



# Oncolytic Immunotherapies for Difficult-to-Treat Cancers

**Annual General Meeting**  
**November 22, 2017**

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# Investment highlights

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**Lead drug CAVATAK®** harnesses the common cold virus to infect and kill cancer cells



**Market-leading body of clinical evidence** across multiple cancer indications



**Global opportunity being unlocked** via combination with leading in-market immunotherapies (KEYTRUDA® and YERVOY®) creating a clear path to market in area of high unmet need



**Excellent preliminary results from three ongoing clinical trials:** CAPRA, MITCI and KEYNOTE-200



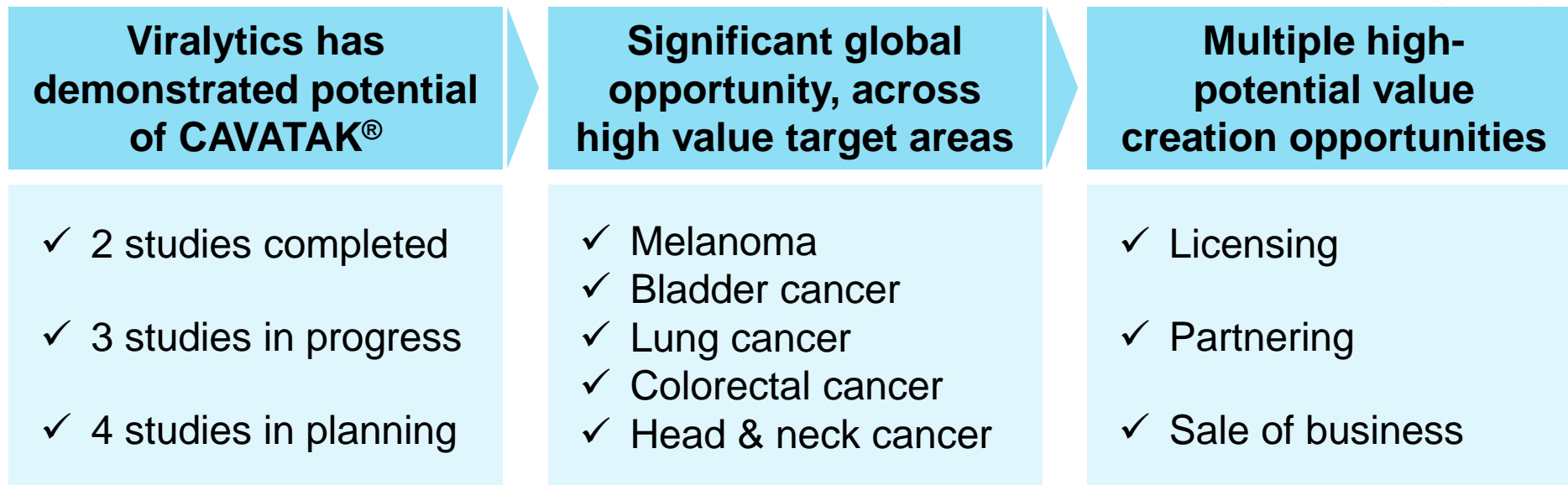
**Globally recognised by** healthcare investors, big-pharma and scientific bodies



**Value inflection potential from near-term milestones** in gold-standard trials for melanoma, lung and bladder cancers

# Viralytics has multiple pathways to commercialisation of CAVATAK<sup>®</sup> across a range of target areas

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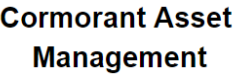











Broad set of value-creation options

# Strong Financial Foundation

## Extensive support from leading institutional healthcare investors

### Key Statistics

Ticker Code	ASX: VLA OTCQX: VRACY
Share Price (as at 21-Nov-17)	A\$0.72
Market Capitalisation (as at 21-Nov-17)	A\$173M
Trading Range (12-month)	A\$0.72 – 1.34
Institutional investors	57%
Cash position (as at 30-Sep-17) <sup>1</sup>	A\$27.7M
Net operating cash burn (2016/2017)	A\$11.4M

Company	Location	Comments
		Private investment firm specialising in public biotechnology investments
		Employee-owned hedge fund sponsor which invests in healthcare companies
		Financial services company with over \$1.5tn in assets under management
		Healthcare-dedicated investment firm which manages over \$14bn
		Independent, trans-atlantic bio-science investment firm
		Australian equities investment manager
		Australian equities investment manager

1. In addition \$6.4M in cash forecast to be received from the Federal Government in Q4 2107

# Cancer Immunotherapy: Emerging, High-Value Therapeutic Approach

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- **Rapidly advancing field**, transforming cancer therapy
- **Big pharma racing to find complementary agents**: Merck, BMS, Roche, AstraZeneca, Pfizer all active
- **Multiple recent transactions and collaborations**
- Value of oncolytic viruses highlighted by Amgen acquisition of Biovex (TVec™) – US
  - \$425 million cash upfront; US \$575 million future milestone payments
- Immuno-oncology **market size forecast at US \$42 billion per annum**<sup>1</sup>



*“There’s a growing sense in the oncology community that immune manipulation may turn out to be an **even more important intervention than chemotherapy** was — maybe the **most important ever**”*

Roger Perlmutter, President, Research – Merck<sup>2</sup>

1. Credit Suisse November 2015  
2. Financial Times 29 May 2015

Viralytics is using the  
common cold virus to  
**KILL CANCER CELLS**

- **Proprietary formulation of the cold virus** Coxsackievirus A 21; targets ICAM-1 receptor overexpressed on cancer cells
- **Kills local and metastatic cells** by both **oncolytic and immunotherapeutic activity**

**Broad application across  
COMMON CANCER types**

- **Potential application across a range of cancer types, including:**

**LUNG**  
*2<sup>nd</sup> most  
common cancer*

**COLORECTAL**  
*4<sup>th</sup> most  
common cancer*

**BLADDER**  
*5<sup>th</sup> most  
common cancer*

**MELANOMA**  
*6<sup>th</sup> most  
common cancer*

**Can be used  
STANDALONE or in  
COMBINATION**

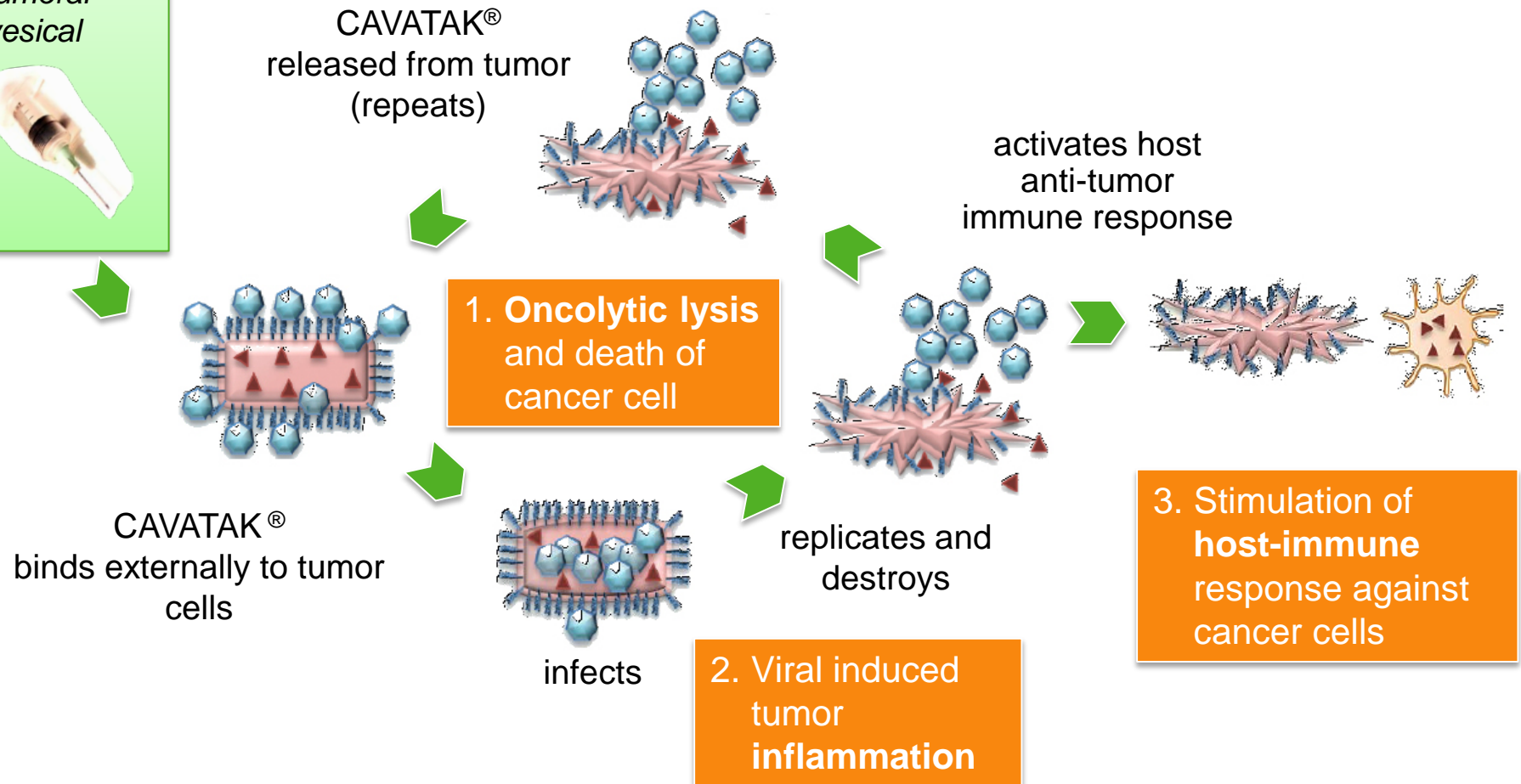
- **When used standalone**, CAVATAK has exceeded expectations, with a strong response rate in a phase II trial
- Demonstrated potential in clinical trials to **enhance activity of leading cancer immunotherapies**, potentially **unlocking a global opportunity**

# CAVATAK<sup>®</sup>

## Local and Systemic Activity

### Administration


- Intravenous
- Intratumoral
- Intravesical



# CAVATAK® may enhance leading oncolytic immunotherapy drugs, unlocking a global opportunity

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- Merck and Bristol-Myers Squibb (BMS) are the **global leaders** in the immuno-oncology market
- CAVATAK® is engaged in **clinical studies with KEYTRUDA® and YERVOY®**
- Opportunity to generate massive sales alongside existing, **multi-billion dollar benchmark treatments**
- **Merck has partnered with Viralytics** and is collaborating on the KEYNOTE-200 clinical trial

Company	Product in market
	 (pembrolizumab) Injection 100 mg
<ul style="list-style-type: none"><li>▪ Global pharmaceutical company</li><li>▪ Market cap of ~US\$150bn</li></ul>	<ul style="list-style-type: none"><li>▪ Leading global oncolytic immunotherapy drug</li><li>▪ <b>US\$1.4bn</b> in sales in 2016</li></ul>
	
<ul style="list-style-type: none"><li>▪ Global pharmaceutical company</li><li>▪ Market cap of ~US\$100bn</li></ul>	<ul style="list-style-type: none"><li>▪ YERVOY® approved for treatment of Melanoma</li><li>▪ <b>US\$1.1bn</b> in sales in 2016</li></ul>
<b>Other potential partners with approved PD1s include:</b>	
 A Member of the Roche Group	
	

# Overview of CATAVAK® clinical programs – Targeting Major Indications

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## CAVATAK standalone

### *Studies completed*

- **Two studies completed:**
  - CALM (Phase II)
  - CANON (Phase I)
- **Target areas include:**
  - Melanoma
  - Bladder cancer
- **Encouraging signs of efficacy & shrinkage of uninjected tumours** from CALM, strong signal from CANON

*Excellent response rate demonstrated in CALM study*

## CAVATAK in combination

### *Studies underway*

- **Three studies underway:**
  - CAPRA (Phase Ib)
  - MITCI (Phase Ib)
  - KEYNOTE-200(Phase Ib)
- **Target areas include:**
  - Melanoma
  - Lung cancer
  - Bladder cancer
- **Excellent preliminary efficacy results**

*Potential to enhance in-market therapies*

*Prime focus*

## CAVATAK in combination

### *Studies planned*

- **Four phase Ib studies planned:**
  - ITCAHN
  - CLEVER
  - PaCKMAN
  - Colorectal study
- **Target areas include:**
  - Head and neck cancer
  - Melanoma
  - Colorectal cancer

*Continually pursuing new target areas*

## Pre-clinical pipeline

- **Preclinical study completed** using a triple combination of CAVATAK, Anti-PD-1 and IDO Inhibitor
- **Potential in broad range of tumour types**
- **Demonstrated significant reduction in overall mouse tumour burden**

*Growing body of scientific evidence*

# Trial update: CAPRA Phase 1b

## TRIAL OVERVIEW

- CAVATAK (Intralesional) and KEYTRUDA® combination
- Plan to enrol 50 late stage melanoma patients
- Lead investigator: Dr Ann Silk MD, Rutgers Cancer Institute of New Jersey

## PROGRESS AND PRELIMINARY RESULTS

- 26 of 50 patients enrolled
- Best Overall Response Rate of 61% (14/23 pts) and DCR of 78% (18/23 pts)
- Tumour responses are ongoing at 12 months in 6 patients
- 4 patients have demonstrated complete responses in the target lesions
- BORR of 64% (7/11 pts) in patients with late stage IV M1c disease
- Reductions in a number of injected and non-injected visceral/non-visceral lesions
- Only two Grade 3 pembrolizumab-related adverse events in 26 enrolled patients
- Preliminary but encouraging response rates compared to KEYTRUDA alone (33%\*) or other KEYTRUDA combination studies

\*Robert et al., N Engl J Med 2015; 372:2521-2532

Note: Summary information only – see Viralytics website for further details

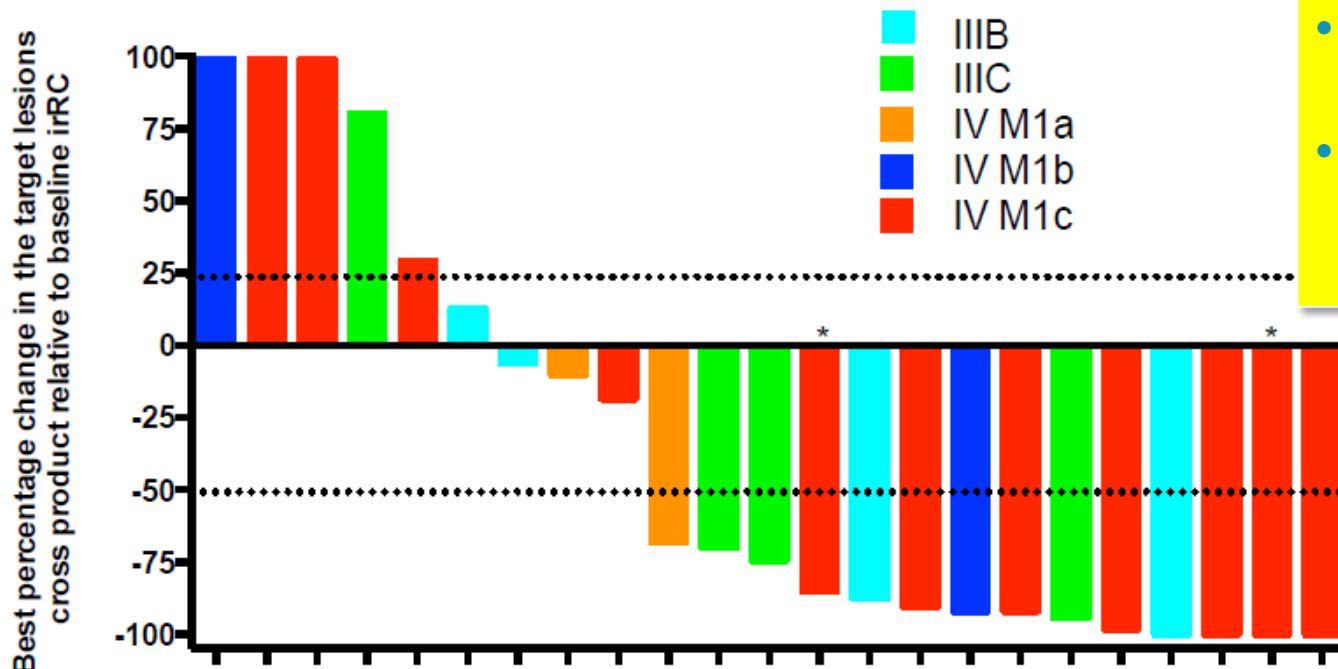
# Trial update: CAPRA Phase 1b

## Best Overall Response

12

Impressive Activity in Patients with Advanced Melanoma

**Best percentage change in target lesions irRC criteria**  
*(Preliminary data, investigator assessed)*



- Overall Response Rate of 61%
- Preliminary but encouraging response rates, versus KEYTRUDA® alone (33%±)

\* Prior ipilimumab treatment

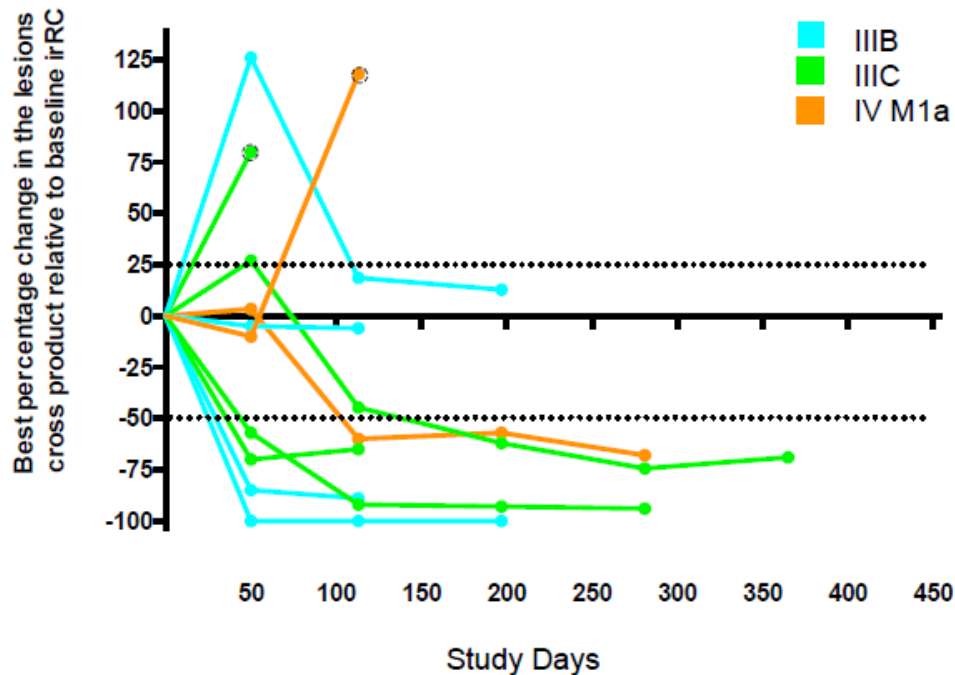
# Trial update: CAPRA Phase 1b

## Changes in Tumour Burden by Disease Stage

13

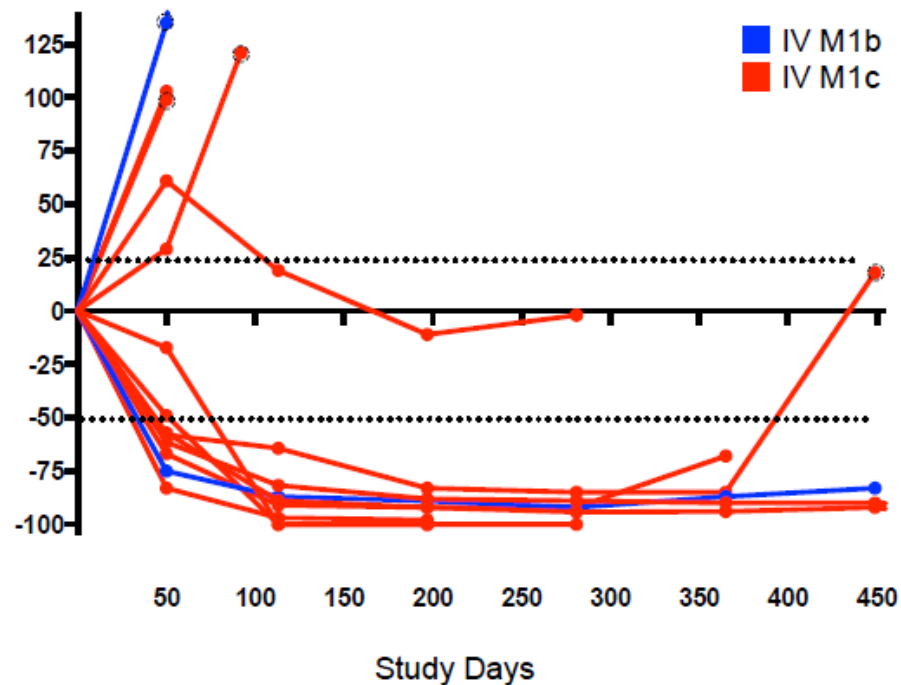
Promising durability in responding patients

Stage IIIB, IIIC, IV M1a



○ Discontinued study due to progressive disease

Stage IV M1b/c



# Trial update: CAPRA Phase 1b

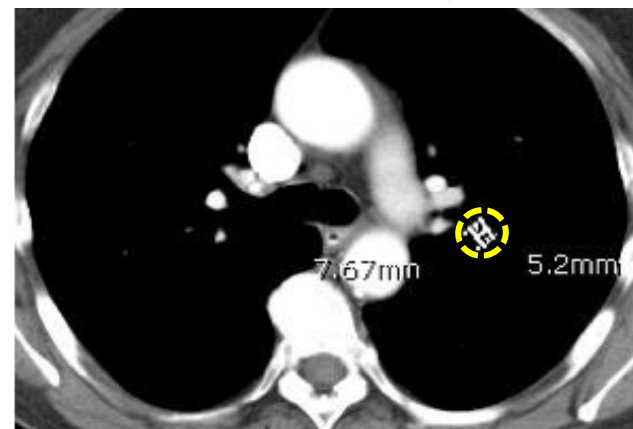
**Pt1105003**  
**Stage IVM1c**  
**Partial response**

*Non-injected lung  
 lesion upper left lobe*

**Baseline**



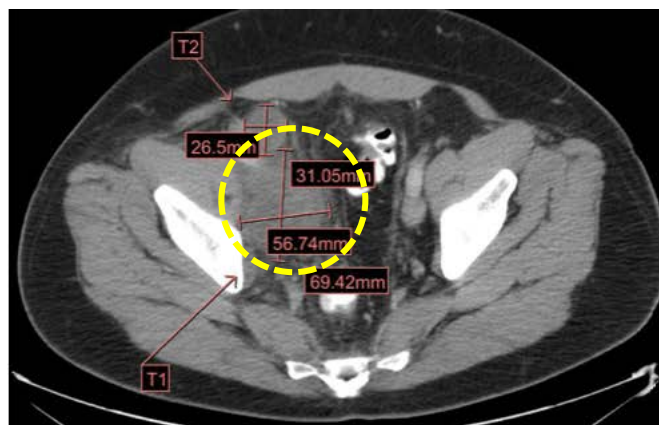
**Day 197**



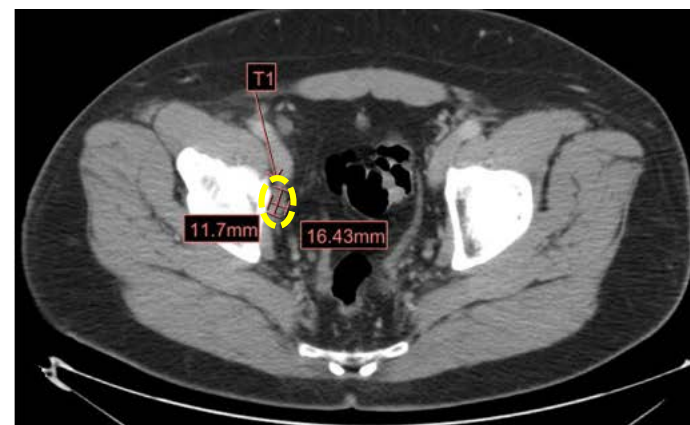
**Pt1106023**  
**Stage IIIC**  
**Partial response**

*Non-injected lymph  
 node lesion Right  
 internal Obturator  
 region*

**Baseline**



**Day 113**



# Trial update: MITCI Phase 1b

## TRIAL OVERVIEW

- CAVATAK (Intralesional) and YERVOY® combination
- Focus on an unmet need in patients who have failed prior anti-PD1 therapy
- Plan to enrol 60 melanoma patients
- Lead investigator: Dr Brendan Curti MD, Providence Cancer Center, Portland

## PROGRESS AND PRELIMINARY RESULTS

- 38 of 60 patients enrolled
- Safety:
  - No dose-limiting toxicities reported
  - Six Grade 3+ adverse events in 4 patients (all YERVOY-related: fatigue, elevated liver enzymes [2], pruritis, dehydration, hyperglycaemia) with an overall study Gr 3+ treatment-related AE rate of 11% (4/38 pts)
- Efficacy:
  - 57% (8/14) Best overall response rate in patients naïve to checkpoint therapy
  - 29% (2/7) Best overall response rate in patients administered prior single line anti-PD1 therapy
  - Preliminary but encouraging response rates, versus YERVOY alone (11%\*) or other YERVOY combination studies

**Potential to lead to a pivotal study**

\*YERVOY® FDA approved label

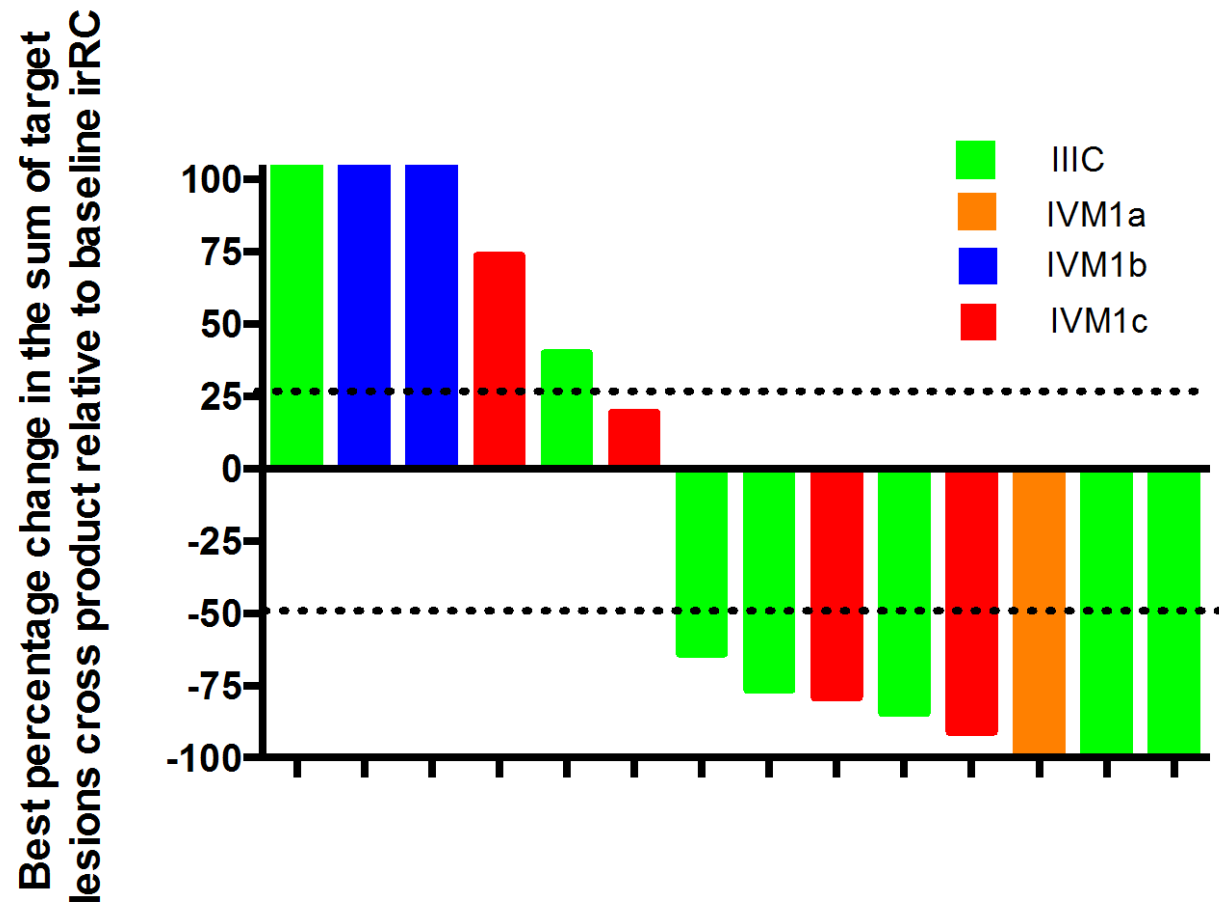
Note: Summary information only – see Viralytics website for further details

# Trial update: MITCI Phase 1b

## Best Percentage Change in Target Lesions

16

### Checkpoint therapy naïve (n=14)



- Overall Response Rate of 57%
- Preliminary but encouraging response rates, versus YERVOY® alone (11%±)

\* irRC criteria: Preliminary data, investigator assessed

+ First response assessment at Day 106

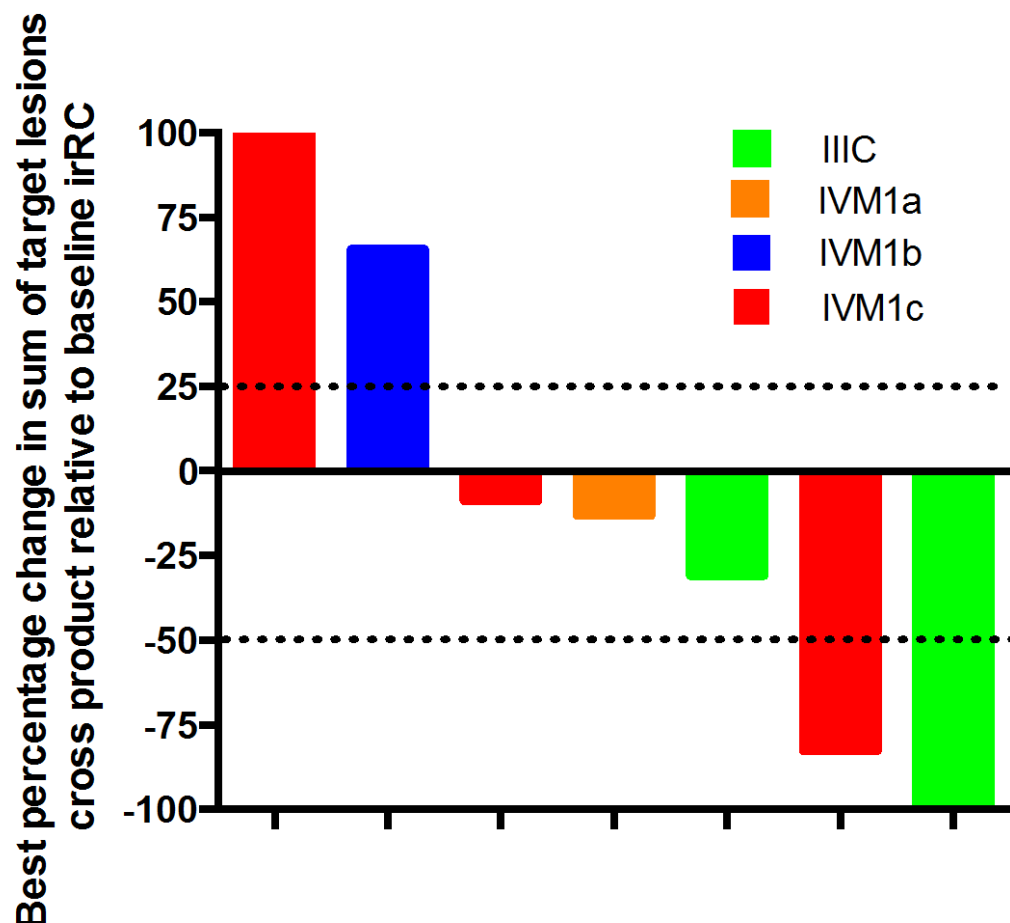
± YERVOY® FDA approved label

# Trial update: MITCI Phase 1b

## Best Percentage Change in Target Lesions

17

### Prior single line anti-PD-1 therapy (n=7)



- Promising initial data in a heavily pretreated population
- Overall Response Rate of 29%
- Preliminary but encouraging response rates, versus YERVOY® alone in this setting (10-13%)

\*, irRC criteria: Preliminary data, investigator assessed

\*, First response assessment at Day 106

# Trial update: MITCI Phase 1b

## Complete Response Stage IIc patient

18

### Prior cancer treatments

1. BCG (PD)
2. Nivolumab (PD)

Pre-Treatment



Day 30



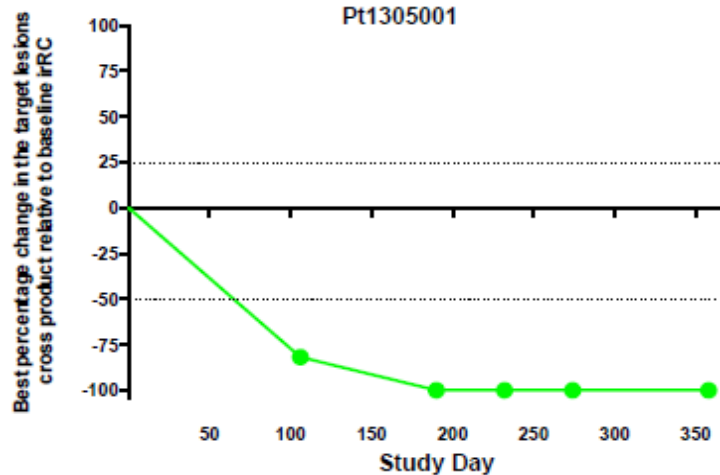
Day 90



Day 180



Pt1305001



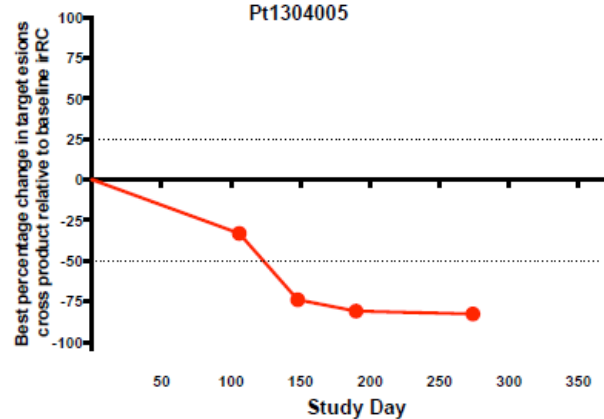
# Trial update: MITCI Phase 1b

## Partial Response Stage IVM1c patient

### Prior cancer treatments

1. Ipilimumab/Nivolumab (PR)
2. Nivolumab (PD)
3. Surgery (NE)

Pt1304005



Pre-treatment



Day 127



Day 310



# Trial update: KEYNOTE-200 Phase 1b

## TRIAL OVERVIEW

- Trial conducted in collaboration with Merck (MSD)
- Combination of intravenous CAVATAK / KEYTRUDA in late-stage cancer patients
- 17 sites in the US, Australia and UK
- Major tumour indications:
  - Non-small cell lung cancer
  - Metastatic bladder cancer
- Primary objective: Safety and tolerability
- Secondary objective: Efficacy

## PROGRESS AND PRELIMINARY RESULTS

- Currently 64 subjects enrolled at the top CAVATAK dose level used in the expansion phase, total of ~90 patients targeted
- Dose escalation complete with no dose limiting toxicity for the combination of CAVATAK and KEYTRUDA in heavily pre-treated patient population

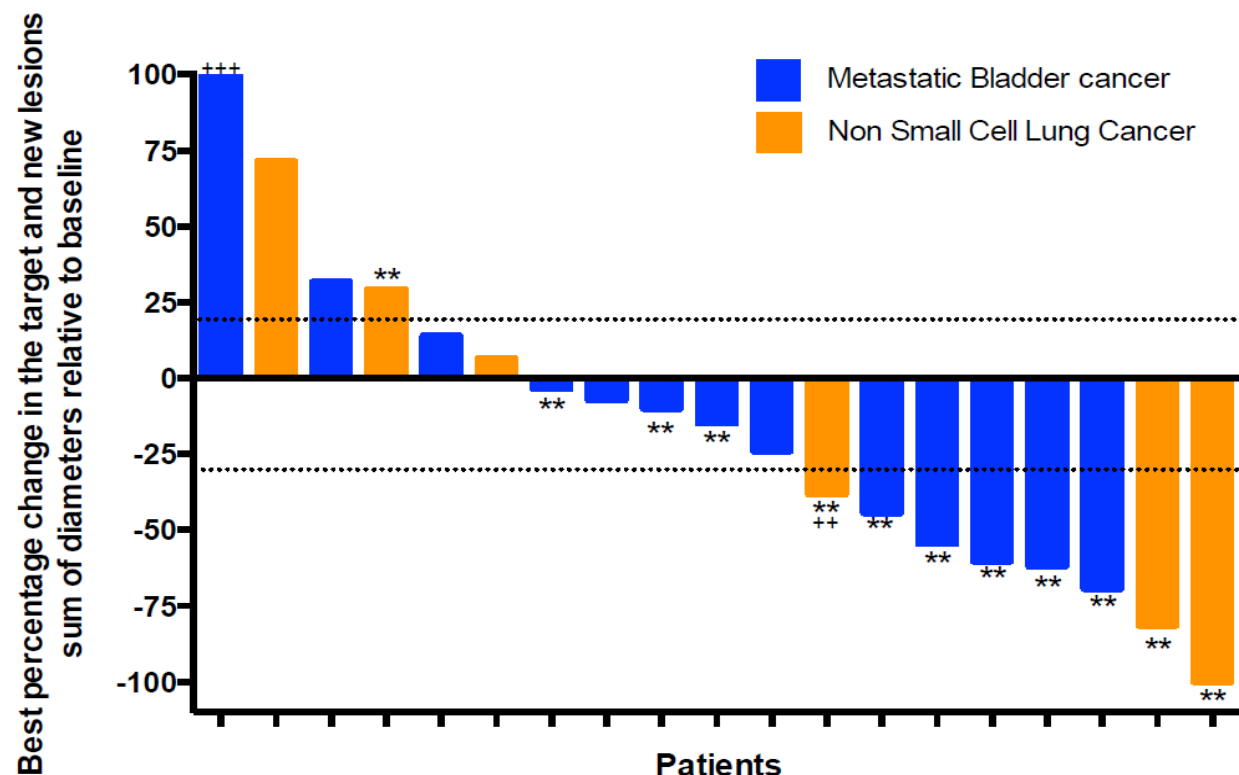
**Clinical Updates in Q2 2018**

# Trial update: KEYNOTE-200 Phase 1b

## Preliminary First Investigator Assessment in Checkpoint Naïve Patients

21

Best percentage change in target lesions of checkpoint naïve patients + \*



Encouraging early data in lung and bladder cancer patients

Well tolerated with 11% (7 of 64 ) patients have displayed treatment related >grade 3 adverse events

+, Preliminary first investigator assessment of best percentage change in target and new lesions within the first 92 days of combination treatment in checkpoint naïve patients, Data cutoff 8 November 2017;

\*, Not evaluable due to early disease progression prior to first response assessment, 4 NSCLC pts + 5 Bladder cancer pts;

\*\*, Patient currently on study;

++, Day 176 response assessment;

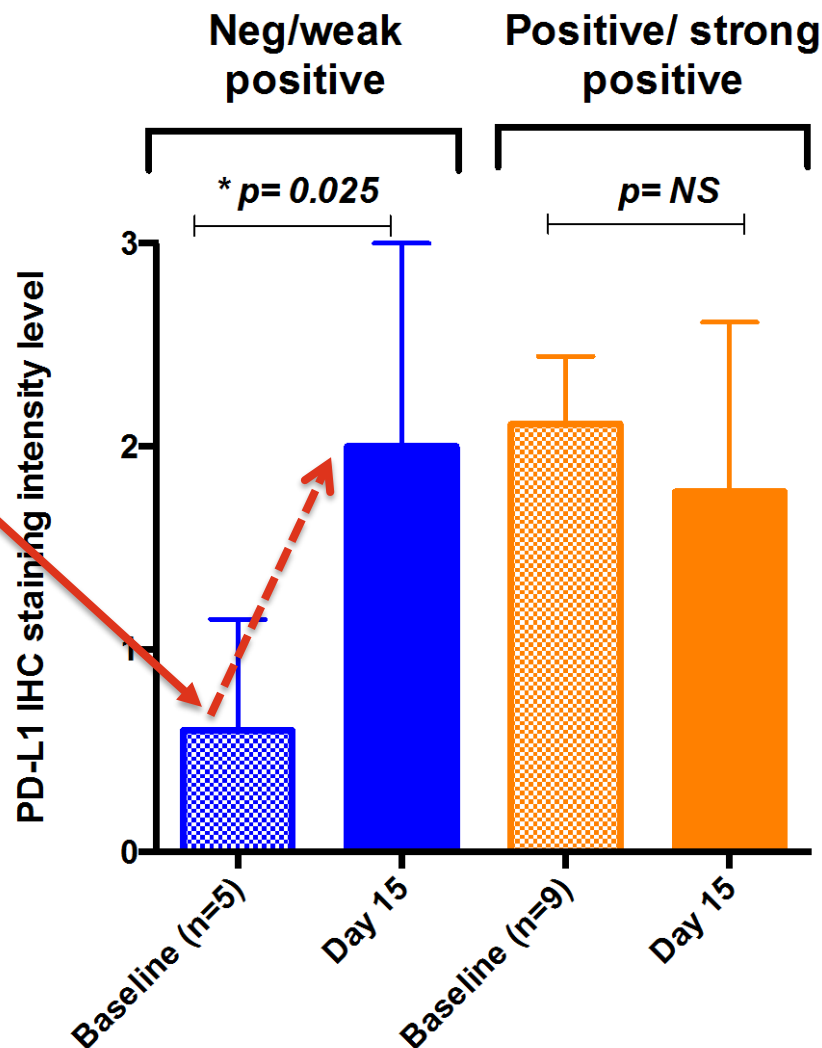
+++, Day 43 response assessment.

# Trial update: KEYNOTE-200 Phase 1b

## Preliminary PD-L1 Expression Levels on Paired Tumour Biopsies

22

Upregulation of PD-L1 in lung and bladder cancer patients with pre-existing low levels



**IHC Scoring**  
0= Negative  
1= Weak positive  
2= Positive  
3= Strong positive

# Recognition received with podium positions at pre-eminent American Cancer Conferences

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The world's oldest and largest professional association related to cancer research



**AACR**  
American Association  
for Cancer Research



Leading cancer research meeting, attended by oncology experts from around the world



**ASCO**  
American Society of  
Clinical Oncology



World's leading member driven organisation specifically dedicated to cancer immunotherapy



**sitc**  
Society for Immunotherapy of Cancer

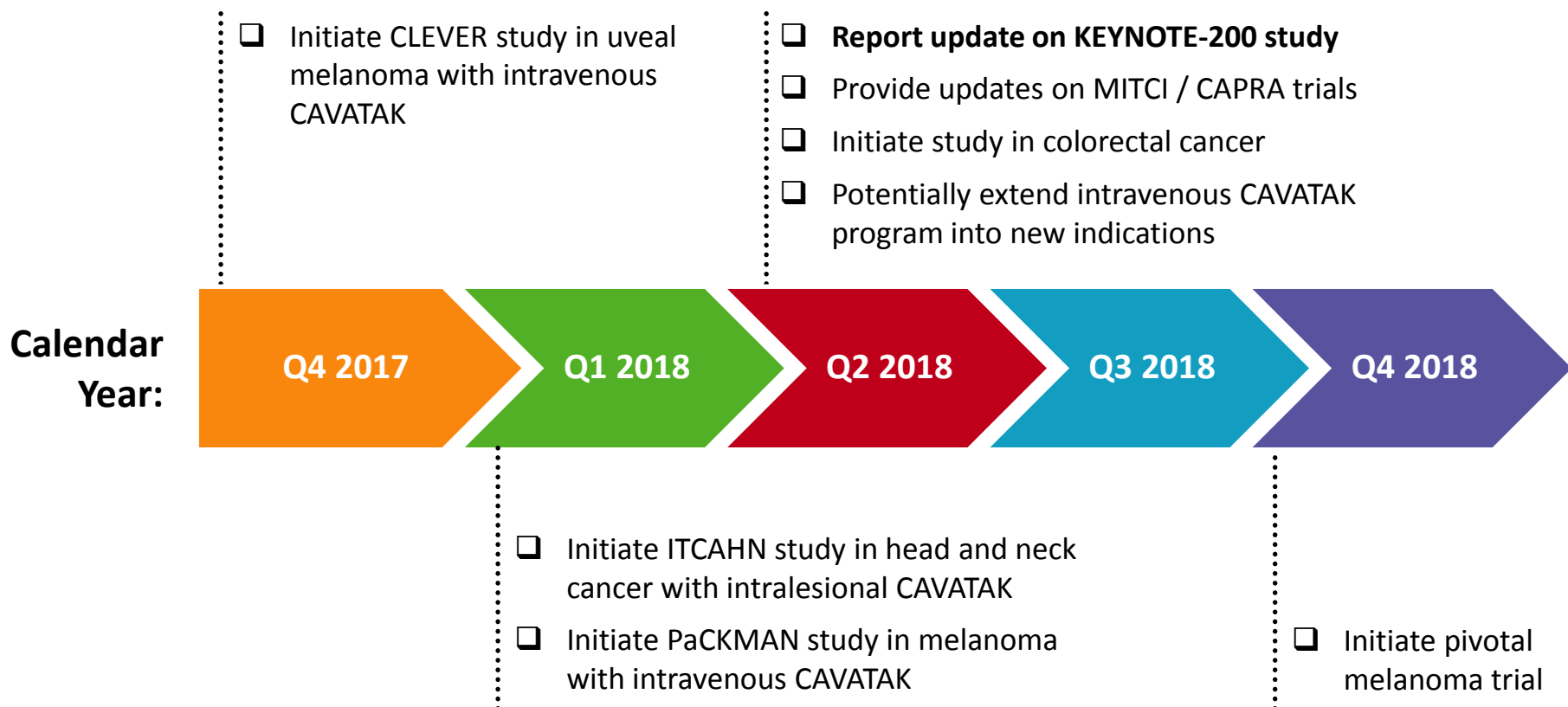


# Demonstrated ability to manage and progress a comprehensive schedule of clinical trials

- ✓ Reported positive interim results CAPRA study
- ✓ Reported positive interim results MITCI study
- ✓ Identified potential path to market in melanoma in setting of high unmet need
- ✓ Sites initiated in US, Australia and UK with strong enrolment in KEYNOTE-200 study
- ✓ Pre-clinical work to identify further target indications
- ✓ Developed CAVATAK manufacture program
- ✓ Well advanced in preparations for clinical studies in new indications

# Multiple near-term and medium-term value inflection milestones

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# CATAVAK® trials overviews

## Completed / In Progress

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	Program		Target	Phase	Progress	Highlights
<b>CAVATAK standalone:</b> Studies completed	<b>CALM</b>	Intratumoral CAVATAK in late stage melanoma	Melanoma	II	Complete	Efficacy exceeded expectations with overall response rate of 28%
	<b>CANON</b>	Intravesicular CAVATAK in non muscle invasive bladder cancer	Bladder cancer	I	Complete	CAVATAK was well tolerated with promising results underpinning strong potential in combination with checkpoints
<b>CAVATAK in combination therapy:</b> Studies underway	<b>CAPRA</b>	Intralesional CAVATAK and Pembrolizumab (KEYTRUDA®)	Melanoma	Ib	26 of 50 patients enrolled	<b>Well tolerated with encouraging initial efficacy data: 61% best overall response rate vs 33% KEYTRUDA alone</b>
	<b>MITCI</b>	Intra-tumoral CAVATAK and Ipilimumab (Yervoy®)	Melanoma	Ib	38 of 60 patients enrolled	<b>Well tolerated with encouraging initial efficacy data: 57% best overall response rate vs 11% YERVOY alone</b>
	<b>KEY NOTE-200</b>	CAVATAK and KEYTRUDA®	Lung and bladder cancer	Ib	64 of 90 patients enrolled	Part A (CAVATAK alone) completed successfully, Part B underway in collaboration with Merck; encouraging initial positive signals of activity

# CATAVAK® trials overviews

## In Planning

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	Program		Target	Phase	Progress	Overview
<b>CAVATAK in combination therapy:</b> Studies planned	<b>ITCAHN</b>	Intralesional CAVATAK and KEYTRUDA®	Head and neck cancer	Ib	Planning	24 patient study targeting commencement in Q1 CY18
	<b>CLEVER</b>	Intravenous CAVATAK and YERVOY® for uveal melanoma	Melanoma	Ib	Planning	6-10 patient study targeting commencement in Q4 CY17
	<b>PaCKMAN</b>	Intravenous CAVATAK and Pembrolizumab (KEYTRUDA®)	Melanoma	Ib	Planning	15 patient study targeting commencement in Q1 CY18
	<b>Colorectal Study</b>	Intralesional CATAVAK and checkpoint inhibitor	Colorectal cancer	Ib	Planning	18-30 patient study targeting commencement in Q2 CY18
<b>Pre-clinical pipeline</b>	<b>Triple combination</b>	Triple combination of CAVATAK, Anti-PD-1 and IDO Inhibitor	Melanoma	Pre-clinical	Complete	Demonstrated significant reduction in overall mouse tumour burden

### CAVATAK® is highly active in key cancer types

- Used in combination therapy to enhance effect of leading in-market existing drugs
- Multiple target areas including melanoma, lung, metastatic bladder, non-muscle invasive bladder cancer, colorectal and head and neck cancer

### Encouraging results from clinical trials to date

- KEYNOTE-200 – CAVATAK / KEYTRUDA combination in NSCLC and metastatic bladder recruiting strongly with early positive signal
- Preliminary results from MITCI (CAVATAK / YERVOY) and CAPRA (CAVATAK / KEYTRUDA) trials very encouraging and point to potential path to market in area of high unmet need
- CANON - Promising results in non-muscle invasive bladder cancer

### Board and management focused on driving shareholder value

- Aggressive expansion of clinical program planned, with goal of driving partnering discussions and shareholder value
- Recent high value transactions in growing field of cancer immunotherapy indicate relevant interest from leading global pharma companies

# Thank You



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