ROTH Capital Partners

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COMPANY NOTE | EQUITY RESEARCH | October 01, 2020

Healthcare: Biotechnology

Imugene Limited | IMU.AX - AUD0.05 - ASX | *Buy*

Initiation of Coverage

Stock Data	
52-Week Low - High	AUD0.02 - AUD0.07
Shares Out. (mil)	4,491.54
Mkt. Cap.(mil)	AUD215.59
3-Mo. Avg. Vol.	23,535,880
12-Mo.Price Target	AUD0.13
Cash (mil)	AUD35.7
Tot. Debt (mil)	AUD0.0

Cash (mil): Proforma due to AUD$5.6M net raise in FY1H21

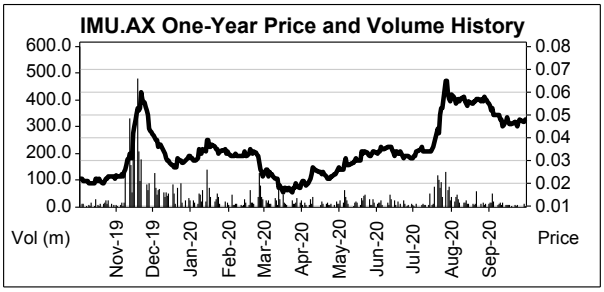
FY ends June 30

EPS $AUD

Yr Jun	—2020—	—2021E—	—2022E—
		Curr	Curr
1Half	(0.00)A	(0.00)E	-
2Half	(0.00)A	(0.00)E	-
YEAR	(0.00)A	(0.00)E	(0.00)E

Revenue ($AUD millions)

Yr Jun	—2020—	—2021E—	—2022E—
		Curr	Curr
1Half	0.0A	0.0E	-
2Half	0.0A	0.0E	-
YEAR	0.0A	0.0E	0.0E



IMU.AX: Engineered Oncolytic Viruses and B Cell Immunotherapies to Fight Cancer

Imugene is a clinical stage immuno-oncology company developing several novel immunotherapies that either directly lyse tumor cells or activate the immune system to produce cancer fighting polyclonal antibodies. Imugene's Phase 1 ready oncolytic virus candidates (VAXinia and CHECKvacc), and leading B cell immunotherapy candidates (Phase 2 HER-Vaxx and Phase 1 PD1-Vaxx) are aimed at treating multiple solid tumor types, most likely in combination with approved drugs. We look forward to several clinical efficacy releases starting in calendar 2H21.

- We are initiating coverage of Imugene with a Buy rating and a 12-month price target of AUD0.13, which is based on a DCF analysis using a 35% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of our projected FY2031 operating income of AUD1.6 billion. We arrive at this valuation by projecting future revenue from CHECKvacc in TNBC, HER-Vaxx in advanced HER2+ gastric cancer, and PD1-Vaxx in NSCLC, products that we project will generate about AUD1.7 billion in global royalty revenue to Imugene in FY2031. We believe that Imugene has prudently selected areas of unmet need, and therefore ultimately market demand, with a high likelihood of clinical success.
- Imugene's oncolytic viruses are designed to infect, replicate in, and kill cancer cells, leaving healthy cells essentially unharmed, having undergone accelerated evolution *in vitro* until their cancer cell killing was sufficiently optimized, and they have proven effective at killing a broad range of tumor cell lines, including all members of the NCI-60 cell line panel. The viruses are highly potent, potentially allowing for far lower dosing than other clinical stage oncolytic viruses, and therefore more favorable safety and lower COGS. CHECKvacc differs from VAXinia in that CHECKvacc includes the inserted transgene for an anti-PD-L1 mAb. Many competitors are combining viral therapies with checkpoint inhibitors to increase the immunogenicity of immunologically cold tumors, the goal being to increase the percentage of patients currently benefiting from durable responses to this blockbuster class of drugs. We see four pillars of differentiation with these viruses: potency once inside a cancer cell, strong cancer cell tropism, the potential for intravenous use, and durable patent life.
- Active immunization with B cell immunotherapy has the potential to offer patients a safer, lower cost, more conveniently dosed, and potentially more effective treatment modality than the passive immunity gained from infusion of specific mAbs against disease antigens. We believe that eliciting production of polyclonal antibodies that are 100% self can circumvent certain toxicities observed after intravenous infusion of hundreds of milligrams of a given mAb. We believe that if a tumor can respond to passive immunity directed against a single epitope, then it should respond to active immunity against several epitopes.

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Business Overview

Imugene Limited (ASX: IMU and OTCMKTS: IUGNF) is a clinical-stage immuno-oncology company engaged in discovering, developing, and ultimately commercializing novel oncolytic viruses and B cell immunotherapies for unmet needs. Imugene's unique platform intends to redirect a patient's immune system to kill their own tumors. Imugene's therapeutic candidates are oncolytic viruses that directly kill cancer cells (VAXinia), oncolytic viruses that also supply the gene for a potent immunotherapy (CHECKvacc), and B cell immunotherapies that either supply antigens to generate direct antitumor polyclonal antibodies (HER-Vaxx) or polyclonal antibodies for checkpoint inhibition (PD1-Vaxx).

In November 2019, Imugene gained control of oncolytic viruses VAXinia (a.k.a., CF33) and CHECKvacc by acquiring Vaxinia Pty Ltd. The chimeric vaccinia poxviruses were developed at City of Hope in Los Angeles, CA by noted oncolytic expert Professor Yuman Fong, Chair of Surgery at City of Hope. Oncolytic viruses can be fully natural in their genomic nucleic acid sequence and/or can be genetically modified (directly or via selection of desirable mutants), but they are all intended to infect, replicate in, and kill cancer cells, while sparing healthy cells. VAXinia was generated via recombination among multiple strains of vaccinia virus and other species of poxvirus, with the virus under development having been selected for its ability to efficiently replicate in and kill numerous cancer cell lines, and strongly prefer to infect cancer cells rather than nonmalignant cells. The virus was shown to reduce the size of various types of tumors injected into animals regardless of whether the tumor was directly injected with virus or it was a distant non-injected tumor in the same animal. The preclinical adverse event profile was highly favorable, and the potency of this particular virus is evident in how low of a dose is required for significant antitumor effect (essentially a dose that is several orders of magnitude lower than doses currently used for T-VEC and oncolytic viruses in clinical trials). CF33 is being developed as two different constructs, VAXinia (CF33+hNIS) and CHECKvacc (CF33+hNIS+anti-PD-L1). Both viruses contain a functional human iodide symporter (hNIS) gene enabling both virus tracking and radioiodine therapy, but CHECKvacc also contains the gene for an anti-PD-L1 checkpoint inhibitor to avoid having to necessarily give the virus in combination with an expensive checkpoint inhibitor mAb, a potentially strong competitive advantage. We look forward to the start of Imugene's first Phase 1 trial with VAXinia, with potential indications including advanced melanoma, head and neck cancer, TNBC, non- small cell lung, cancer, bladder cancer, gastric cancer, colorectal cancer, and renal cell carcinoma. We anticipate VAXinia efficacy results in calendar 2022 (monotherapy) and calendar 2023 (in combination with checkpoint inhibitors). We also look forward to the first Phase 1 CHECKvacc trial, estimated to generate initial clinical efficacy results in calendar 2H22 (monotherapy intratumoral dose escalation).

Imugene is also developing its B cell immunotherapy HER-Vaxx for advanced gastric cancer expressing HER2, with Phase 1b completed and Phase 2 currently enrolling up to 68 patents, having passed an interim analysis in May 2020 with the recommendation to continue the trial without modification. Given the highly competitive breast cancer market, we believe that it is prudent for Imugene to target the more severe, but vastly less well served advanced gastric cancer market. Phase 1b evaluated three different HER-Vaxx doses in combination with standard of care chemotherapy in 14 patients, met all key endpoints, and identified an optimal Phase 2 dose. Phase 1b results have been broadly presented at medical conferences and peer-reviewed publication is in progress. We anticipate Phase 2 efficacy data from HER-Vaxx in calendar 1H22 (PFS) and 1H23 (OS).

Additionally, Imugene is developing PD1-Vaxx, its B cell immunotherapy to generate polyclonal antibodies against immune checkpoint PD-1, in an effort to achieve endogenous production of checkpoint inhibitors (i.e., active immunity), rather than rely on the relatively frequently given and expensive checkpoint inhibitors (passive immunity). Checkpoint inhibitors are a multibillion dollar market success story, with numerous approved and several more in the clinic. The Phase 1 NSCLC trial will start soon in Australia and the U.S, with results to be available in calendar 2H21 (monotherapy) and 1H22 (combination therapy). Imugene will also evaluate the combination of PD1-Vaxx and HER2-Vaxx in HER2+ cancers.

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Investment Summary

- We are initiating coverage of Imugene with a Buy rating and a 12-month price target of AUD0.13, which is based on a DCF analysis using a 35% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of our projected FY2031 operating income of AUD1.6 billion. We arrive at this valuation by projecting future revenue from CHECKvacc in TNBC, HER-Vaxx in advanced HER2+ gastric cancer, and PD1-Vaxx in NSCLC. The geographies modeled for commercialization include the U.S., E.U., and China. Our valuation excludes potential commercial upside from B-Vaxx (not discussed further in our report) because it is not a current focus, from VAXinia given our view that CHECKvacc will be preferentially developed, and from any of Imugene's early preclinical assets, and therefore commercial success with these programs would serve as potential upside to our valuation. We believe that Imugene has prudently selected areas of unmet need, and therefore ultimately market demand, with a high likelihood of clinical success. In calendar 2H21 and 1H22, we look forward to Phase 1 results for PD1-Vaxx (determination of optimal biological dose as monotherapy and combination therapy, respectively). In calendar 1H22 and 1H23, we look forward to Phase 2 data for HER-Vaxx (PFS and OS, respectively). Initial Phase 1 results for CHECKvacc and VAXinia are expected in calendar 2H22, all of which should serve as meaningful investment catalysts.
- We believe that Imugene would be best served to engage commercial partners for all of its assets that demonstrate clear clinical proof-of-concept, with the potential to market its products itself in Australia, and thus we incorporate royalty revenue from several major markets into our financial model. Delivering partnerships that provide meaningful economics would likely serve as additional significant investment catalysts, as well as supply non-dilutive upfront capital, in our view.
- The market potential for HER-Vaxx, when only considering the disease focus of its current trial, amounts to U.S., E.U., and China disease incidences at launch of about 5,700, 7,600, and 98,000, respectively, when using 20% as the rate for HER2-positivity in advanced gastric cancer (1). We project an initial price for therapy of $50,000 in the U.S., and $35,000 ex-U.S., which yields total royalty revenue from HER-Vaxx of AUD131 million in FY2031, using our estimated 15% royalty rate. We model HER-Vaxx launch in the U.S., E.U., and China in FY2025. FY2026, and FY2026, respectively. Financial forecasting for PD1-Vaxx in NSCLC in these same three geographies and using the same treatment costs and 15% royalty rate, (U.S, E.U., and China NSCLC disease incidences at launch of about 195,000, 313,000, and 622,000, respectively (2,3,4)), yields total royalty revenue from PD1-Vaxx of AUD768 million in FY2031. We model PD1-Vaxx launch in the U.S., E.U., and China in FY2026. FY2027, and FY2027, respectively. For the oncolytic virus program, the initial VAXinia clinical trial will be in mixed solid tumors and the initial CHECKvacc clinical trial will be in TNBC, and we have elected to model CHECKvacc in TNBC as, at least initially, the most likely approved indication for the oncolytic virus program overall. Modeling these sales much the same way as with the other two programs (U.S, E.U., and China TNBC disease incidences at launch of about 43,000, 57,000, and 185,000, respectively (5,6)), but using drug costs of $65,000 in the U.S. and $45,000 ex-U.S., we arrive at FY2031 CHECKvacc royalty revenue of AUD785 million. We model CHECKvacc launch in the U.S., E.U., and China in FY2026. FY2027, and FY2027, respectively. In all potential future commercialization deals, COGS is modeled as being the responsibility of the potential partner, hence our relatively low royalty rate despite our expectation that Imugene advances all programs past clear proof-of-concept prior to signing any commercialization deals.
- As of the end of Imugene's FY2020 (June 30, 2020), the company had cash and cash equivalents of AUD30.1 million, which when combined with the recent net AUD5.6 million raise from option exercise, and the highly likely net AUD6.2 million raise from additional option exercise in FY1H21, is enough to fund operations into FY2H23, as per our projections. Imugene has no debt. We also note that Imugene options exist that are potentially exercisable in FY1H22 (generating net AUD9.7 million) and FY1H23 (generating net AUD12 million), which would provide funding well into FY2024, as per our projections.

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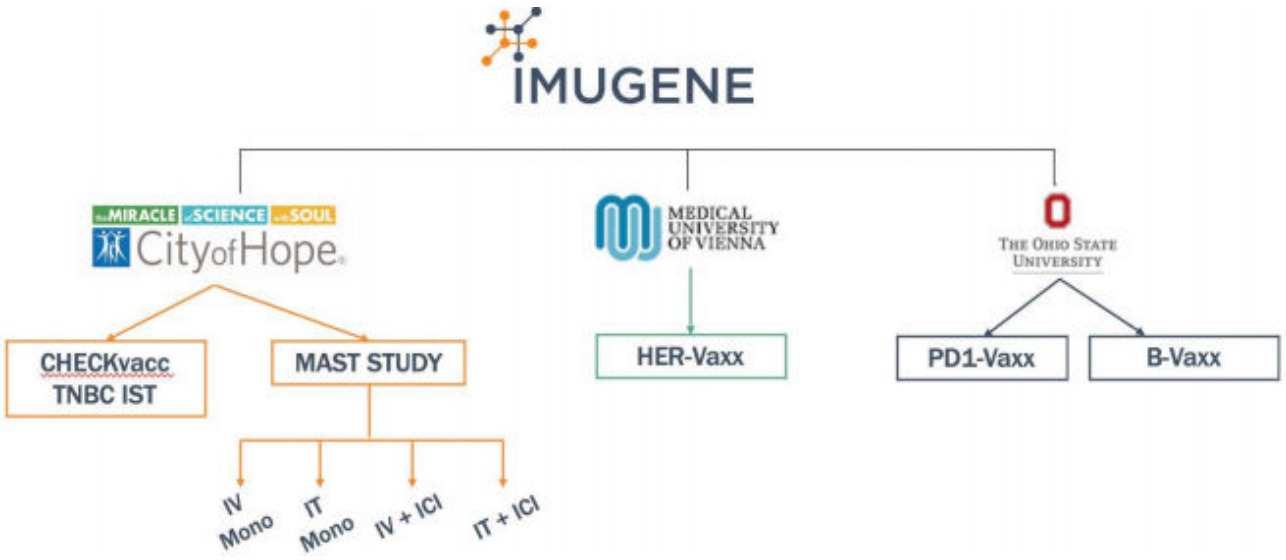
Product Pipeline and Affiliations

Product pipeline

	Pre-Clinical	Clinical development Phase 1	Clinical development Phase 2	Key Data / Results	Intellect Property
AXINIA CF33)		Mixed Advanced solid tumors		• 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 203
HECKvacc CF33 & aPD-1)		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 20
ER-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	Expiring 203
D1-Vaxx		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	Expiring 203

Source: Imugene Ltd. corporate presentation July 2020

Pipeline product affiliations



Source: Imugene FY2020 Annual Report

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Anticipated Milestones Over the Next 12 Months

- **HER-Vaxx IDMC review upon PFS in 16 patients**
- **PD1-Vaxx cohort review outcome**
- **CHECKvacc FDA IND clearance**
- **HER-Vaxx IDMC review upon PFS in 24 patients**
- **CHECKvacc first patient dosed**
- **HER-Vaxx enrollment complete**
- **VAXinia FDA IND clearance**
- **VAXinia first patient dosed**
- **HER-Vaxx secondary endpoint completion upon PFS in 32 patients**
- **PD1-Vaxx determine monotherapy optimal biological dose**

Source: Imugene Ltd. corporate presentation July 2020

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Oncolytic Virus Platform Background

- Oncolytic viruses are naturally occurring or genetically modified viruses that infect, replicate in, and kill cancer cells, leaving healthy cells essentially unharmed. Viruses can also be engineered to engage the immune system and enhance local and systemic antitumor immune reactions. VAXinia (a.k.a. CF33-hNIS) is a novel, chimeric, oncolytic, orthopoxvirus, which was derived from numerous strains of virus from this viral family. VAXinia is attenuated due to its thymidine kinase (TK) gene being disrupted by the insertion of the hNIS transgene, thereby inhibiting the virus from being able to enhance its DNA replication via thymidine synthesis. Expression of the hNIS (human sodium/iodide symporter) gene allows iodide ion to enter an infected cell, thereby allowing radioactive iodine and a PET scan to be used to track exactly what tissues are infected by the virus, in addition to allowing for radioiodine anticancer therapy. VAXinia underwent accelerated evolution *in vitro* until its cancer cell killing ability was sufficiently optimized, and it has proven effective at killing a broad range of tumor cell lines, including all members of the NCI-60 cell line panel.
- CHECKvacc differs from VAXinia in that CHECKvacc includes the inserted transgene for an anti-PD-L1 mAb that binds PD-L1 just like the approved checkpoint inhibitor atezolizumab because the inserted mAb DNA sequence is identical. CHECKvacc therefore has the potential to obviate the need for combination therapy with checkpoint inhibitors. Many competitors are combining viral therapies with checkpoint inhibitors to increase the immunogenicity of immunologically cold tumors, the goal being to increase the percentage of patients currently benefiting from durable responses to this blockbuster class of drugs.
- Delivering therapeutic or prophylactic payloads via viruses hit a temporary, but substantial, roadblock back in 1999, when a patient named Jesse Gelsinger, the last of 18 in a gene therapy trial to correct ornithine transcarbamylase deficiency (OTCD) due to a genetic defect, died four days after receiving the highest dose given (3.8×10^{13} adenovirus particles (6×10^{11}/kg of body weight)). OTCD is perhaps the worst type of condition to treat with a massive amount of virus or anything else that would generate a cascade of protein that requires cleaning up, as OTCD directly stops or reduces the break down and removal of nitrogen, which then accumulates to toxic levels. As therapeutic virus programs were halted, intellectual property continued to run out, thereby disincentivizing many companies to pick up where they left off. We mention this story to emphasize what we see as advantages with Imugene's approach, namely high potency and durable intellectual property until at least 2037. We believe that the extensive *in vitro* evolution of VAXinia (and CHECKvacc, for that matter) has led to a high enough potency such that these viruses can likely be administered at a low dose relative to other oncolytic viruses (i.e., several orders of magnitude fewer virus particles). Lower doses also confer the obvious economic benefit of reducing COGS. VAXinia-based oncolytic viruses could potentially be potent enough to administer intravenously, rather than only intratumorally, given their strong cancer cell tropism and thus their low likelihood of infecting normal cells. We note that viral-based therapies have historically had too low of a potency or too promiscuous of a tropism to give intravenously, and that intravenous administration allows a therapy to be used for less accessible tumors. VAXinia's extensive *in vitro* evolution has led to a completely unique viral DNA sequence that should provide patent protection for at least 17 more years. In summary, we see four pillars of differentiation with VAXinia: potency once inside a cancer cell, strong cancer cell tropism, the potential for intravenous use, and durable intellectual property.
- In 3Q20, Imugene received guidance from the FDA regarding development of VAXinia in Australia and the U.S., which covered both preclinical and clinical work. The pre-IND meeting served to provide Imugene with regulatory guidance and agreement of the preclinical, chemistry, manufacturing, and clinical development plan to be included in the VAXinia IND. More specifically, FDA guidance focused on Phase 1 items such as patient population, safety monitoring plan, and strategy for evaluating drug exposure. The FDA also guided on key aspects of non-clinical investigations and provided feedback on studies required to support the Phase 1 trial, giving Imugene a clear roadmap for a successful future IND submission. Imugene is also pursuing a parallel regulatory pathway in Australia. The single center Phase 1 CHECKvacc trial in TNBC (City of Hope, Los Angeles) is poised to begin once COVID-19 headwinds subside.

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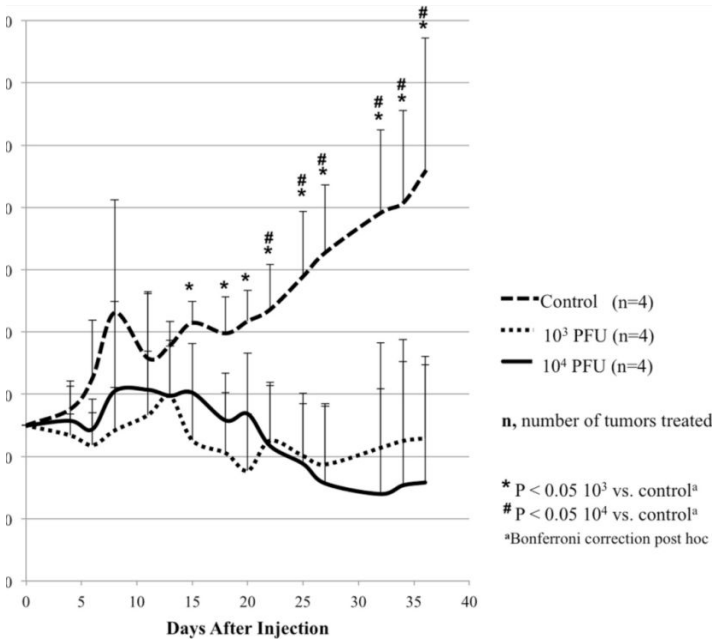
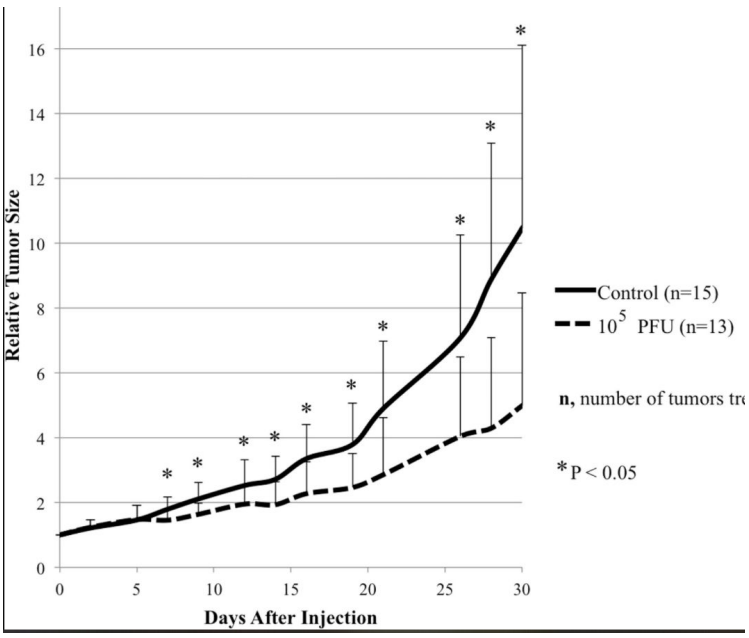
VAXinia Reduces or Inhibits Tumors in Mice

- To determine the effect of VAXinia *in vivo*, two xenograft mouse models were created by implanting MDA-MB-468 or MDA-MB-231 cells into the mammary fat pads of athymic nude mice. Tumors in the MDA-MB-468 group were treated with either PBS or VAXinia at 10^3 or 10^4 PFU per tumor. Given that MDA-MB-231 showed the most resistance to VAXinia treatment *in vitro*, these tumors were treated with either PBS or VAXinia at the higher dose of 10^5 PFU per tumor. MDA-MB-468 xenografts were significantly reduced in tumor size 15 days after treatment for both VAXinia dose groups compared to control ($p<0.05$; left panel below), and this effect was sustained for five weeks after injection. No significant systemic toxicity was noted as determined by body weight measurements after viral injection.
- MDA-MB-231 xenografts treated with VAXinia demonstrated significant inhibition in tumor growth starting seven days after injection compared to control ($p<0.05$; right panel below). In this experiment, there was marked weight loss in one mouse that was shown to have intraperitoneal disease at time of necropsy, likely due to inadvertent intraperitoneal injection during tumor implantation and thus was excluded from the final analysis. There were no other mice with signs of systemic toxicity from the viral treatment, although one mouse was noted to have a cutaneous pox lesion on its hind paw.
- We note the relatively low dose of virus in these experiments compared to doses typically given in human trials (10^6 to 10^{13} PFU). The dose recommendation for T-VEC, the only approved oncolytic virus, is up to $4x10^6$ PFU for the initial intratumoral dose, and up to $4x10^8$ PFU for all subsequent doses, the exact dose being determined by the size of the melanoma lesion(s) being treated.

Intratumoral VAXinia reduces MDA-MB-468, and inhibits MDA-MB-231, xenograft size





Source: doi.org/10.1016/j.omto.2018.04..001

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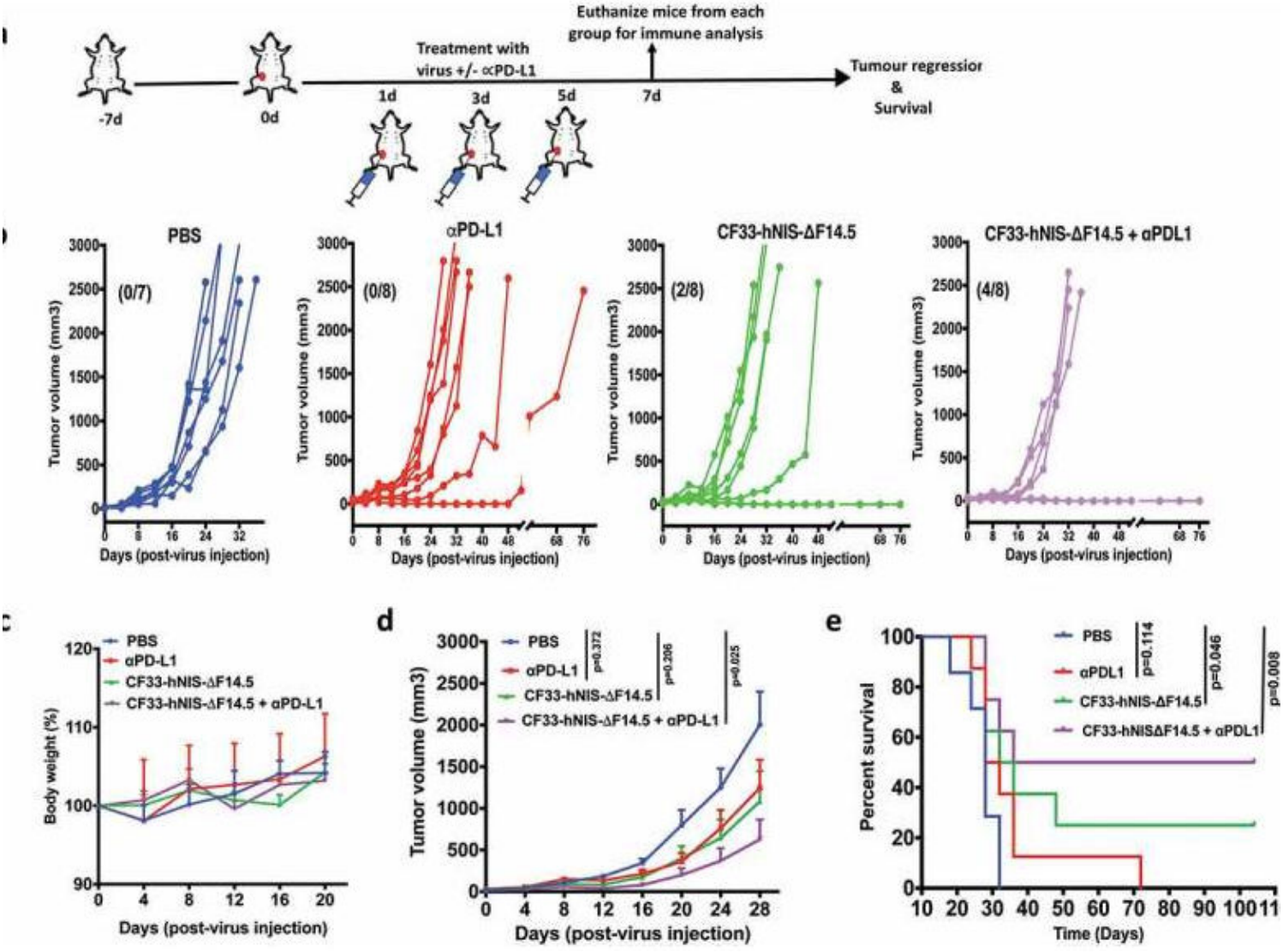
VAXinia Synergizes with Anti-PD-L1 Antibody in TNBC Animal Model

- E0771 mouse breast cancer tumor cells were injected into mice, followed by intratumoral injection of VAXinia and anti-PD-L1 mAb, injection of just one therapy, or injection of PBS control as shown in the schematic below. We note that even though the tumor volume in at least some mice increased regardless of therapy, combination therapy led to four of eight mice (50%) having no tumor growth, versus two or one of eight with monotherapy and none with PBS control (panel b). We also note the absence of overt toxicities or weight loss (panel c) regardless of treatment, and therefore are confident that combination therapy in this model system safely reduced tumor volume (p=0.025) and increased overall survival (p=0.008), by contrast to the non-statistical clinical improvement seen with either monotherapy. The authors also demonstrated a numerical increase in PD-L1 expression upon VAXinia monotherapy, thus providing further support for the combination therapy given the increase in expression of the mAb's target.

Combination of VAXinia with intratumoral injection of anti-PD-L1 results in synergistic antitumor effect



Source: OncoImmunology. 2020; 9(1): 1729300.

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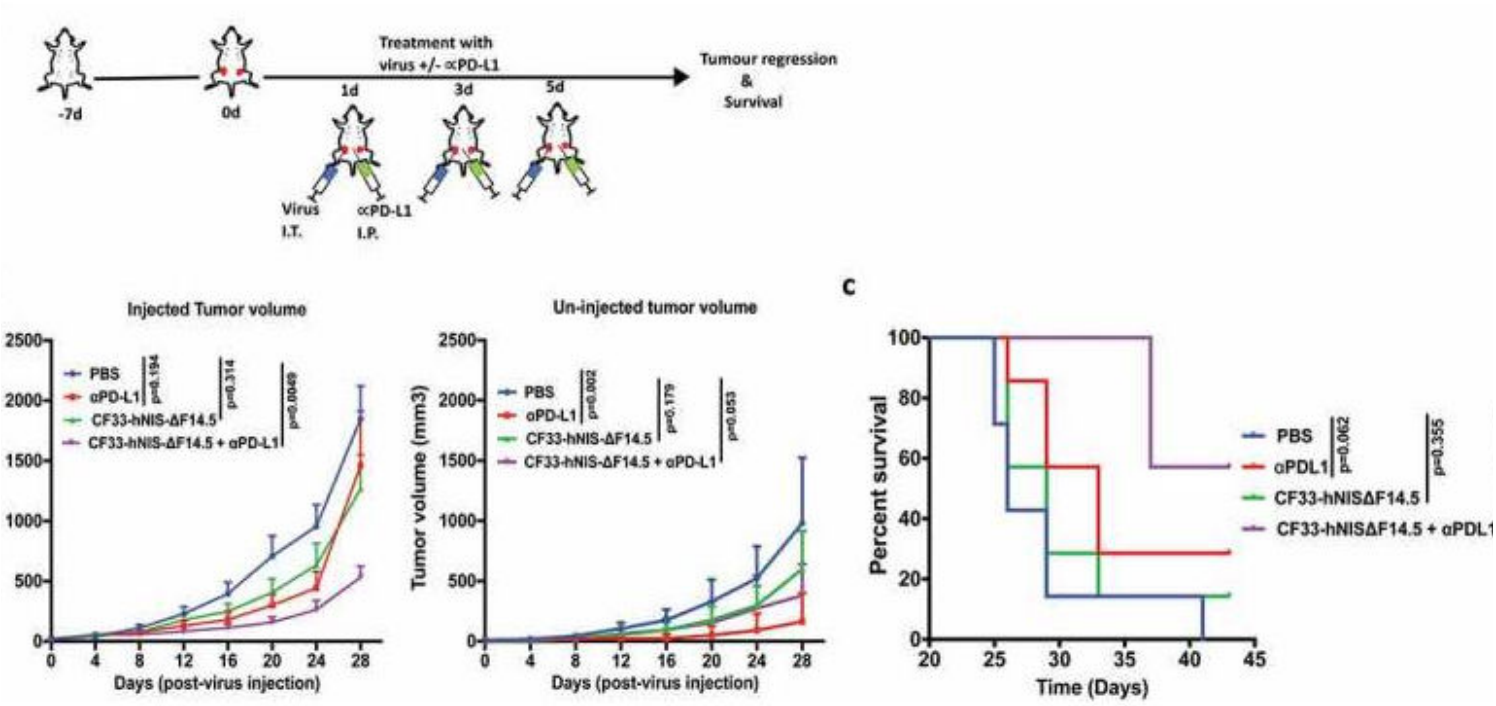
VAXinia Synergizes with Anti-PD-L1 Antibody in TNBC Animal Model

- E0771 mouse breast cancer tumor cells were injected into mice to generate two tumors per animal, followed by either intratumoral injection of VAXinia and intraperitoneal injection of anti-PD-L1 mAb, injection of just one therapy, or injection of PBS control as shown in the schematic below. We note that combination therapy statistically benefited the tumor directly receiving VAXinia more than it did the uninjected tumor (p=0.049 and p=0.053, respectively), as we would expect. We find it puzzling that the uninjected tumor did numerically worse with combination therapy than with only systemic anti-PD-L1 monotherapy, but that could be explained by greater mAb binding at the injected tumor if VAXinia in fact locally upregulates PD-L1 expression, as the authors suggest. Regardless of tumor volume outcome, combination therapy outperformed all other groups with respect to survival, with a statistical benefit seen versus PBS (p=0.002).

Intratumoral VAXinia plus intraperitoneal anti-PD-L1 delays tumor growth and increases survival of mice



Source: OncoImmunology. 2020; 9(1): 1729300.

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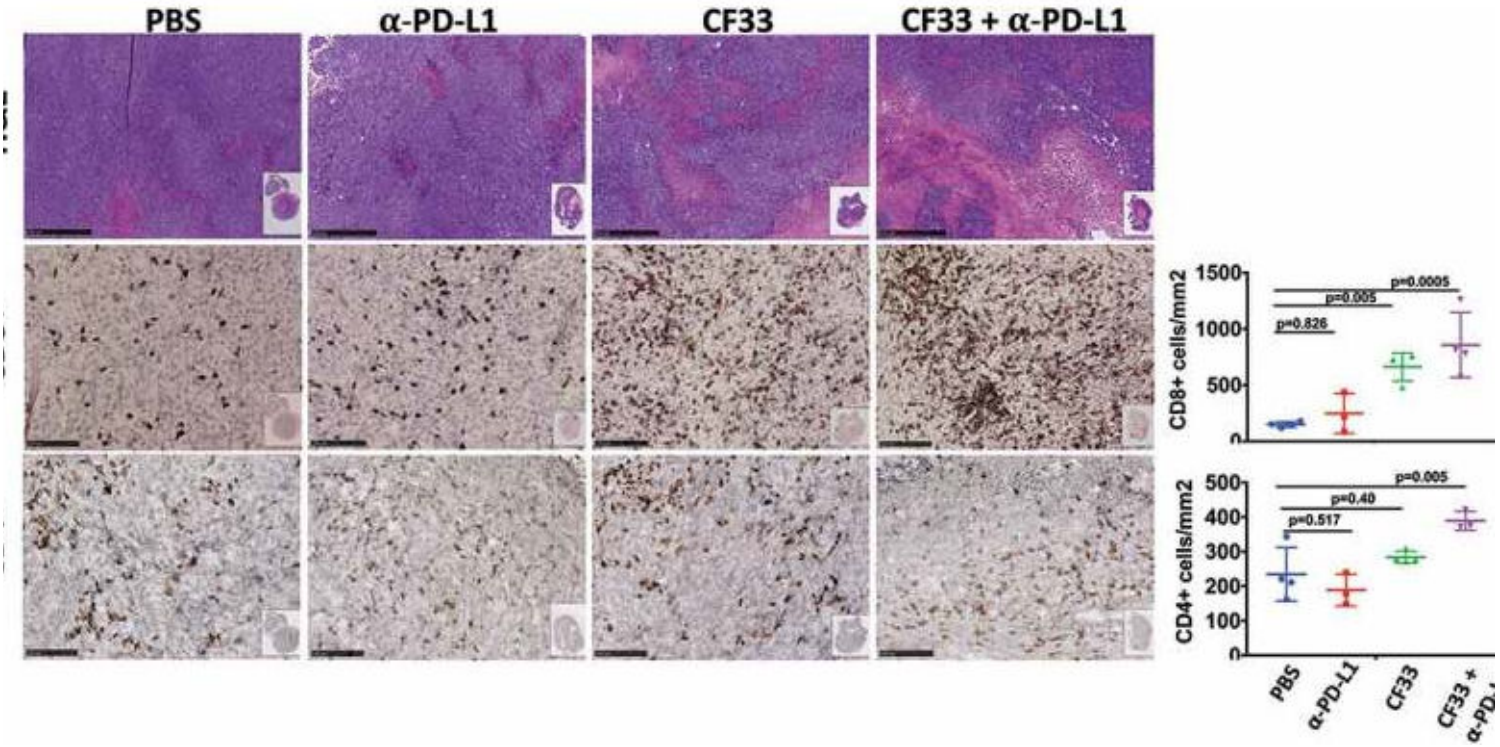
VAXinia Favorably Alters Tumor Microenvironment in TNBC Animal Model

- Tumor sections were stained with H&E to visualize tumor morphology and immunohistochemical analyses were performed to visualize CD4+ or CD8 + T cells. We note that there was significant CD8+ T cell infiltration in tumors treated with VAXinia alone or in combination with anti-PD-L1 mAb (p=0.005 and p=0.0005, respectively), versus PBS control, but not with anti-PD-L1 monotherapy versus PBS control (p=0.826), and that only combination therapy produced a significant increase in CD4+ T cell infiltration (p=0.005). We view these results as evidence that VAXinia is immuno-stimulatory and likely to sensitize tumors to checkpoint inhibition.

Favorable modulation of tumor immune microenvironment by VAXinia



Source: OncoImmunology. 2020; 9(1): 1729300.

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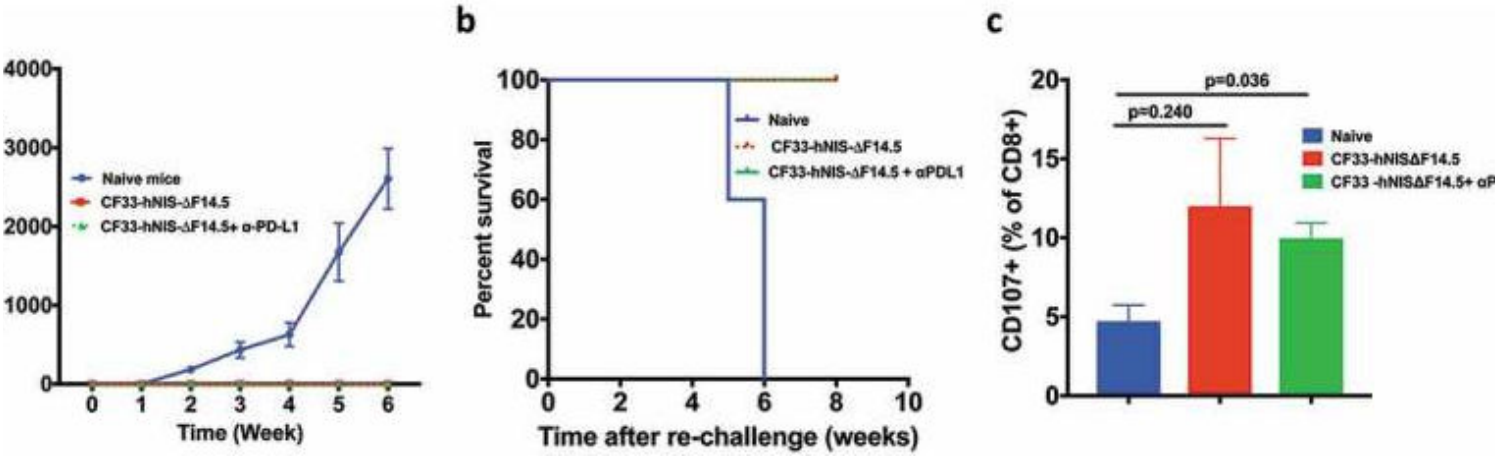
VAXinia Drives Development of Tumor Specific Immunity in TNBC Animal Model

- It is optimal for immunotherapy with an antigen to induce long-term immunity, thus providing long-term protection against the cause of disease and obviating the need for additional immunotherapy. In this TNBC model, tumor re-challenge experiments demonstrated that VAXinia monotherapy or VAXinia/anti-PD-L1 mAb combination therapy induced antitumor immunity. Mice that experienced complete tumor regression in response to treatment and remained tumor free for 30 days were re-injected with the same E0771 tumor cells. Age-matched naïve mice were used as control and all of these mice had palpable tumors two weeks after injection of tumor cells and by six weeks they all had to be euthanized due to tumor burden. By contrast, mice that previously experienced complete tumor regression upon therapy did not develop tumors upon re-challenge and survived. To specifically demonstrate E0771 tumor-specific immunity, splenocytes collected at the end of experiments were re-stimulated with E0771 cells and levels of CD107+ CD8 T cells were measured, showing that a higher percentage of CD8+ T cells were also CD107+ in the tumor immune mice than in the naïve mice.

Mice treated with VAXinia alone or in combination develop tumor-specific immunity



Source: OncoImmunology. 2020; 9(1): 1729300.

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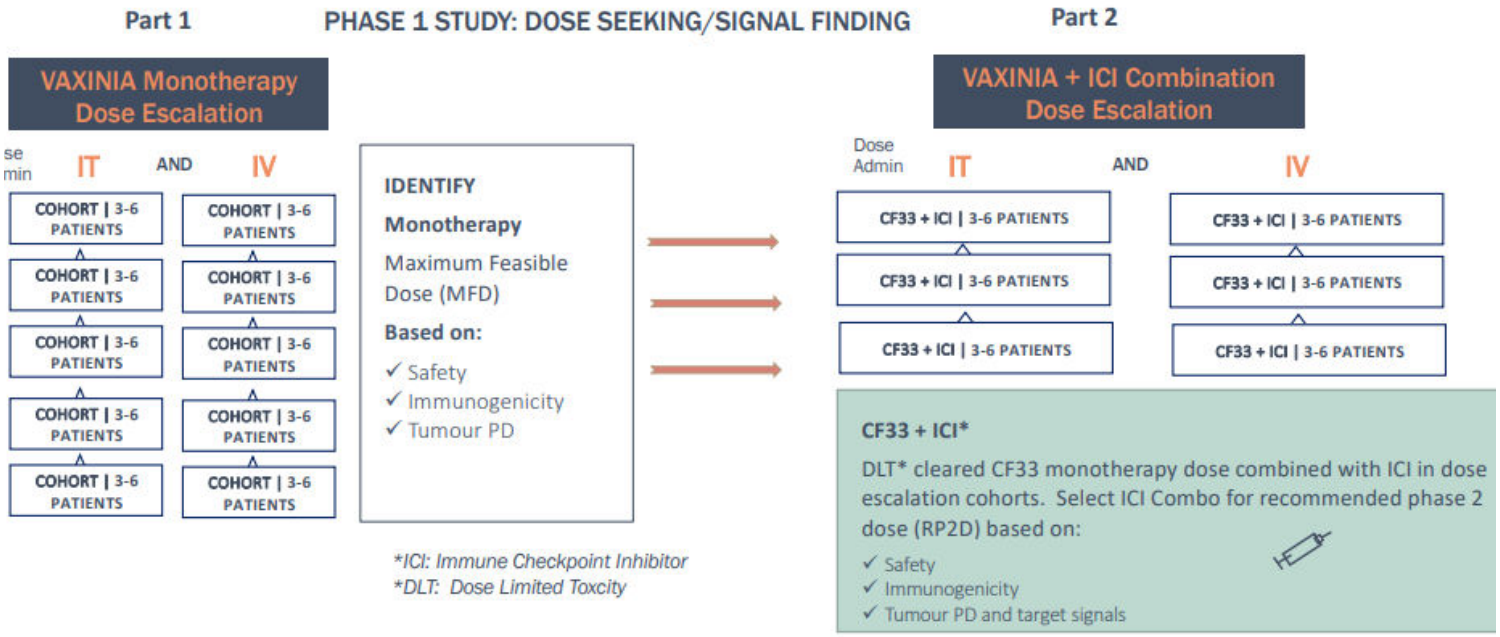
Initial Clinical Trial for VAXinia

- The initial Phase 1 trial for VAXinia will be the MAST (mixed advanced solid tumor) trial, which will evaluate intratumoral and intravenous administration of VAXinia monotherapy (Part 1), followed by combination therapy with approved checkpoint inhibitors. Intratumoral injection will be used for more easily accessible lesions such as advanced or metastatic melanoma, TNBC, and head and neck squamous cell carcinoma, and intravenous injection will be used for bladder cancer, NSCLC, colorectal cancer, gastroesophageal adenocarcinoma, renal cell carcinoma, and primary hepatocellular cancer, given that all eligible tumor types must be approved indications for checkpoint inhibitors. Six cycles of VAXinia will be given at three-week intervals, at doses likely ranging from 10^5 to 10^9 PFU (two doses given on cycle one only, one dose per cycle thereafter). Safety is the primary objective, but ORR, PFS, PFS6, and OS will also be evaluated, with determination of the RP2D as the ultimate objective. Viral titers within and outside the tumors will also be evaluated. We expect the trial to enroll somewhere between 60 and 120 patients and to be conducted in Australia and the U.S. We project the first patient to be dosed in calendar 1H21, and for clinical efficacy results to be available in calendar 2H22 (intratumoral and intravenous monotherapy maximum feasible dose) and 2H23 (intratumoral and intravenous combination therapy maximum feasible dose).

VAXinia Phase 1 MAST (Mixed Advanced Solid Tumor) Trial Schematic



Source: Imugene Ltd. corporate presentation July 2020

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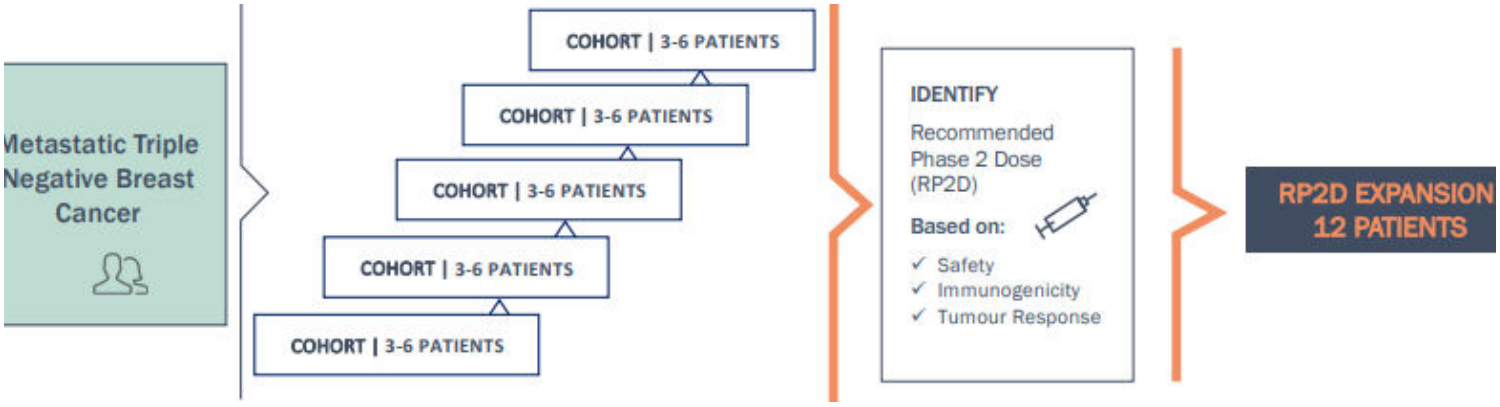
Initial Clinical Trial for CHECKvacc

- The initial Phase 1 for CHECKvacc will be a single center trial at City of Hope (Los Angeles, CA) in metastatic TNBC. The trial will evaluate intratumoral administration of CHECKvacc monotherapy (Part 1; 18 to 24 patients), followed by expansion at the RP2D (Part 2; 12 patients). Given that this trial will initially investigate CHECKvacc monotherapy rather than evaluating CHECKvacc in combination with standard of care TNBC regimens, these TNBC patients will on average be further along in the course of their disease than the TNBC patients selected for the VAXinia trial. Despite the trial schematic below, Imugene is still uncertain if the RP2D expansion phase will only be monotherapy or if it will include combination therapy with a checkpoint inhibitor. Such combination therapy would amount to a near term boost of antibody from the checkpoint inhibitor, followed by endogenous checkpoint inhibitor production due to CHECKvacc.
- We note than metastatic TNBC patients have about an eight to 13 month survival and that few treatments exist. However, given that these tumors express PD-L1 (atezolizumab therapy yields 24% ORR and 6% ORR in first-line and second-line patients, respectively (7)), we view CHECKvacc as a viable approach to this disease setting. We also note that there is the potential for CHECKvacc to be approved on a single well-designed, randomized Phase 2 trial. We estimate the Phase 1 CHECKvacc trial to dose its first patient in early calendar 2021 and generate efficacy results in calendar 2H22 (intratumoral monotherapy dose escalation determining the maximum feasible dose).

CHECKvacc Phase 1 TNBC Trial Schematic



Source: Imugene Ltd. corporate presentation July 2020

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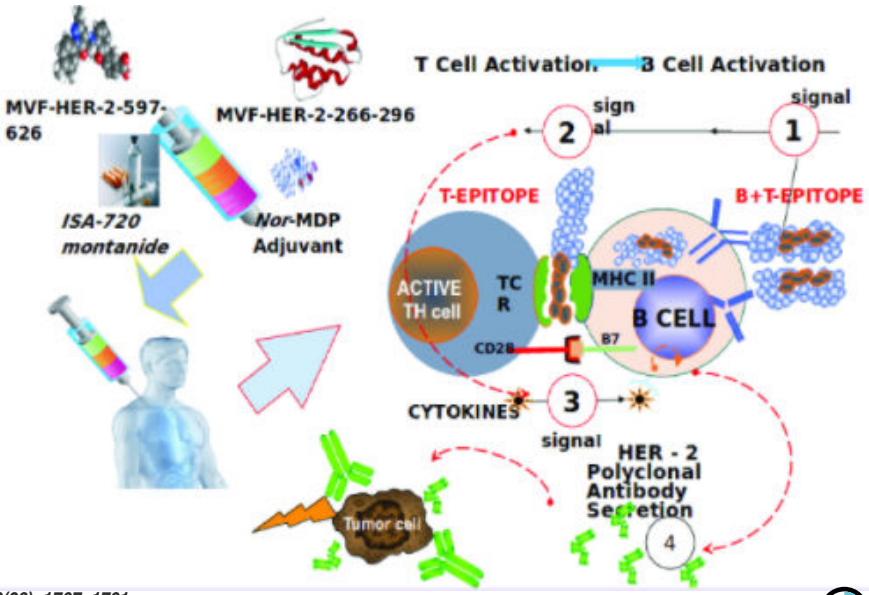
B Cell Immunotherapy Rationale

- We believe that active immunization with B cell immunotherapy has the potential to offer patients a safer, lower cost, more conveniently dosed, and potentially more effective treatment modality than the passive immunity gained from infusion of specific mAbs against disease antigens. While blockbuster anti-PD-1 checkpoint inhibitor mAbs such as nivolumab and pembrolizumab are not as broadly toxic as older classes of chemotherapy drugs, they still can create serious problems for patients such as immune-mediated pneumonitis: immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis and renal dysfunction, immune-mediated skin adverse reactions, immune-mediated encephalitis, infusion-related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity. We believe that eliciting production of polyclonal antibodies that are 100% self can circumvent certain toxicities observed after intravenous infusion of hundreds of milligrams of a given mAb. Large amounts of mAb could also stimulate production of anti-drug antibodies, which would directly negate the benefits of the therapy. The requirement to produce relatively large quantities of mAb, rather than elicit polyclonal antibodies, also leads to these therapies costing substantially more than $100,000 per year, with the cost quickly escalating further with combination therapy requiring two checkpoint inhibitors. There is also a relative inconvenience factor for mAbs, given their requirement for relatively long and frequent (typically every week to three weeks) infusions, by contrast to rapid injection of a vaccine and the likelihood that less frequent administration would be required, with therapy potentially able to end due to immunologic memory. We believe that if a tumor can respond to passive immunity directed against a single epitope, then it should also respond to active immunity against several epitopes. Checkpoint inhibitor therapy, despite these disadvantages, has quickly become a multibillion dollar business annually, given the potent and durable efficacy achieved in a minority (20-30%) of patients, in addition to the broad utility of a class of cancer drugs that is relatively indication agnostic. Patients resistant to mAb monotherapy and those that respond but relapse due to the complexity of resistance mechanisms leave a substantial unmet medical need that requires attention. We believe that B cell immunotherapy, given its similar goal of using antibodies to defeat cancer, has an even greater market potential should its potential competitive advantages to mAbs hold up in clinical trials, but we acknowledge that these two classes of therapy may ultimately be best given in combination, with the ultimate goal of neither requiring chronic administration.

Mechanism of a representative B cell active immunotherapy



Source: Future Oncol. 2020 Aug; 16(23): 1767–1791.

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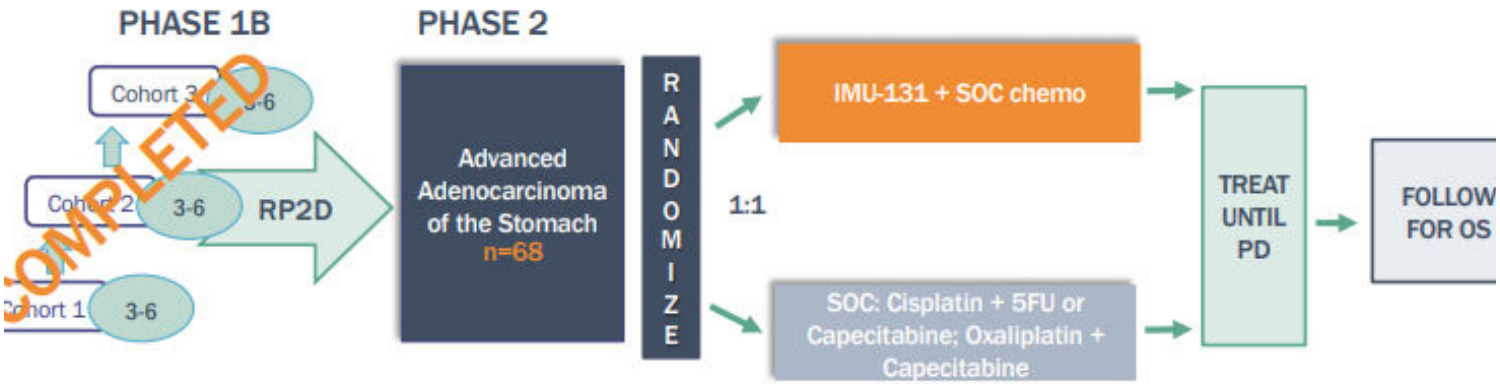
Description of HER-Vaxx and its Phase 1b/2 Trial

- HER2/neu is overexpressed in about 15% to 25% of gastric cancers and associated with poor prognosis. Gastric cancer has the fifth highest incidence and the seventh highest prevalence among all cancers worldwide (1,8). There were an estimated 783,000 gastric cancer deaths worldwide in 2018, with the disease accounting for almost 6% of all newly diagnosed cancers and being most common among older males throughout Asia (8). The cumulative risk of developing gastric cancer from birth to age 74 is 1.87% in males and 0.79% in females worldwide (8). HER-Vaxx is a single peptide having three unique HER2/neu sequences that is injected into cancer patients in order to generate polyclonal antibodies against this cancer antigen. The antibodies elicited by this antigen bind three separate extracellular regions of the HER2 receptor, including the dimerization loop, thus preventing dimerization, which in turn inhibits the intracellular signaling that promotes uncontrolled cell growth. Preclinical studies have shown that these antibodies collectively block HER2 signaling pathways better than single agent trastuzumab. An initial formulation of HER-Vaxx (three separate antigens rather than a single fusion peptide) demonstrated safety and immunogenicity in a Phase 1a trial, but shelf stability of that version of the immunotherapy was not optimal and therefore the three peptides (called P4, P6, and P7) were combined in a specific order, resulting in a single 49 amino acid long fusion peptide (called P467). Single peptide HER-Vaxx was shown to exhibit improved stability and immunogenicity over the earlier version, producing a stronger and more rapid polyclonal antibody response, in addition to being more efficient to manufacture.
- The optimized version of HER-Vaxx (10µg, 30µg, or 50µg; all patients to be dosed on days zero, 14, and 35) has completed Phase 1b evaluation in combination with a dual chemotherapy regimen (cisplatin combined with either 5-FU or capecitabine) in 14 patients (from Asia and Eastern Europe) with stage IIIb/IV HER2/neu overexpressing gastric or gastroesophageal junction (GEJ) adenocarcinoma (collectively referred to as advanced gastric cancer). An open-label, randomized, controlled Phase 2 trial is currently recruiting an expected 68 stage IIIb/IV patients from Eastern Europe and Asia and is proceeding with the 50µg HER-Vaxx dose (a RP2D selected given the potency and highly favorable safety profile) in combination with either cisplatin combined with 5-FU or capecitabine, or oxaliplatin combined with capecitabine, versus a chemotherapy only control group. Phase 1 patients were HER2+++, HER2++/FISH+, or HER2++/FISH-, but Phase 2 patients must be advanced or metastatic and either HER-2+++, or HER2++ and FISH/CISH+. The Phase 1b primary endpoints were safety and tolerability through day 56, identification of a RP2D based on safety/tolerability and immunogenicity data (IgG titers), and clinical efficacy based on OS. Main secondary endpoints included PFS, TTP, DCR, ORR, response duration, among others. The Phase 2 primary endpoint is OS, with key secondary endpoints being PFS, safety/tolerability, and immune response.

HER-Vaxx Phase 1b/2 Trial Schematic



Source: Imugene Ltd. corporate presentation July 2020

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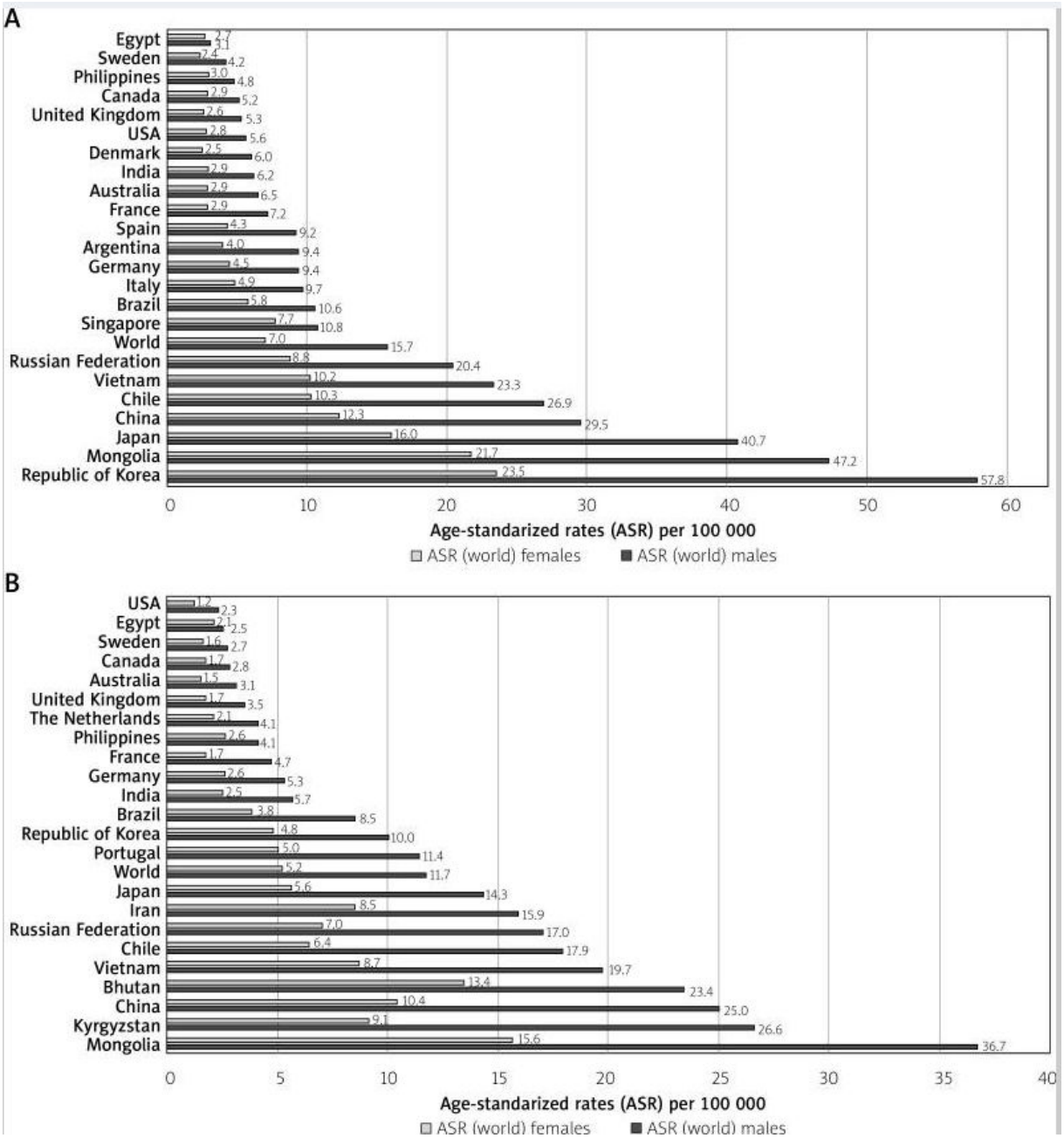
Gastric Cancer Incidence and Mortality Rates in Selected Countries

- This histogram below shows the estimated 2018 incidence (panel A) and mortality (panel B) rates for gastric cancer. In East Asia, the average incidence of gastric cancer is 32.1 per 100,000 among males and 13.2 among females, whereas in North America, the incidence drops to 5.6 per 100,000, a differential influenced largely by preventable risk-increasing behavior, such as diet and smoking, and *Helicobacter pylori* infection (8).

Estimated 2018 gastric cancer incidence rates (A) and mortality rates (B) per country as indicated



Source: https://gco.iarc.fr/today

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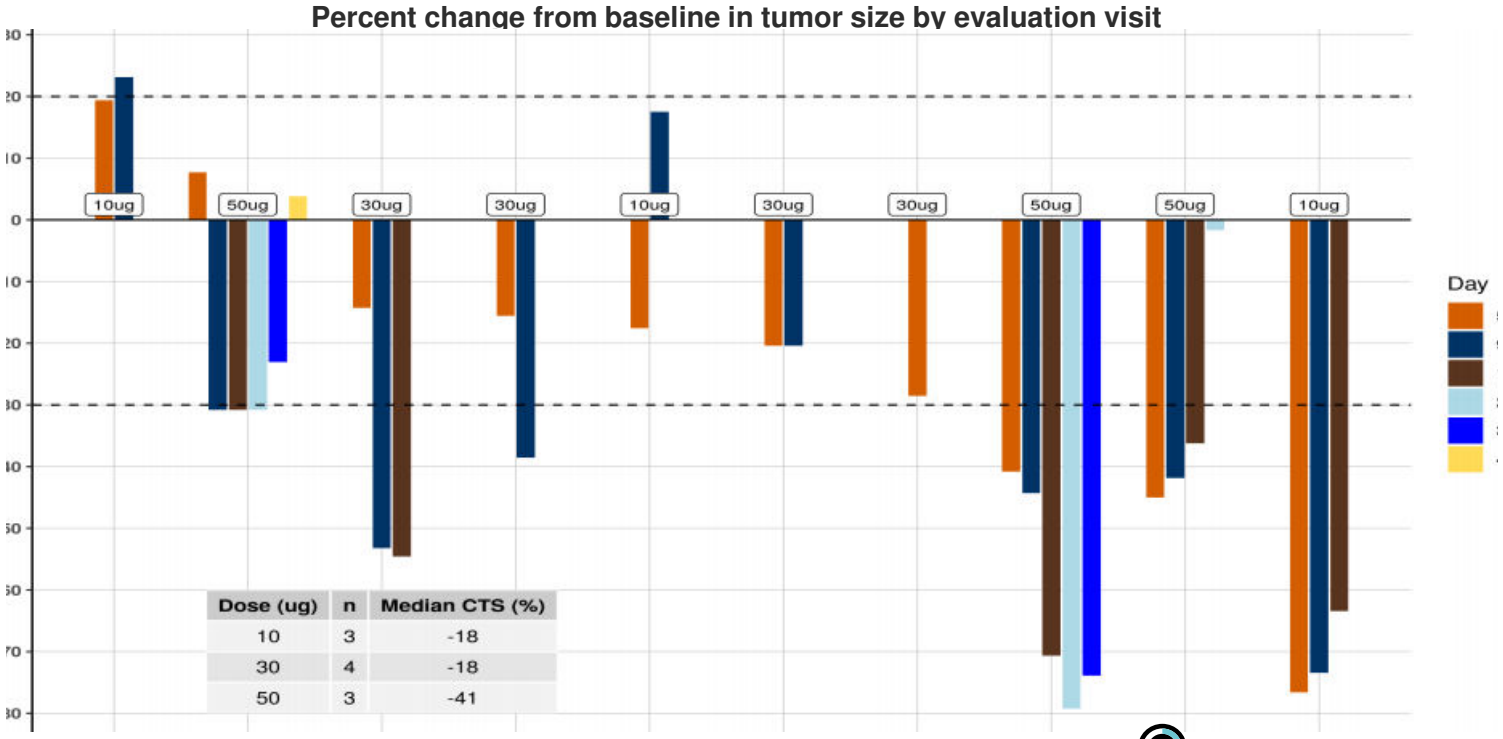
HER-Vaxx Phase 1b Trial – Clinical Results

- The response graph below (from ESMO Asia in 4Q19) describes results from 10 advanced gastric cancer patients out of a total of 14 that received all three doses and were evaluable for response at day 56 and later. All patients had increased antibody responses and generally promising preliminary immune responses to HER-Vaxx. There were no safety issues related to HER-Vaxx, not even the significant local injection site reactions often observed when injecting foreign proteins. There were no toxicity issues and thus no determination of any dose-limiting toxicities for HER-Vaxx, as well as no vaccine-related serious adverse events or events leading to HER-Vaxx discontinuation. There were 207 treat-emergent adverse events (TEAEs) reported by the 14 patients with the majority of events being Grade 1 to 3 in severity and with almost all of them deemed unrelated to HER-Vaxx. Two Grade 1 vaccination site reactions (pruritus and erythema) were reported by one 50µg patient and deemed as possibly related to HER-Vaxx, one 30µg patient reported two TEAEs (hypoalbuminemia and hyponatremia) that were assessed as related to HER-Vaxx, and another 30µg patient reported two TEAEs (decreased appetite and weight decreased) that were deemed possibly related to HER-Vaxx. Furthermore, the TEAEs observed were in line with, and expected for, the chemotherapy each patient received.
- The figure below quantifies objective responses as far out as 434 days for one patient on 50µg HER-Vaxx (the RP2D), and in total for this still preliminary data evaluation there was one CR (10µg), five PR (50µg, 50µg, 50µg, 30µg, and 30µg), four SD (30µg, 30µg, 10µg, and 10µg), and one PD (30µg). Median change in tumor size for each dose is also shown below, with the 50µg dose clearly numerically favored. The one evaluable patient (30µg) not shown in the figure had PD, and the three patients (30µg, 50µg, 50µg) not described at all in the poster received only the first two of three HER-Vaxx doses before their disease progressed. The two 50µg patients of the three not described below dropped out of the trial early due either to incorrect enrollment or a non-vaccine related serious adverse event. The 50µg dose produced the most consistent specific antibodies to P467 and HER-2, compared to the 10µg and 30µg doses, and all three evaluable patients taking that dose had an objective response as per RECIST criteria.



Source: Imugene ESMO Asia 2019 poster

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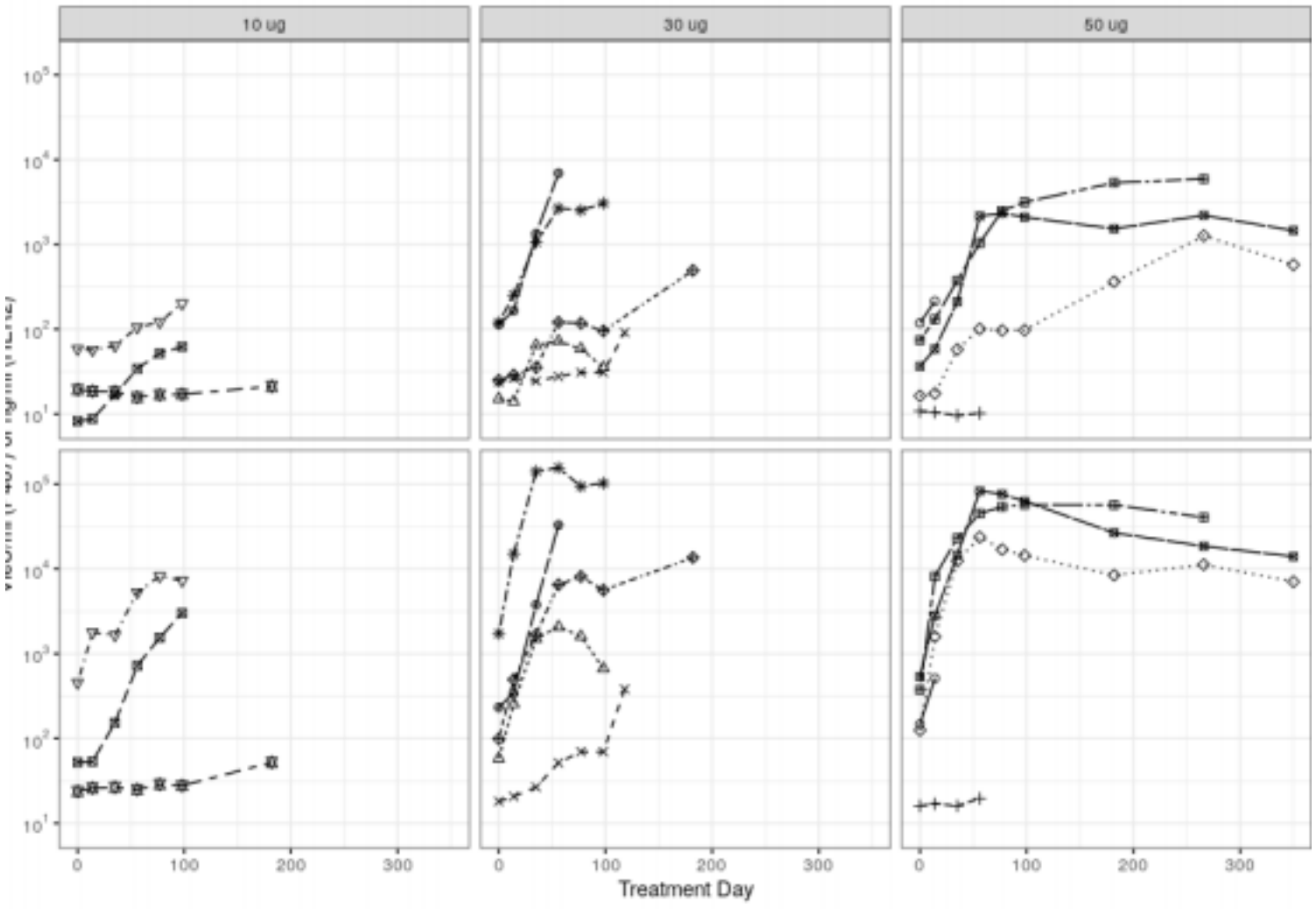
HER-Vaxx Phase 1b Trial – Immunological Results

- Patients were assessed for the amount of antibodies that cross-reacted with the HER2/neu extracellular domain and with the injected P467 peptide. The figure below from Imugene's ESMO Asia 2019 poster shows that for both antibody specificities, their abundance was dose and time dependent. We note the encouraging disparity between the immunotherapy's potent B cell immunogenicity and the complete absence of significant injection site reactions (only one patient experienced both a Grade 1 pruritus and a Grade 1 erythema that were assessed as possibly related to HER-Vaxx). We also note that there was a correlation between tumor reduction and level of anti-HER2 antibodies for eight of the 11 patients evaluable for efficacy; in five of the 11 patients, tumor reduction was associated with high HER2-specific IgG levels, which also were capable of inhibiting HER2-phosphorylation. We note the marked increases in HER2-specific antibodies at the 50µg dose.

Polyclonal antibody levels against HER2 andP467



Source: Imugene ESMO Asia 2019 poster

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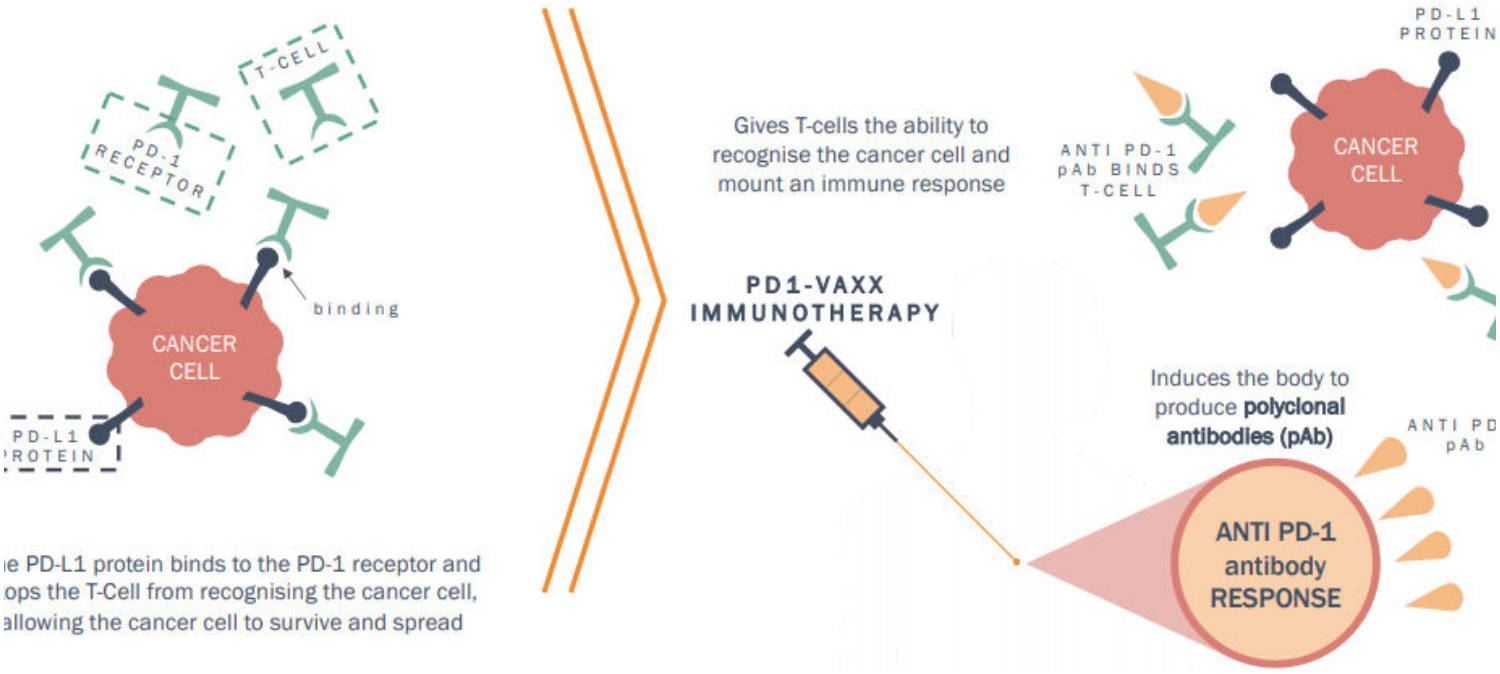
PD1-Vaxx – Background and Rationale

- Therapy with checkpoint inhibitor mAbs has shown potent clinical results in numerous tumor types, but the cost intensiveness is a potential limiting factor, given the requirement for repeated infusions. We believe that a more cost effective and safer approach could potentially be to induce active immunity by direct injection of checkpoint antigen such as PD-1 to drive a longer lasting and potentially safer and more potent polyclonal antibody response.
- PD1-Vaxx is an injected peptide antigen derived from extracellular amino acids 92-110 of PD-1 linked to a particularly immunogenic peptide (amino acids 288-302 of the measles virus fusion protein). It works by eliciting a B cell response that results in the production of polyclonal antibodies against the PD-1 receptor located on the surface of T cells. These antibodies then bind PD-1, thereby preventing a T cell from interacting with a cancer cell's PD-L1 ligand, which ultimately prevents the cancer cell from inactivating the T cell. PD1-Vaxx is essentially a vaccination to induce an endogenous immune response having at least the efficacy of blockbuster checkpoint inhibitor mAbs such as nivolumab and pembrolizumab, but with a more favorable safety profile and potentially requiring far fewer administrations.

PD1-Vaxx mechanism of action



Source: Imugene Ltd. corporate presentation July 2020

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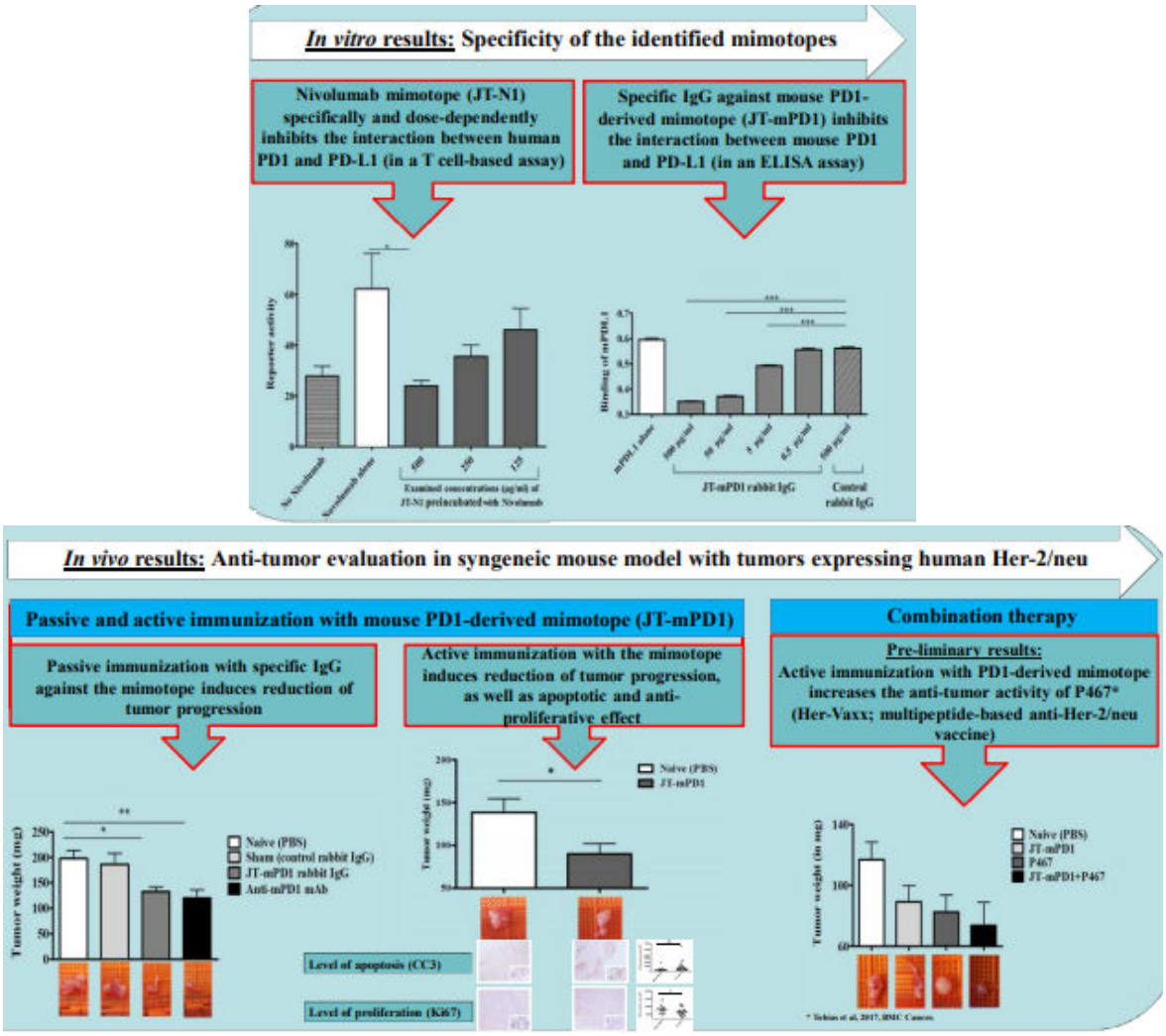
PD1-Vaxx – Preclinical Results

- Preclinical investigation with PD1-Vaxx showed it to outperform the industry-standard mouse anti-PD-1 mAb in a mouse model of HER2-positive colorectal cancer. The figures below, from an ESMO 2019 presentation, show that by generating overlapping peptides spanning the PD-1 extracellular domain, a T cell-based cellular assay, and a syngeneic mouse model with tumor expressing HER2/neu, mimotopes of nivolumab and of anti-mouse PD-1 mAb could be generated and evaluated. A mimotope is a peptide that mimics the structure of an epitope and thus it elicits an antibody response similar to the one elicited by the natural epitope. Furthermore, active immunization with a PD-1-derived mimotope induced polyclonal antibodies demonstrated antitumor activity that was comparable to passive immunization with the corresponding checkpoint inhibitor. Active immunization with a PD-1-derived mimotope induced antitumor activity *in vivo,* and active immunization with a PD-1-derived mimotope along with HER-Vaxx produced a stronger antitumor effect than injection of either component alone. These results suggest that active immunization with immune checkpoint mimotopes is feasible as monotherapy, combination active immunization therapy, or in combination with passive immunization with a checkpoint inhibitor mAb.

***In vitro* and *in vivo* results with mouse polyclonal anti-PD-1 antibodies and active PD-1 antigen immunization**



Source: Imugene ESMO 2019 poster, Tobias et al.

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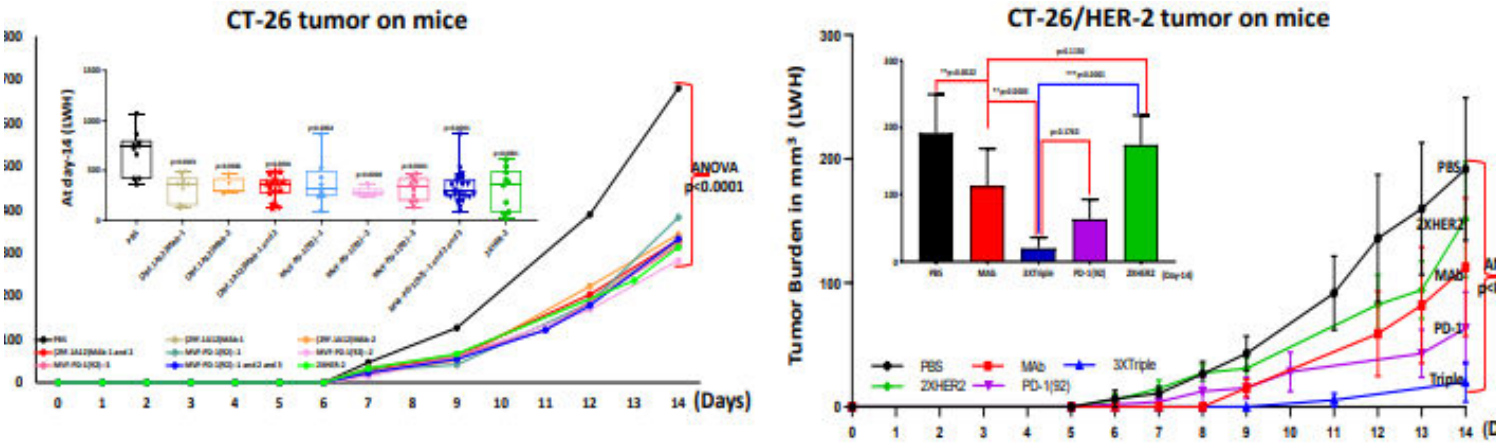
PD1-Vaxx – Additional Preclinical Results

- The figure below shows preclinical results demonstrating how vaccinations with PD1-Vaxx, vaccinations with HER-Vaxx, or a combination of both, were able to reduce tumor burden in mice in a tumor challenge study. Mice were immunized with PD-1 peptide, twice with HER2 peptides, or with a combination of both treatments at three-week intervals and challenged with tumor 10 days after the third vaccination. PBS buffer served as the negative control and anti-mouse PD-1 mAb (mAb 29F.1A12; given twice weekly) served as a positive control. Tumor volume was measured for 14 days post challenge and each treatment group was comprised of five to 10 mice.
- The ESMO 2019 presentation demonstrated strong HER2 and PD-1 antibody responses in mice, with significant tumor reduction after treatment with PD1-Vaxx and positive control mAb 29F.1A12 in the CT-26 Balb/c mouse model, versus PBS treated negative control mice.
- Triple vaccination with antigens against PD-1 and HER2 was more effective in the CT26/HER2 carcinoma cell line in syngeneic Balb/c mice, showing better antitumor activity compared to the positive control anti-mouse PD-1 mAb. Anti-PD-1 vaccination also showed no toxicity or autoimmunity in mice, rabbits, and canines.
- Immunotherapy with a combination of antigens derived from HER2 and PD-1 could be a safer, lower cost, and potentially more effective treatment alternative to the numerous currently approved checkpoint inhibitors.

Antitumor activity of PD-1 and HER2 combo in CT26 and CT26-HER2 syngeneic tumor models



Source: Imugene ESMO 2019 poster, Kaumaya, et al., abstract 1218P

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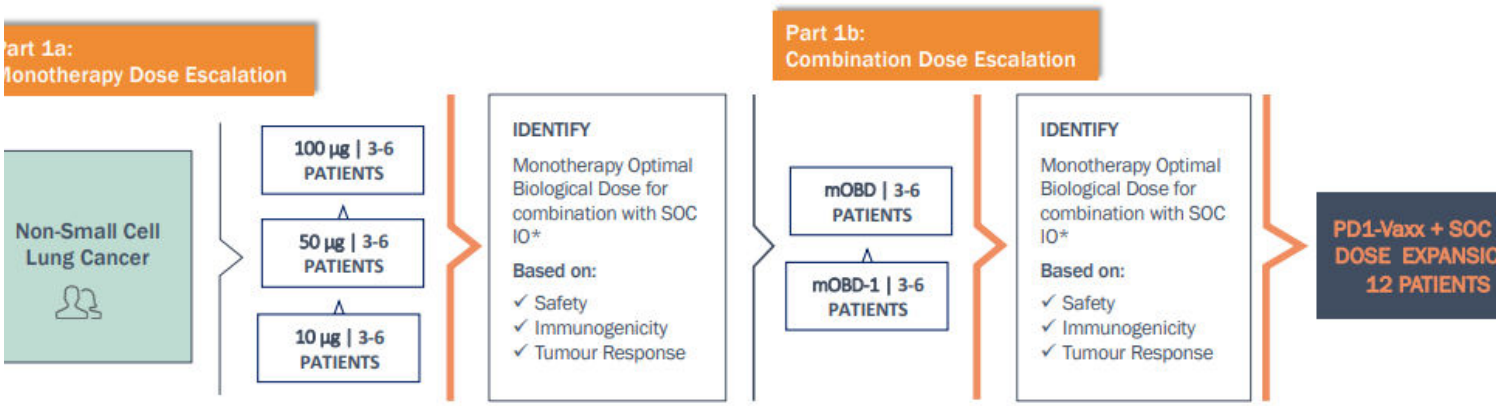
PD1-Vaxx – Phase 1 Trial Design

- The PD1-Vaxx Phase 1 trial is comprised of a monotherapy dose escalation portion followed by a combination therapy (with standard of care checkpoint inhibitor therapy) dose escalation portion (Parts1a and 1b), all of which is being conducted in 15 to 30 patients with NSCLC expressing PD-L1. Key objectives are safety/tolerability, immunogenicity, and determining the optimal biological dose of PD1-Vaxx for use in Part 2, which will be a 12-patient combination therapy dose expansion cohort conducted with a more intense scrutiny of efficacy (ORR, PFS, response duration, and OS). Initial PD1-Vaxx monotherapy doses will be 10µg, 50µg, and 100µg, with vaccinations given on days one, 15, 29, 64, and every 63 days thereafter until disease progression. Tumors are evaluated as per RECIST criteria on day 43 and every 42 days thereafter until disease progression. The trial is being conducted at six to 10 sites in Australia and the U.S., with patient recruitment already underway in Australia and site activation and patient recruitment in the U.S. expected to start late in calendar 2020. No patients have actually yet been dosed, but we estimate the first patients will be dosed in Australia in calendar 2020, and in early calendar 2021 in the U.S., with results to be available in calendar 2H21 (monotherapy) and 1H22 (combination therapy).

PD1-Vaxx Phase 1 Trial Design



Source: Imugene Ltd. corporate presentation July 2020

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Potentially Lucrative Pre-Commercial Outcome

- We note below several oncolytic virus transactions that reflect the potential value creation that Imugene and its investors could experience well before late stage clinical success. With so many checkpoint inhibitors on the market and their sponsors looking for a way to differentiate them, a promising immune-activating oncolytic virus could be just the acquisition.

  - In 1Q11, Amgen (AMGN-NC) acquired Biovex in 2011, when currently approved T-VEC was in Phase 3, for $425 million upfront and $575 million in potential milestone payments.
  - In 4Q16, Bristol-Myers Squibb (BMY-NC) partnered with PsiOxus Therapeutics (private) for a Phase 1 adenovirus for $50 million upfront, up to $886 million in potential milestone payments, and potential royalties.
  - In 4Q17, Abbvie (ABBV-NC) partnered with Turnstone Biologics (private) for Phase 1/2 rhabdovirus isolates (economics undisclosed).
  - In 1Q18, Merck & Co. (MRK-NC) acquired Viralytics for a Coxsackie virus therapy in Phase 1b for $394 million.
  - In 2Q18, Janssen (JNJ-NC) acquired Benevir for its undisclosed preclinical oncolytic viral asset for $140 million upfront and up to $900 million in potential milestone payments.
  - In 3Q18, Boehringer Ingelheim (private) acquired ViraTherapeutics for its preclinical vesicular stomatitis virus program for $245 million.
  - In 3Q18, Merck KGaA (MKKGY-NC) partnered with Vyriad for a Phase 1/2 measles virus (economics undisclosed).
  - In 4Q19, Takeda (TAK-NC) partnered with Turnstone Biologics for preclinical Rival-01, a vesicular stomatitis virus for $120 million upfront, up to $900 million in potential milestone payments, and potential royalties.

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Competition

- **CF33 platform**
  - In general, oncolytic viruses show strong promise in turning immunologically cold tumors hot, and therefore can potentially increase the response rate observed thus far with approved checkpoint inhibitors. Checkpoint inhibitors already cause highly durable responses, but only in a fraction of treated patients. Oncolytic viruses are under clinical development at several companies, and one (T-VEC) was approved in 2015 in the U.S. and E.U. for unresectable melanoma.
  - T-VEC is a genetically modified HSV (two viral genes removed, gene for immuno-stimulatory cytokine GM-CSF added) from Amgen, and is the first successful demonstration that an intratumoral oncolytic virus can make immunologically cold tumors amenable to PD-1 inhibition.
  - Replimune Group (REPL-Buy) is developing a clinical stage combination therapy with its proprietary oncolytic virus RP1 and an approved checkpoint inhibitor, currently in Phase 2 development, as well as its subsequent development of armed oncolytic viruses RP2 and RP3. RP1 contains a strain of HSV-1 that was engineered to include GM-CSF, and fusogenic protein GALV to achieve a large bystander killing effect. RP2 is RP1 plus the gene for an anti-CTLA-4 antibody, thereby adding an immune checkpoint inhibitor. RP3 is RP2 plus two additional immune activating ligands, CD40L and 4-1BBL, which stimulate innate and adoptive immune responses, and generate memory immune responses.
  - Merck and Amgen are working on T-VEC in combination with checkpoint inhibition in advanced sarcoma, with promising Phase 2 results published in 1Q20.
  - Merck is in the clinic with adenovirus and Coxsackie virus programs, both of which are being given along with checkpoint inhibitors to treat advanced melanoma, glioblastoma, and bladder cancer.
  - Turnstone Biologics is developing its oncolytic Rival-01 vaccinia virus, which is armed with genes for Flt3 ligand, anti-CTLA-4 antibody, and IL-12, comprising a multi-modal attack on cancer.
  - Genelux Corporation (private) has early clinical stage oncolytic vaccinia virus-based diagnostics and therapeutics, and is targeting ovarian cancer, other solid tumors, and AML.
  - Sillajen (private) is also developing vaccinia virus therapeutics (Pexa-Vec and JX-970) that are TK deficient to inhibit viral replication in healthy cells, and that contain the gene for GM-CSF. Pexa-Vec is being given alone and along with checkpoint inhibitors for RCC, CRC, and other solid tumors.
  - Oncolytics (ONCY-NC) is in the clinic with an unmodified reovirus (pelareorep) that it combines with checkpoint inhibitors and other agents, but we are not optimistic for its success given how long it has taken the company to generate meaningful results in its lead indication of breast cancer.
  - Boehringer Ingelheim is developing a vesicular stomatitis virus therapy in combination with checkpoint inhibitors for hepatocellular carcinoma and other solid tumors.
  - VBL Therapeutics (VBLT-Buy) is in the clinic with oncolytic virus VB-111, which is given along with either chemotherapy or a checkpoint inhibitor for ovarian cancer, glioblastoma, and colorectal cancer. VB-111 is a non-replicating adenovirus 5 that incorporates the endothelial cell-specific PPE-1-3X promoter to drive expression of a fusion protein that combines the extracellular and intramembrane domains of the TNF receptor 1 and the intracellular domain of the Fas receptor.

- **HER-Vaxx and PD1 Vaxx**
  - These two therapeutic candidates are more novel than oncolytic viruses and thus have less direct mechanistically related competition. By being comprised of the antigens to which blockbuster mAbs bind and used to elicit a polyclonal response, their competition essentially is the long list of anti-HER2 and anti-PD-1 mAbs already approved or in development. Although this competition is fierce, we note the potential advantages of safety (endogenous therapeutic antibody production), efficacy (potentially a sustained polyclonal antibody production), and economics (ease of production and likely fewer administrations required). The biggest risk to success, in our view, is failure to elicit the production of any therapeutically useful antibodies.

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Intellectual Property

- **HER-Vaxx:** HER-Vaxx intellectual property was acquired through Imugene's 100% acquisition of Biolife Science Qld Pty Ltd in 4Q13. In addition, Imugene holds various worldwide patents granted over the technology. The key patent protection for HER-Vaxx expires in 2036.
- **PD-1 and Non PD-1:** In 2Q18, Imugene signed an exclusive, worldwide license to the entire body of cancer vaccine work and intellectual property developed by Professor Pravin Kaumaya of the Ohio State University Wexner Medical Center, the Comprehensive Cancer Center - Arthur G. James Cancer Hospital, the Richard J. Solove Research Institute and Mayo Clinic. The substantial intellectual property estate licensed comprises a broad patent portfolio including six patent families comprising 16 issued patents or pending applications for compositions of matter and/or methods of use of a large range of B cell peptide and cancer vaccines comprising PD-1, HER-1, HER-2, HER-3, VEGF, IGF-1R, CD28 peptides and combinations thereof. Imugene is obligated to pay the licensor of these patents royalties of 3% of sales, where annual turnover is less than $1 billion and 4% where annual turnover is greater than $1 billion, milestone fees of up to $250,000 payable upon dosing of the first patient in each phase of a clinical trial and $1 million payable upon first commercial sale, as well as an annual license fee of $250,000 upon first commercial sale ($100,000 annually prior to first commercial sale). Imugene must also pay sublicense fees of 25% of sublicensing consideration prior to first patient dosing in a Phase 1 trial, 15% of sublicensing consideration prior to first patient dosing in a Phase 2 trial, 10% of sublicensing consideration prior to first patient dosing in a Phase 3 trial, and 8% of sublicensing consideration after first patient dosing in a Phase 3 trial. The key patent protection for PD-1-Vaxx expires in 2037.
- **CF33:** The main financial terms of acquiring CF33 include a cash payment of $97,588 and the issuance of 127,994,355 Imugene shares to City of Hope Hospital, based in Los Angeles, California, in addition to the following potential share-based milestone payments. Upon allowance of an IND by the FDA in relation to CF33, Imugene will issue 119,354,838 shares. Upon dosing of the first patient in a Phase 1 trial for CF33, Imugene will issue 134,258,064 shares. Upon meeting Phase 1 safety endpoints, excluding efficacy and dose, Imugene will issue 149,193,548 shares. Additionally, Imugene must pay City of Hope potential development milestone payments as follows: dosing of the first patient in a Phase 1 trial of CF33 ($150,000), dosing of the first patient in a Phase 2 trial of CF33 ($300,000), dosing of the first patient in a Phase 3 trial of CF33 ($1 million), receipt of marketing approval in the U.S. for CF33 ($3 million), and receipt of marketing approval in any jurisdiction other than the U.S. ($1.5 million). These developmental milestones, with the exception of "receipt of marketing approval in any jurisdiction other than the U.S." must also be achieved by certain agreed upon dates and Imugene must spend a certain minimum amount on development by certain agreed upon dates. Imugene is also responsible for making sales milestone payments (total aggregate payment of $150 million) to City of Hope upon achievement of the following milestones: net sales first totaling $125 million, net sales first totaling $250 million, net sales first totaling $500 million, and net sales first totaling $1 billion. Further, Imugene must pay a single digit royalty on any net sales, and an annual licensing fee of $50,000. The key patent protection for CF33 expires in 2037.

Source: Imugene FY2020 Annual Report

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Management and Board Member Biographies

Paul Hopper, Executive Chairman

Mr. Hopper has over 20 years of experience in the management and funding of biotechnology and healthcare public companies both as CEO and director in Australia and the U.S. Mr. Hopper's sector experience has covered a number of therapeutic areas with a particular emphasis on immunotherapy and cancer vaccines. He also has extensive capital markets experience in equity and debt raisings in Australia, Asia, Europe, and the U.S. Mr. Hopper is also currently on the board of SUDA Pharmaceuticals Ltd.

Leslie Chong, CEO and Managing Director

Ms. Chong joined the group in September 2015 from the leading oncology clinical development company, Genentech (a member of the Roche family), where she was a Senior Clinical Program Lead at the head office in San Francisco. She has over 21 years of experience in leading clinical and department development in oncology. In November 2016, Ms. Chong was promoted as Imugene's CEO and joined the board as Managing Director in March 2018. Ms. Chong is also currently on the board of the non-profit Cure Brain Cancer Foundation.

Charles Walker, Non-Executive Director

Mr. Walker has broad and successful experience across the biotechnology and life sciences industry. His experience includes significant operational and leadership positions in biotechnology firms, a strong capital markets track record from executing nearly 60 international and domestic corporate transactions, both as principal and advisor, and a detailed scientific understanding gained from a technical background in pharmacology. Mr. Walker was previously CEO and CFO of Alchemia Limited and Managing Director of Imugene.

Dr. Axel Hoos, Non-Executive Director

Dr. Axel Hoos is Senior Vice President, R&D Governance Chair, and Therapeutic Area Head for Oncology at GlaxoSmithKline. At GlaxoSmithKline he leads technical and funding decisions in R&D as well as Discovery and Development in Oncology with a focus on immuno-oncology, epigenetics, cell therapy, and synthetic lethality. Dr. Hoos also serves as Chairman of the Board of Trustees of the Sabin Vaccine Institute, a global health organization, Director on the Board of TCR2, a cell therapy company, Co-Founder and Director on the Board of Imugene, Co-Director of the Cancer Immunotherapy Consortium and Scientific Advisory Board Member of the Cancer Research Institute. Previously, Dr. Hoos was the global medical lead in immunology/oncology at Bristol-Myers Squibb, where he developed Yervoy, the first checkpoint inhibitor in immuno-oncology. For the scientific mechanism of Yervoy, the Nobel prize for Medicine was awarded to Dr. James Allison in 2018. Before Bristol-Myers Squibb, Dr. Hoos was Senior Director of Clinical Development at Agenus Bio.

Dr. Lesley Russell, Non-Executive Director

Dr. Lesley Russell is a hematologist/oncologist and has over 25 years of experience and leadership in the international pharmaceutical field as a chief medical officer. She has undertaken clinical development in a number of therapeutic areas including hematology/oncology has had multiple new drug approvals with both the FDA and EMA. Dr. Russell has extensive experience as a director of NASDAQ listed pharmaceutical companies and is a member of the Royal College of Physicians UK. Dr. Russell is also currently on the board of Enanta Pharmaceuticals (ENTA-Buy).

Source: Imugene FY2020 Annual Report

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Management and Board Member Biographies (cont.)

Dr. Jens Eckstein, Non-Executive Director

Dr. Eckstein has more than 15 years of venture capital experience in the biopharmaceutical industry and 10 years of operational experience in drug discovery and development. He is a Kauffman Fellow and a mentor for life science entrepreneurs and start-up teams in the area of innovative life science and healthcare information technology companies. Before joining Apollo Ventures, Dr. Eckstein served as president of SR One for eight years. He is also co-founder and managing director of Action Potential Venture Capital (APVC). Previously, he was a general partner at TVM Capital.

Dr. Nick Ede, Chief Technology Officer

Dr. Ede has over 25 years of peptide vaccine and drug development experience. He was formerly CEO of Adistem and 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. Rita Laeufle, Chief Medical Officer

Dr. Laeufle leads global clinical development, regulatory, and medical monitoring activities. As a board-certified surgical oncologist, Dr. Laeufle has extensive clinical development experience in immuno-oncology trials in breast and gastrointestinal cancers. Dr. Laeufle has held senior level clinical development, leadership, and senior medical positions at Hoffman-La Roche AG and Novartis Pharmaceuticals Corp., and most recently was the chief medical officer at Oncolytic Biotech. Dr. Laeufle holds M.D. and Ph.D. degrees from the Albert Ludwig University.

Dr. Anthony Good, VP Clinical Research

Dr. Good has over 20 years of global clinical development experience. He was integral to the development of significant new medicines including Viagra, Revatio, Lipitor, and Somavert. He formerly held roles with Pfizer Global Research and Development, and with Covance Clinical Services.

Bonnie Nixon, Project Manager

Ms. Nixon has over eight years of oncology clinical trials experience across Phase 1 – 4 trials. She was formerly a Study Manager for North America at Genentech, Inc. in San Francisco and brings further experience from various prior roles at Roche Australia.

Source: Imugene FY2020 Annual Report and https://www.imugene.com/management-team

ROTH Capital Partners

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VALUATION

Our 12-month price target of AUD0.13 is based on a DCF analysis using a 35% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of our projected FY2031 operating income of AUD1.6 billion. We arrive at this valuation by projecting future revenue from CHECKvacc in TNBC, HER-Vaxx in advanced HER2+ gastric cancer, and PD1-Vaxx in NSCLC, products that we project will generate about AUD1.7 billion in global royalty revenue to Imugene in FY2031. Commercial success outside of these financially modeled programs would serve as potential upside to our valuation. Factors that could impede shares of Imugene from achieving our price target include any of its three modeled immuno-oncology products failing to succeed clinically. Also, the FDA and foreign regulatory authorities could fail to approve Imugene's products even if their respective pivotal clinical trials succeed, in the event the agency views the results as not clinically meaningful. Loss of key management personnel could also impede achieving our Imugene price target, as could the significant delay of clinical progress from, for example, lasting COVID-19 headwinds.

RISKS

- **Clinical risk.** Imugene's clinical staged products could fail to deliver statistically significant results in late-stage clinical trials, substantially reducing the value of Imugene's product candidates and therefore our target price.
- **Regulatory risk.** Even if successful in the clinic, Imugene's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce Imugene's value and therefore our target price.
- **Financing risk.** Imugene will need additional capital to fund its operations, and such financing may not occur or it could be substantially dilutive to existing investors.
- **Competitive risk.** For any future approved Imugene products, they may not be well adopted in a competitive marketplace, which would adversely affect Imugene's value and therefore our target price.
- **High stock price volatility.** This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

Imugene Limited is a clinical stage immuno-oncology company developing a range of novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumors. The company's unique platform technologies seek to harness the body's immune system against tumors, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Imugene's product pipeline includes multiple immunotherapy B cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies. Imugene is supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies, and their prior work has led to many therapies approved for sale and marketing for global markets. Imugene's vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced to deliver on its commercial and clinical milestones.

Imugene Limited
HER-Vaxx revenue

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U.S. HER2+ advanced gastric cancer market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of HER2+ advanced gastric cancer	5,698	5,738	5,779	5,819	5,860	5,901	5,942
Percent market penetration	2.0%	6.0%	12.0%	18.0%	21.6%	23.8%	24.0%
Number of patients treated	114	344	693	1,047	1,266	1,402	1,426
HER-Vaxx price per treatment	$ 50,000	$ 51,000	$ 52,020	$ 53,060	$ 54,122	$ 55,204	$ 56,308
HER-Vaxx revenue to potential U.S. partner	$ 5,698,469	$ 17,559,376	$ 36,071,876	$ 55,576,300	$ 68,501,568	$ 77,396,771	$ 80,292,293
Royalty rate to Imugene	15%	15%	15%	15%	15%	15%	15%
U.S. HER-Vaxx revenue to Imugene in AUD	**$ 1,068,463**	**$ 3,292,383**	**$ 6,763,477**	**$ 10,420,556**	**$ 12,844,044**	**$ 14,511,895**	**$ 15,054,805**

E.U. HER2+ advanced gastric cancer market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of HER2+ advanced gastric cancer		7,572	7,594	7,617	7,640	7,663	7,686
Percent market penetration		2.0%	6.0%	12.0%	18.0%	19.8%	20.8%
Number of patients treated		151	456	914	1,375	1,517	1,598
HER-Vaxx price per treatment		$ 35,000	$ 35,000	$ 35,000	$ 35,000	$ 35,000	$ 35,000
HER-Vaxx revenue to potential E.U. partner		$ 5,300,169	$ 15,948,209	$ 31,992,108	$ 48,132,126	$ 53,104,175	$ 55,926,662
Royalty rate to Imugene		15%	15%	15%	15%	15%	15%
E.U. HER-Vaxx royalty revenue to Imugene in AUD	**$ -**	**$ 993,782**	**$ 2,990,289**	**$ 5,998,520**	**$ 9,024,774**	**$ 9,957,033**	**$ 10,486,249**

China HER2+ advanced gastric cancer market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of HER2+ advanced gastric cancer		97,866	98,257	98,650	99,045	99,441	99,839
Percent market penetration		2.0%	5.0%	9.0%	12.6%	13.9%	14.6%
Number of patients treated		1,957	4,913	8,879	12,480	13,783	14,530
HER-Vaxx price per treatment		$ 35,000	$ 35,700	$ 36,414	$ 37,142	$ 37,885	$ 38,643
HER-Vaxx revenue to potential China partner		$ 68,506,091	$ 175,389,295	$ 323,302,805	$ 463,523,112	$ 522,153,223	$ 561,463,006
Royalty rate to Imugene		15%	15%	15%	15%	15%	15%
China HER-Vaxx royalty revenue to Imugene in AUD	**$ -**	**$ 12,844,892**	**$ 32,885,493**	**$ 60,619,276**	**$ 86,910,583**	**$ 97,903,729**	**$ 105,274,314**

Total HER-Vaxx royalty revenue to Imugene in AUD	**$ 1,068,463**	**$ 17,131,057**	**$ 42,639,259**	**$ 77,038,352**	**$ 108,779,401**	**$ 122,372,657**	**$ 130,815,368**

Source: SEC filings, company press releases, and ROTH Capital Partners

Imugene Limited
CHECKvacc revenue

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U.S. TNBC market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of TNBC		43,211	43,513	43,818	44,124	44,433	44,744
Percent market penetration		2.0%	5.6%	8.4%	10.9%	13.1%	14.4%
Number of patients treated		864	2,437	3,681	4,818	5,823	6,450
CHECKvacc price per course		$ 65,000	$ 66,300	$ 67,626	$ 68,979	$ 70,358	$ 71,765
CHECKvacc revenue to potential U.S. partner		$ 56,173,688	$ 161,555,077	$ 248,909,523	$ 332,364,406	$ 409,661,731	$ 462,857,945
Royalty rate to Imugene		15%	15%	15%	15%	15%	15%
U.S. CHECKvacc revenue to Imugene in AUD	**$ -**	**$ 70,217,110**	**$ 201,943,847**	**$ 311,136,904**	**$ 415,455,507**	**$ 512,077,164**	**$ 578,572,432**

E.U. TNBC market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of TNBC			57,187	57,358	57,530	57,703	57,876
Percent market penetration			2.0%	4.0%	6.0%	7.8%	9.4%
Number of patients treated			1,144	2,294	3,452	4,501	5,417
CHECKvacc price per course			$ 45,000	$ 45,000	$ 45,000	$ 45,000	$ 45,000
CHECKvacc revenue to potential E.U. partner			$ 51,467,973	$ 103,244,755	$ 155,331,733	$ 202,537,047	$ 243,773,590
Royalty rate to Imugene			15%	15%	15%	15%	15%
E.U. CHECKvacc royalty revenue to Imugene in AUD	**$ -**	**$ -**	**$ 9,650,245**	**$ 19,358,391**	**$ 29,124,700**	**$ 37,975,696**	**$ 45,707,548**

China TNBC market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of TNBC			184,972	185,712	186,455	187,201	187,950
Percent market penetration			2.0%	4.0%	6.0%	7.8%	9.4%
Number of patients treated			3,699	7,428	11,187	14,602	17,592
CHECKvacc price per course			$ 45,000	$ 45,900	$ 46,818	$ 47,754	$ 48,709
CHECKvacc revenue to potential China partner			$ 166,475,108	$ 340,967,658	$ 523,767,238	$ 697,293,420	$ 856,901,094
Royalty rate to Imugene			15%	15%	15%	15%	15%
China CHECKvacc royalty revenue to Imugene in AUD	**$ -**	**$ -**	**$ 31,214,083**	**$ 63,931,436**	**$ 98,206,357**	**$ 130,742,516**	**$ 160,668,955**

Total CHECKvacc royalty revenue to Imugene in AUD	**$ -**	**$ 70,217,110**	**$ 242,808,174**	**$ 394,426,731**	**$ 542,786,565**	**$ 680,795,376**	**$ 784,948,935**

Source: SEC filings, company press releases, and ROTH Capital Partners

Imugene Limited
PD1-Vaxx revenue

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U.S. NSCLC market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of NSCLC		194,551	195,913	197,284	198,665	200,056	201,456
Percent market penetration		2.0%	5.0%	1.9%	1.4%	1.5%	1.6%
Number of patients treated		3,891	9,796	3,748	2,781	3,081	3,258
PD1-Vaxx price per treatment		$ 50,000	$ 51,000	$ 52,020	$ 53,060	$ 54,122	$ 55,204
PD1-Vaxx revenue to potential U.S. partner		$ 194,551,087	$ 499,578,008	$ 194,991,891	$ 147,577,663	$ 166,741,213	$ 179,829,898
Royalty rate to Imugene		15%	15%	15%	15%	15%	15%
U.S. PD1-Vaxx revenue to Imugene in AUD	**$ -**	**$ 36,478,329**	**$ 93,670,877**	**$ 36,560,980**	**$ 27,670,812**	**$ 31,263,977**	**$ 33,718,106**

E.U. NSCLC market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of NSCLC			313,200	314,139	315,082	316,027	316,975
Percent market penetration			2.0%	5.0%	8.5%	12.8%	14.0%
Number of patients treated			6,264	15,707	26,782	40,293	44,456
PD1-Vaxx price per treatment			$ 35,000	$ 35,000	$ 35,000	$ 35,000	$ 35,000
PD1-Vaxx revenue to potential E.U. partner			$ 219,239,842	$ 549,743,903	$ 937,368,329	$ 1,410,270,652	$ 1,555,951,610
Royalty rate to Imugene			15%	15%	15%	15%	15%
E.U.PD1-Vaxx royalty revenue to Imugene in AUD	**$ -**	**$ -**	**$ 41,107,470**	**$ 103,076,982**	**$ 175,756,562**	**$ 264,425,747**	**$ 291,740,927**

China NSCLC market	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
Annual incidence of NSCLC			621,507	623,993	626,489	628,995	631,511
Percent market penetration			2.0%	4.0%	6.4%	9.0%	9.9%
Number of patients treated			12,430	24,960	40,095	56,358	62,242
PD1-Vaxx price per treatment			$ 35,000	$ 35,700	$ 36,414	$ 37,142	$ 37,885
PD1-Vaxx revenue to potential China partner			$ 435,054,950	$ 891,062,146	$ 1,460,030,275	$ 2,093,262,926	$ 2,358,035,567
Royalty rate to Imugene			15%	15%	15%	15%	15%
China PD1-Vaxx royalty revenue to Imugene in AUD	**$ -**	**$ -**	**$ 81,572,803**	**$ 167,074,152**	**$ 273,755,677**	**$ 392,486,799**	**$ 442,131,669**

Total PD1-Vaxx royalty revenue to Imugene in AUD	**$ -**	**$ 36,478,329**	**$ 216,351,150**	**$ 306,712,114**	**$ 477,183,050**	**$ 688,176,523**	**$ 767,590,702**

Source: SEC filings, company press releases, and ROTH Capital Partners

Imugene Limited
Income Statement
Fiscal Year ends June
(in AUD$000, except per share items)

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	FY2018A	FY2019A	FY1H20A	FY2H20A	FY2020A	FY1H21E	FY2H21E	FY2021E	FY2022E
CHECKvacc royalty revenue									
HER-Vaxx royalty revenue									
PD1-Vaxx royalty revenue									
Total royalty evenue									
Gross profit									
R&D	3,224	7,612	4,234	5,131	9,364	5,746	6,436	12,182	18,273
SG&A	2,554	4,777	3,022	2,493	5,515	2,793	3,072	5,864	6,216
Total operating expenses	**5,778**	**12,389**	**7,255**	**7,624**	**14,879**	**8,539**	**9,508**	**18,046**	**24,489**
Operating income	**(5,778)**	**(12,389)**	**(7,255)**	**(7,624)**	**(14,879)**	**(8,539)**	**(9,508)**	**(18,046)**	**(24,489)**
Other income/loss (R&D tax incentive, etc)	1,750	4,205	2,357	1,717	4,074	2,500	2,800	5,299	7,949
Finance income/expense net	94	409	107	190	297	160	130	290	305
Net income (pretax)	**(3,934)**	**(7,775)**	**(4,791)**	**(5,717)**	(10,508)	**(5,879)**	**(6,578)**	**(12,457)**	**(16,236)**
Income tax expense (benefit)									
Net income	**(3,934)**	**(7,775)**	**(4,791)**	**(5,717)**	**(10,508)**	**(5,879)**	**(6,578)**	**(12,457)**	**(16,236)**
EPS basic	**(0.0015)**	**(0.0022)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0029)**
EPS diluted	**(0.0015)**	**(0.0022)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0013)**	**(0.0013)**	**(0.0026)**	**(0.0029)**
Basic shares outstanding	2,637,870	3,581,919	3,727,634	4,422,155	4,074,894	4,643,262	5,107,588	4,875,425	5,618,347
Diluted shares outstanding	2,637,870	3,581,919	3,727,634	4,422,155	4,074,894	4,643,262	5,107,588	4,875,425	5,618,347

Source: SEC filings, company press releases, and ROTH Capital Partners

Imugene Limited
Income Statement
Fiscal Year ends June
(in AUD$000, except per share items)

Jonathan Aschoff, Ph.D. (646) 616-2795
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	FY2018A	FY2019A	FY2020A	FY2021E	FY2022E	FY2023E	FY2024E	FY2025E	FY2026E	FY2027E	FY2028E	FY2029E	FY2030E	FY2031E
CHECKvacc royalty revenue									70,217	242,808	394,427	542,787	680,795	784,949
HER-Vaxx royalty revenue								1,068	17,131	42,639	77,038	108,779	122,373	130,815
PD1-Vaxx royalty revenue									36,478	216,351	306,712	477,183	688,177	767,591
Total royalty evenue								**1,068**	**123,826**	**501,799**	**778,177**	**1,128,749**	**1,491,345**	**1,683,355**
Gross profit								**1,068**	**123,826**	**501,799**	**778,177**	**1,128,749**	**1,491,345**	**1,683,355**
R&D	3,224	7,612	9,364	12,182	18,273	23,755	29,693	32,663	35,929	37,725	39,612	40,008	40,408	40,812
SG&A	2,554	4,777	5,515	5,864	6,216	6,589	6,985	7,404	7,774	8,163	8,571	8,999	9,449	9,922
Total operating expenses	**5,778**	**12,389**	**14,879**	**18,046**	**24,489**	**30,344**	**36,678**	**40,066**	**43,703**	**45,888**	**48,182**	**49,007**	**49,857**	**50,734**
Operating income	**(5,778)**	**(12,389)**	**(14,879)**	**(18,046)**	**(24,489)**	**(30,344)**	**(36,678)**	**(38,998)**	**80,124**	**455,911**	**729,995**	**1,079,742**	**1,441,487**	**1,632,621**
Other income/loss (R&D tax incentive, etc)	1,750	4,205	4,074	5,299	7,949	9,146	11,432	12,575	13,833	14,524	15,250	15,403	15,557	15,713
Finance income/expense net	94	409	297	290	305	320	336	352	423	550	825	1,237	1,856	2,784
Net income (pretax)	**(3,934)**	**(7,775)**	(10,508)	**(12,457)**	**(16,236)**	**(20,879)**	**(24,910)**	**(26,070)**	**94,379**	**470,985**	**746,070**	**1,096,382**	**1,458,900**	**1,651,118**
Income tax expense (benefit)									-	141,295	223,821	328,915	437,670	495,335
Net income	**(3,934)**	**(7,775)**	**(10,508)**	**(12,457)**	**(16,236)**	**(20,879)**	**(24,910)**	**(26,070)**	**94,379**	**329,689**	**522,249**	**767,468**	**1,021,230**	**1,155,782**
EPS basic	**(0.0015)**	**(0.0022)**	**(0.0026)**	**(0.0026)**	**(0.0029)**	**(0.0034)**	**(0.0038)**	**(0.0038)**	**0.0132**	**0.0439**	**0.0662**	**0.0927**	**0.1174**	**0.1266**
EPS diluted	**(0.0015)**	**(0.0022)**	**(0.0026)**	**(0.0026)**	**(0.0029)**	**(0.0034)**	**(0.0037)**	**(0.0037)**	**0.0128**	**0.0425**	**0.0643**	**0.0901**	**0.1143**	**0.1234**
Basic shares outstanding	2,637,870	3,581,919	4,074,894	4,875,425	5,618,347	6,180,182	6,489,191	6,813,651	7,154,333	7,512,050	7,887,652	8,282,035	8,696,137	9,130,944
Diluted shares outstanding	2,637,870	3,581,919	4,074,894	4,875,425	5,618,347	6,180,182	6,727,851	7,052,311	7,392,993	7,750,710	8,126,312	8,520,695	8,934,797	9,369,604

Source: SEC filings, company press releases, and ROTH Capital Partners

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

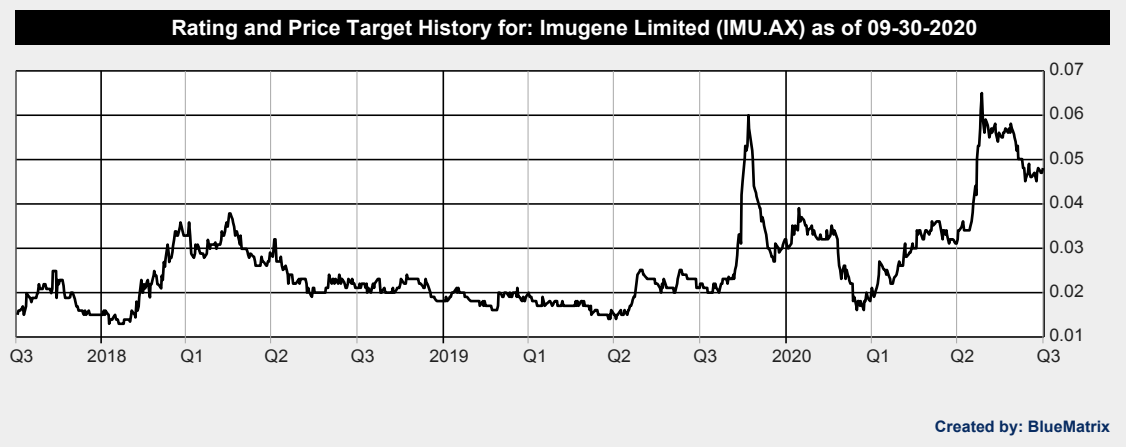
Disclosures:

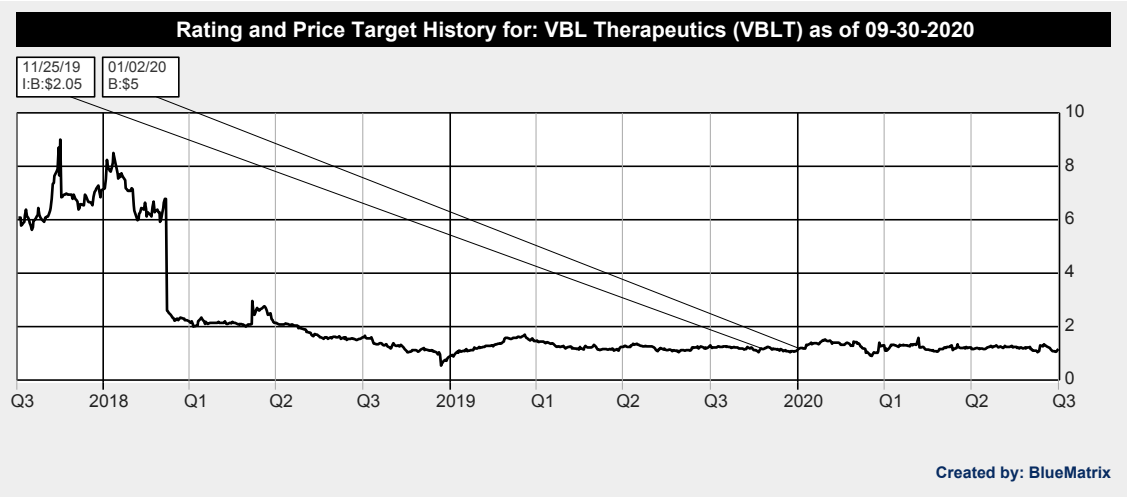
Within the last twelve months, ROTH has received compensation for investment banking services from Imugene Limited and Replimune Group, Inc..

ROTH makes a market in shares of Enanta Pharmaceuticals, Inc., Replimune Group, Inc. and VBL Therapeutics and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for Replimune Group, Inc..

Shares of VBL Therapeutics may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.





Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of 10/01/20	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**263**	**71.86**	**149**	**56.65**
Neutral [N]	**58**	**15.85**	**20**	**34.48**
Sell [S]	**3**	**0.82**	**2**	**66.67**
Under Review [UR]	**41**	**11.20**	**23**	**56.10**

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

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