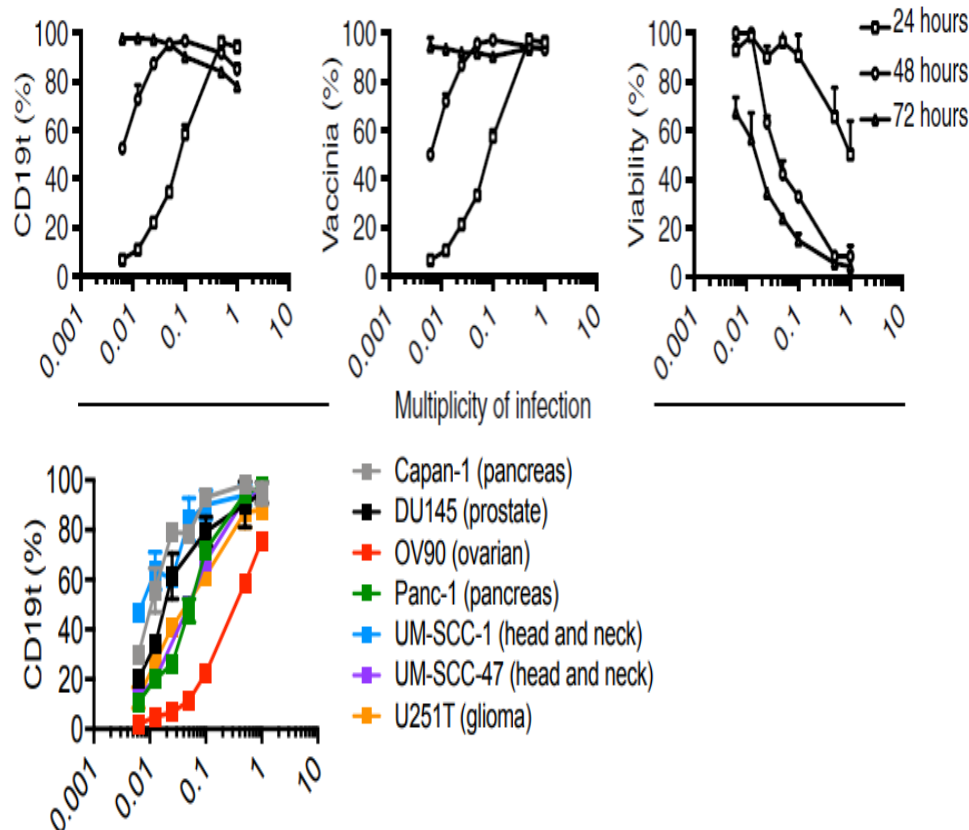


Exhibit 32: Quantification of Percent CD19t+ (left), Vaccinia+ (middle), and Viable (right) MDA-MB-468 Tumor Cells after 24-, 48-, and 72-hour Exposure to the Indicated MOIs of CF33-CD19 and CD19 Expression in a Wide Array of Solid Tumor Cell Lines. Source: [Park et al. 2020](#)

The combination therapy was also evaluated in the human tumor xenograft model and in the murine immunocompetent tumor model. Anti-tumor activity was assessed under both these models post the intratumoral delivery of oncolytic virus carrying CD19 gene followed by intratumoral delivery of CD19 CAR-T cells. Both models indicated similar findings, confirming the therapeutic benefit of the combination approach. Oncolytic virus carrying CD19 gene promoted endogenous antitumor immunity and tumor recruitment of CD19-CAR T cells leading to marked tumor regression. Additionally, greater killing of M38 tumor cells infected with OVm19t and cocultured with mCD19-CAR T cells at 24 hours was observed compared with the killing of cells infected with OVmCD19t alone. Similar combination effects were observed with MDA-MB-468 and U251T cells in human tumor xenograft models. Marked reduction in CD19t+ tumor cells was observed at all MOIs evaluated.

The combination of CF33-CD19 and CAR-T cell therapy promotes cytotoxic T cells, CAR T cells, and memory T-cells responses. The trial results also indicated that the therapy was well-tolerated with minimal off-tumor targets. These findings indicate the ability of the combination therapy to overcome the challenges (targeting surface proteins that are heterogeneously distributed



in tumors and the presence of these surface proteins on some normal tissues) that existed in CAR-T as a monotherapy. Leveraging the antigen delivery mechanism of OV's, the use of CAR-T cell therapy can be extended beyond the scope of hematological malignancies, potentially treating solid tumors.

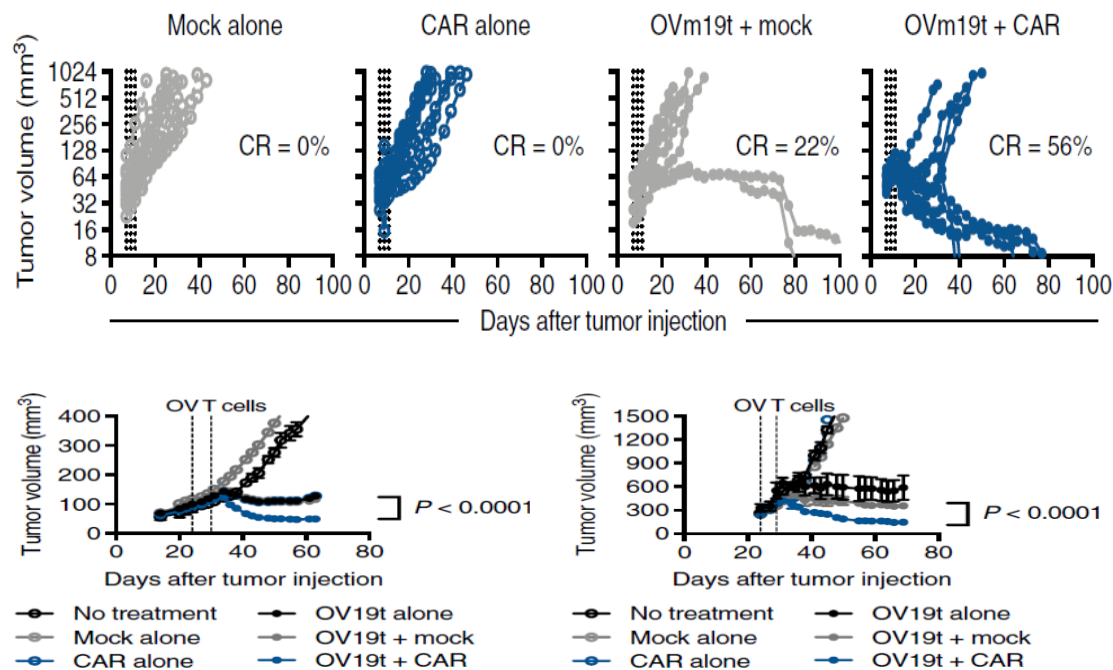


Exhibit 33: Tumor Volume data of CF33-CD19 and CAR-T Treated Mice with Subcutaneous MC38 Tumors and Percent of Mice with Complete Response (top). Tumor Volume Data of CF33-CD19 and CAR Treated Mice with MDA-MB-468 (bottom-left) and U251T Tumor (bottom-right). Source: [Park et al. 2020](#)

## Strategic Partnerships

To further the progress of onCARlytics, the company entered into research collaboration agreements with Eureka Therapeutics Inc., Celularity Inc and Arovella Therapeutics Ltd. These partnerships would employ the clinical development expertise of the respective parties in the agreement benefiting Imugene to fast-track the clinical development of onCARlytics. The FDA IND approval is anticipated by the year-end and the first patient in the phase 1 trial to be dosed in 2023.

The collaboration will explore the use case of Imugene's onCARlytics (CF33-CD19) in combination with Eureka's anti-CD19 ARTEMIS® autologous T-cell therapy, Celularity's allogeneic CAR T-cell therapy (CyCART-19) and Arovella's CAR19-iNKT (ALA-101) cell therapy. The readout from the preclinical studies performed in collaboration with Arovella is expected in H1 2023. These partnerships will allow Imugene to evaluate onCARlytics in both allogeneic and autologous therapeutic settings targeting solid tumors. The agreement yields highly complementary oncology therapies that have the ability to force CD19 expression on the surface of tumor cells leading to CAR-T recognition and killing of cancer cells.

## Management Overview

Imugene Ltd. is led by an experienced team with deep expertise and extensive experience in biotech, life sciences, healthcare, and related fields. The management strives to develop a range of new treatments that seek to activate the immune system of cancer patients to identify and eradicate tumors.

### **Leslie Chong, Chief Executive Officer and Managing Director**

Ms. Leslie Chong holds the position of Chief Executive Officer and Managing Director of Imugene Ltd. She has more than 24 years of oncology experience in Phase I – III of clinical program development and played a leadership role in two marketed oncology products. Ms. Chong was previously Senior Clinical Program Lead at Genentech, Inc., in San Francisco. Genentech is widely regarded as one of the world's most successful biotech companies with a strong oncology franchise, including the best-selling breast cancer drug Herceptin. She holds a Bachelor's degree in Science from the University of North Carolina.

### **Paul Hopper, Executive Chairman**

Mr. Paul Hopper is the Executive Chairman of Imugene Ltd. He has over 25 years of experience in the biotech, healthcare & life sciences sectors. Focussed on start-up and rapid growth companies, Paul has served as either Founder, Chairman, non-executive director, or CEO of more than fifteen companies in the US, Australia, and Asia. His experience covers extensive fundraising in the US, Australia, Asia, and Europe, and he has deep experience in corporate governance, risk, and strategy. His previous and current Boards include Imugene, Radiopharm Theranostics, Chimeric Therapeutics, Viralytics, Prescient Therapeutics, Polynoma, and Arovella Therapeutics. Paul holds a Bachelor's degree from the University of New South Wales.

### **Dr. Monil Shah, Chief Business Officer**

Dr. Monil Shah is the Chief Business Officer of Imugene Ltd. He has over 20 years of pharmaceutical and biotechnology industry experience in oncology drug development. His previous stint includes being Chief Development Officer at WindMIL Therapeutics, Chief Operating Officer of IRX Therapeutics /Brooklyn ImmunoTherapeutics, and Medical Affairs Lead for Immuno-Oncology at Bristol Myers Squibb. Dr. Shah was also the Founder and Head of Clinical Development and Operations at Ventrus Biosciences prior to its merger with Assembly Biosciences. Dr. Shah holds a Bachelor's degree in Science and received his Doctorate of Pharmacy from Rutgers University.

### **Mike Tonroe, Chief Financial Officer**

Mike Tonroe is the Chief Financial Officer of Imugene Ltd. He has extensive experience being a CFO and Company Secretary within the biopharmaceutical industry. Before assuming the CFO position at Imugene, Mr. Tonroe was the CFO at Genetic Technologies Limited (ASX: GTG), Opthea Limited (ASX: OPT), and Australian Synchrotron Company Limited. He was actively involved in the NASDAQ listing of Opthea (NASDAQ: OPT) along with M&A, restructuring, capital raising, and leading the finance function across these businesses. Mr. Tonroe graduated in

Business Studies with Honours from Buckingham University UK, later becoming a Fellow of the Institute of Chartered Accountants in England & Wales. He is Australian Institute of Company Directors (AICD) accredited.

**Dr. Nick Ede, Chief Technology Officer**

Dr. Nick Ede holds the position of Chief Technology Officer at Imugene Ltd. He has over 25 years of experience in peptide vaccine and drug development and was formerly the CEO of Adistem and the CEO of Mimotopes. Prior to that, he was VP of Chemistry at Chiron (now Novartis) and has been a Research Fellow at the CRC for Vaccine Technology. Dr. Ede holds a Bachelor's in Science and a Doctorate in Bioorganic Chemistry from Monash University.

**Dr. Anthony Good, Senior VP of Clinical Research**

Dr. Anthony Good is the VP of Clinical Research at Imugene Ltd. He has over 20 years of global clinical development experience. Dr. Good was integral to developing significant new medicines, including Viagra, Revatio, Lipitor, and Somavert. He formerly held roles with Pfizer Global Research and Development and Covance Clinical Services. Dr. Good holds a Bachelor's in Science and a Doctorate in Neuroscience from the University of New South Wales.

**Ursula McCurry, Senior VP of Clinical Operations**

Ursula is a seasoned clinical operations leader with over 20 years of global clinical development experience across a number of biotech and pharmaceutical companies, including Genentech, Exelixis, Astex, QLT Inc, and Amunix. Prior to joining Imugene, Ursula served as the VP of Clinical Operations at Amunix Pharmaceuticals and was a Clinical Program Director at Genentech, leading multiple programs from entry into the clinic to phase three development, including Taselisib and GDC-9545. Ursula received a Master of Arts degree from Simon Fraser University and a certificate in Biotechnology, Clinical Trial Design, and Management from San Francisco State University.

**Dr. Sharon Yavrom, Executive Director, Clinical Scientist**

Dr. Sharon is a clinical scientist with more than 20 years of industry experience, with more than a decade working exclusively with startups. She has been the clinical study lead for several clinical trials and has experience with multiple tumor types, including HER2+ breast cancer, NSCLC, glioblastoma, colorectal cancer, non-invasive bladder cancer, NHL, CLL, and Ewing's Sarcoma. Dr. Sharon received her Bachelor of Science degree in Biology from San Jose State University and her Ph.D. in Pathobiology from Keck School of Medicine, University of Southern California.

**Dr. Nimali Withana, Senior Director of Clinical Science**

Dr. Withana is the Senior Director of Clinical Science and has over 18 years of drug development experience spanning both academia and industry. Most recently, she was the Lead Country Medical Manager for the Breast Cancer and Cancer Immunotherapy portfolios, including bevacizumab, trastuzumab emtansine, ipatasertib, and atezolizumab at Hoffman-La Roche New Zealand. Dr. Withana has an in-depth understanding and grasp of the development process with experience in R&D, Clinical Trials, and Patient Advocacy. She received her academic training at Stanford University and The Peter MacCallum Cancer Centre majoring in Immunology and Molecular Medicine.

## Financial Positioning

Imugene Limited is a pre-revenue biotechnology company with multiple therapies being in clinical development. The company recently concluded an A\$80 million institutional placement and is well capitalized, providing a good enough runway for the existing pipeline candidates. Post the completion of institutional placement, Imugene has a cash balance of A\$175 million without any material interest-bearing financial obligations. The robust financial position also provides flexibility to license complementary assets should attractive opportunities present.

The cash outflow from operating activities more than doubled from A\$13.28 million in 2021 to A\$30.84 million in 2022. This has been majorly due to a 138% increase in research and development expenses to A\$36.61 million. Assuming an average annualized cash burn rate of A\$45 million, the current liquidity position would be enough to support the company's operating and research activities for approximately four years.

Year-end 30 June (in A\$mm)	2021A	2022A	2023E	2024E	2025E
<b>INCOME STATEMENT</b>					
Revenue	\$0	\$0	\$0	\$0	\$0
Gross Profit	\$0	\$0	\$0	\$0	\$0
EBITDA	(\$24)	(\$48)	(\$61)	(\$66)	(\$72)
Depreciation & Amortization	(\$2)	(\$2)	(\$2)	(\$2)	(\$2)
Profit Before Tax (PBT)	(\$18)	(\$38)	(\$49)	(\$50)	(\$55)
Profit After Tax (PAT)	(\$18)	(\$38)	(\$49)	(\$50)	(\$55)
Basic Shares Outstanding	4,614	5,652	6,268	6,268	6,268
EPS - basic	(\$0.00)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)
EPS - diluted	(\$0.00)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)
<b>BALANCE SHEET</b>					
Cash and cash equivalents	\$29	\$100	\$134	\$92	\$43
Other current assets	\$7	\$14	\$14	\$14	\$14
Total current assets	\$36	\$114	\$148	\$106	\$57
Non-current assets	\$35	\$34	\$32	\$30	\$29
<b>Total Assets</b>	<b>\$72</b>	<b>\$148</b>	<b>\$180</b>	<b>\$137</b>	<b>\$86</b>
Short-term borrowing	\$0	\$0	\$0	\$0	\$0
Other current liabilities	\$4	\$7	\$8	\$8	\$9
Total current liabilities	\$4	\$7	\$8	\$9	\$9
Long-term borrowing	\$0	\$0	\$0	\$0	\$0
Other non-current liabilities	\$2	\$1	\$1	\$1	\$1
Total liabilities	\$7	\$9	\$10	\$10	\$11
Total Equity	\$65	\$139	\$170	\$126	\$75
<b>Total Liabilities &amp; Equity</b>	<b>\$72</b>	<b>\$148</b>	<b>\$180</b>	<b>\$137</b>	<b>\$86</b>

Exhibit 34: Income Statement Snapshot. Source: Diamond Equity Research

## Valuation

We have valued the company using risk-adjusted DCF as our preferred methodology. We have estimated revenue for the company's four therapeutic candidates currently in clinical trials based on the targeted disease incidence rates and the company's ability to capture the market share. For HER-Vaxx, we have assumed a probability of success of 35%, while for the other three candidates in the phase 1 clinical trial, we have assumed a probability of success of 15%. Further, we have accounted for the royalty and milestone payments to Ohio State University, Mayo Clinic, and City of Hope relating to licensing of PD-1 and non-PD-1 IP and CF33 oncolytic virus technology.

We have also valued the company using a comparable company analysis, assigning a weightage of 10%. Using a discount rate of 10.7% and assigning a weightage of 90% to the risk-adjusted DCF methodology, we have arrived at an equity value of A\$0.48 per share, contingent on successful execution by the company.

Therapy	Targeted Disease	Probability of Success	Status	Commercialization Year
HER-Vaxx	Gastric Cancer	35%	Phase 2	2026e
PD-1 Vaxx	Non-Small Cell Lung Cancer	15%	Phase 1	2028e
CHECKvacc	Triple Negative Breast Cancer	15%	Phase 1	2029e
VAXINIA	Metastatic Solid Tumors	15%	Phase 1	2029e

		Approaches (in \$ mm)	Value (AUD)	Weight	Wtd. Value (AUD)
<b>Calculated Equity Value (\$mm)</b>		DCF	\$3,219.79	90%	\$2,897.81
Enterprise Value	\$3,045.58	GPCM	\$899.32	10%	\$89.93
- Debt and Preferred Stock	\$0.67	GTM	-	0%	\$0.00
+ Cash	\$174.88	<b>Wtd Avg. Equity Value (AUD)</b>		<b>\$2,987.74</b>	
Net Debt	\$174.21	<b>No. of Shares Outstanding</b>		<b>6268.34</b>	
Equity Value	\$3,219.79	<b>Intrinsic Value Per Share</b>		<b>\$0.48</b>	

Company Name	Ticker	Price	Currency	Market Cap.	LTM P/B	LTM P/R&D
Innovent Biologics, Inc.	IVBXF	4.67	USD	6540.00	4.00x	16.77x
Fate Therapeutics, Inc.	FATE	30.87	USD	2989.00	5.20x	10.83x
Oncolytics Biotech, Inc.	ONCY	1.51	USD	89.10	3.70x	8.27x
Spectrum Pharmaceuticals, Inc.	SPPI	1.32	USD	242.52	7.30x	4.11x
Celldex Therapeutics, Inc.	CLDX	32.37	USD	1509.00	4.50x	21.71x
Incyte Corporation	INCY	72.68	USD	16170.00	4.30x	10.37x
Mirati Therapeutics, Inc.	MRTX	78.27	USD	4350.00	3.90x	8.22x
Celularity Inc.	CELU	2.78	USD	395.94	-	4.15x
Immunocore Holdings plc	IMCR	54.75	USD	2400.00	12.00x	26.08x
Checkpoint Therapeutics, Inc.	CKPT	1.33	USD	123.02	16.50x	2.51x
<b>Median</b>					<b>4.50x</b>	<b>9.32x</b>
<b>Mean</b>					<b>6.82x</b>	<b>11.30x</b>

Exhibit 35: Valuation Snapshot. Source: Diamond Equity Research

## Key Risks

- **Clinical Development Risk** - Imugene's market value is tied to its therapeutic products currently in clinical trials. Failure to deliver satisfactory efficacy and safety profile or statistically significant results could negatively impact the company's value.
- **Regulatory Risk** - Post successful completion of clinical trials, the company is required to gain regulatory approval from foreign and or domestic regulatory bodies. Failure to obtain regulatory approval in any of the targeted geographies could negatively impact the company's addressable market and, therefore, the overall value of the company.
- **Foreign Exchange Risk** - The company is exposed to foreign exchange risk, given that clinical trials and other research activities are carried out in foreign geographies. Wide fluctuations in foreign currency could impact the company's cost profile and cash burn.
- **Financing and Dilution Risk** - Imugene is a pre-revenue biotechnology company and relies on external sources of financing to progress its pipeline. Failure or delays in obtaining the required capital would hinder the company's operating and research activities leading to deferment in expected clinical and approval timelines. Financing capital by issuing further equity will dilute the shareholding of existing shareholders.
- **Competitive Risk** - The cancer Immunotherapy market has expanded in the past decade with multiple approvals and thousands of therapeutic products currently in clinical trials. Imugene faces competition from many of the therapeutic products being evaluated in clinical trials, which might affect the company's ability to position and gain market share in its targeted geographies.

*These risk factors are not comprehensive. For a full list of risk factors, please read Imugene's latest prospectus and/or annual filings.*

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