



Oncolytic Immunotherapies for Difficult-to-Treat Cancers

4 May 2016

Disclaimer

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Positioned for Growth

- Lead investigational product CAVATAK™ with demonstrated potential across a range of indications and treatment settings
- Opportunity for use as monotherapy or in combination with new 'blockbuster' agents
- Resources to conduct key global clinical trials
- Collaborative clinical trial program with Merck in lung and bladder cancer
- Corporate strategy to license, partner, or sell at key value point

CALM and CALM extension:
Success in Phase 2 melanoma trial (US)

STORM / KEYNOTE-200:
CAVATAK / KEYTRUDA®
Collaboration with Merck in lung and bladder cancer (US & UK)

CANON:
Superficial bladder cancer (UK)

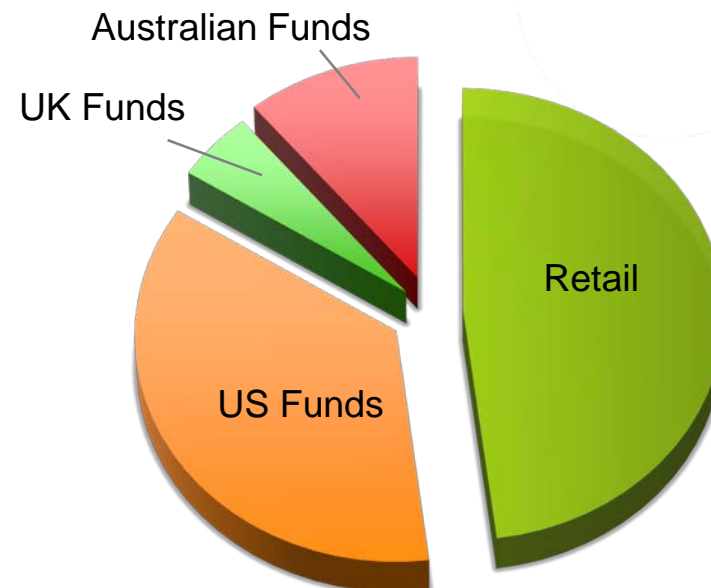
MITCI:
CAVATAK / YERVOY™
Melanoma (US)

CAPRA:
CAVATAK / KEYTRUDA®
Melanoma (US)

Strong Financial Foundation

Key Statistics

Ticker Code	ASX: VLA OTCQX: VRACY
Share Price (May 3, 2016)	A\$0.73
Market Capitalisation	A\$173M
Trading Range (12 month)	A\$0.43 - 0.93
Institutional investors	52%
Cash position (March 31, 2016)	A\$46M
Net operating cashburn 2014/15	A\$2.8M



Leading specialist healthcare institutional investors:

- **BVF Partners** San Francisco
- **Cormorant Asset Management** Boston
- **Quest Asset Partners** Sydney
- **Orbimed Advisors** New York
- **Abingworth** London

Cancer Immunotherapy: Emerging, High-Value Therapeutic Platform

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- Rapidly emerging field, transforming cancer therapy
- Value of oncolytic viruses highlighted by Amgen acquisition of Biovex (TVec™) – US \$425 million cash upfront; US \$575 million future milestone payments
- Multiple recent commercial transactions and collaborations
- Big pharma race to find complementary agents; Merck, BMS, Roche, GSK, Astra Zeneca, Pfizer all active
- Immuno-oncology market size forecast at US \$42 billion per annum¹

“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 – Merck²



**Opportunities for CAVATAK™ in multiple settings
including combination with new agents**

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

Lead Product - Many Indications Under Study

- Proprietary formulation of the cold virus Coxsackievirus A 21
- Targeted to ICAM-1 receptor overexpressed on cancer cells
- Kills local and metastatic cells by both oncolytic *and* immunotherapeutic activity
- Potential application across a range of cancer types:
 - Intratumoral – melanoma, colorectal, breast
 - Intravenous – melanoma, prostate, lung, metastatic bladder
 - Intravesical – non-muscle invasive bladder cancer
- Early clinical evidence of potential to enhance activity of new blockbuster cancer immunotherapies
- Well tolerated in patients
- Manufactured under cGMP at SAFC USA
- Regulatory pathway forged by Amgen's TVec™ - FDA approved in October 2015

Cancer Type	Rank *	Estimated New Cases in the US in 2016 *
Breast	1 st	249,260
Lung	2 nd	224,390
Prostate	3 rd	180,890
Colorectal	4 th	134,490
Bladder	5 th	76,960
Melanoma	6 th	76,380

* USA National Cancer Institute, 2016



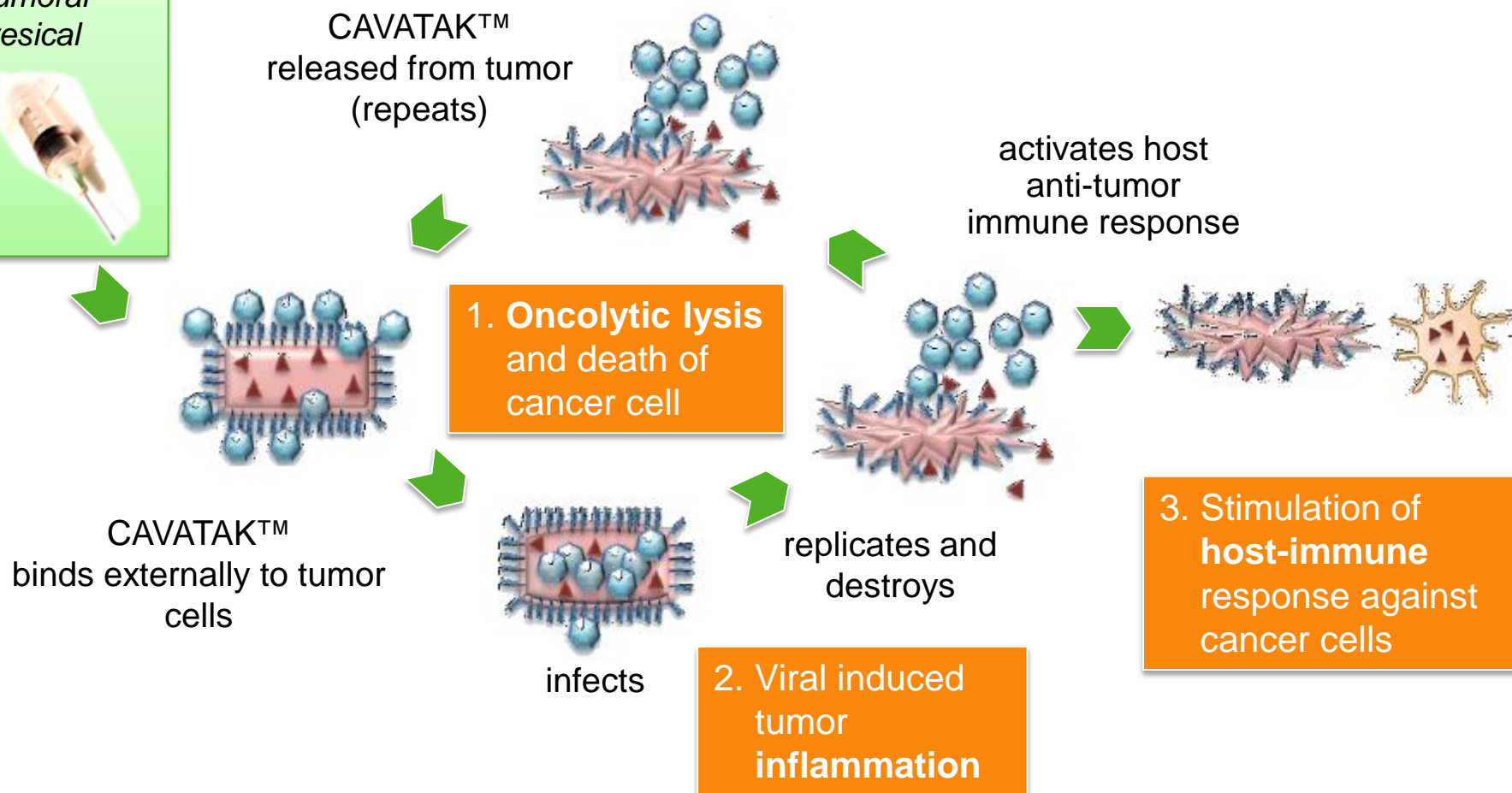
CAVATAK™

Local and Systemic Activity

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Administration

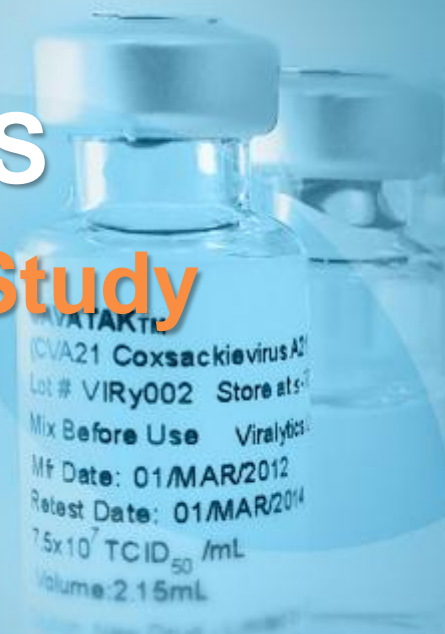
- Intravenous
- Intratumoral
- Intravesical





CLINICAL TRIAL PROGRESS

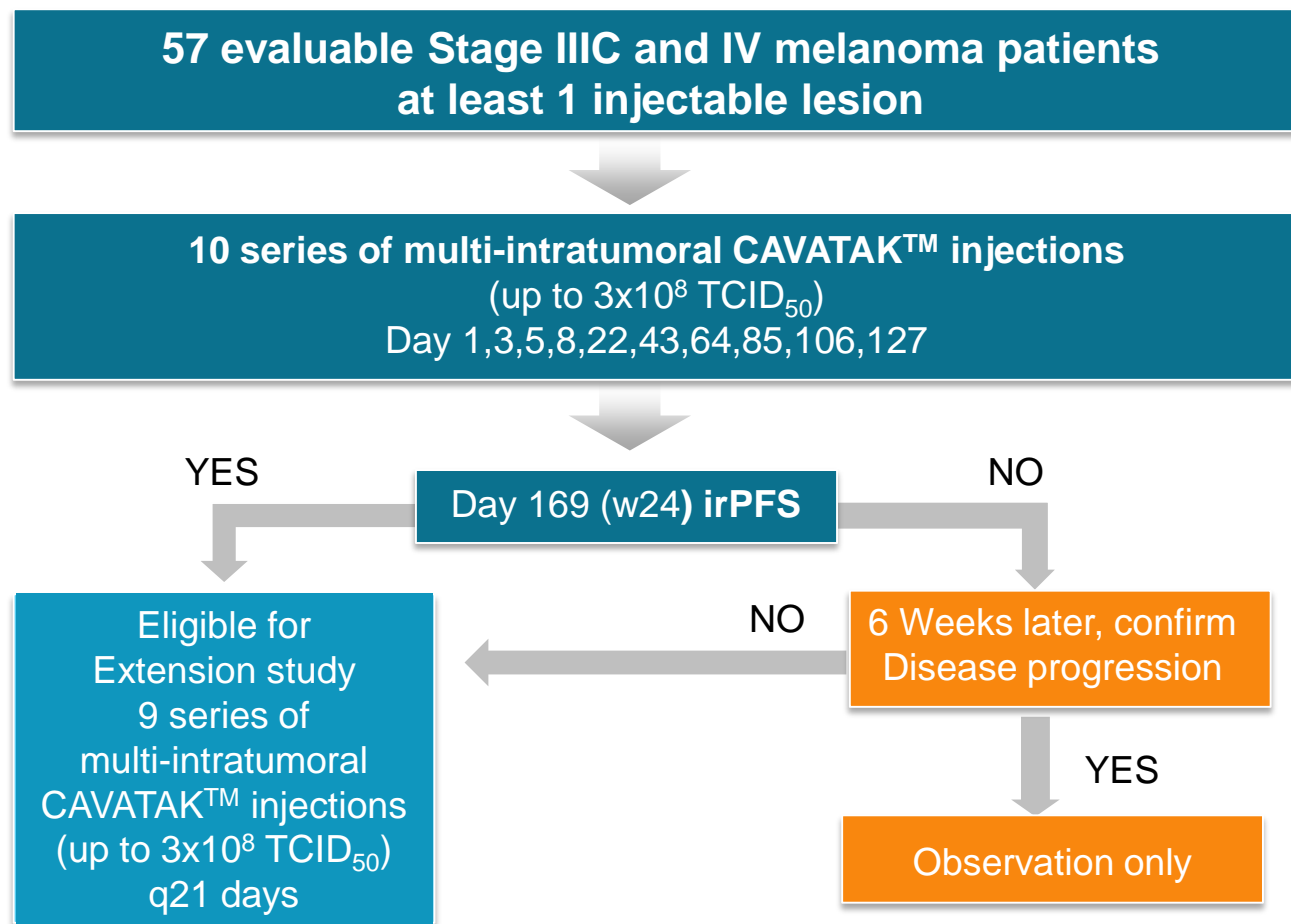
CALM Phase 2 Melanoma Study



CAVATAK™ – Phase 2 CALM Melanoma Study

(CAVATAK IN LATE STAGE MELANOMA)

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- 11 leading US cancer centres
- Primary endpoint achieved
- Responses in injected and metastatic (non injected) tumors
- Well tolerated
- **Final results at ASCO June 2015**

CAVATAK™ – Phase 2 CALM Melanoma Study / Biovex OncoVex™ Results

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	Viralytics CAVATAK™ Phase 2 CALM Melanoma Final Data *	Biovex OncoVex™ Phase 2 Melanoma Final Data ^
Number of patients	57	50
Stage of Disease	IIIC-IV	IIIC-IV
Primary Endpoint ≥ 10/ 54 patients with ir Progression-Free Survival at 6 months	39% (22/57)	Not reported
One-year survival rate	75.4% (43/57)	58%
Median Overall Survival (OS)	26.7 months	Not reported **
Overall Response Rate	28% (16/57) 8 CR's + 8 PR's	26% (13/50) 8 CR's and 5 PR's
Durable Response Rate (DRR)	21% (12/57)	Not reported **
Median Time to Response (TTR) Onset	3.4 months	Not reported **
Activity in injected and non injected lesions	✓	✓
No grade 3 or 4 drug-related adverse events	✓	

* Final data lodged with ASX and Investigator assessed (refer ASX announcement and ASCO poster presentation for full details)

^ Data from Senzer et al, 2009. J. Clin.Oncol., (34):5763-7

** Median OS of 23.3 months, DRR of 16% and Median TTR reported at 4.1 months in Phase 3 trial ESMO 2013

CALM Phase 2 Trial:

CAVATAK™ — Well Tolerated in Clinical Testing

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CAVATAK-related adverse events

AE Term	*Grade 1 n(%)	Grade 2 n(%)	Grade 3 n(%)	Grade 4 n(%)
Injection site pain	16 (28%)	2 (4%)		
Tiredness (fatigue)	15 (26%)	2 (4%)		
Chills	15 (26%)			
Pyrexia	7 (12%)			
Injection site erythema	7 (12%)			
Myalgia	6 (11%)			
Headache	6 (11%)			
Hyperhidrosis	5 (9%)			

No drug-related
grade 3 or 4 or serious
adverse events

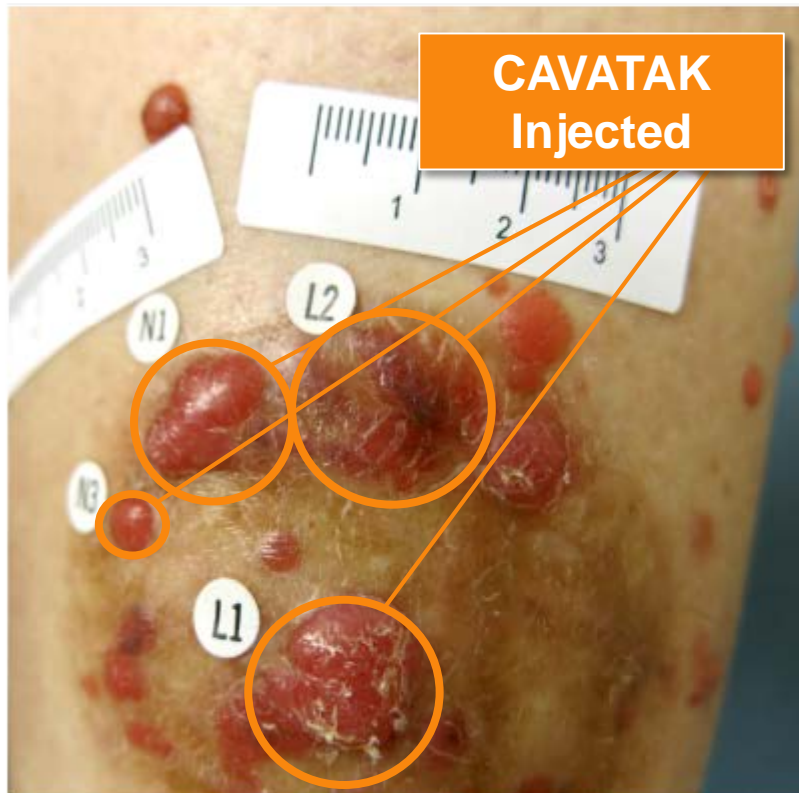
Toxicity is a well
recognized shortcoming
in established therapies
and new cancer
immunotherapies

* Only Grade 1 AE's occurring in $\geq 10\%$ of patients are listed.

CALM Phase 2 Trial:

Local Injected And Non-injected Lesion Responses

Baseline



Day 85



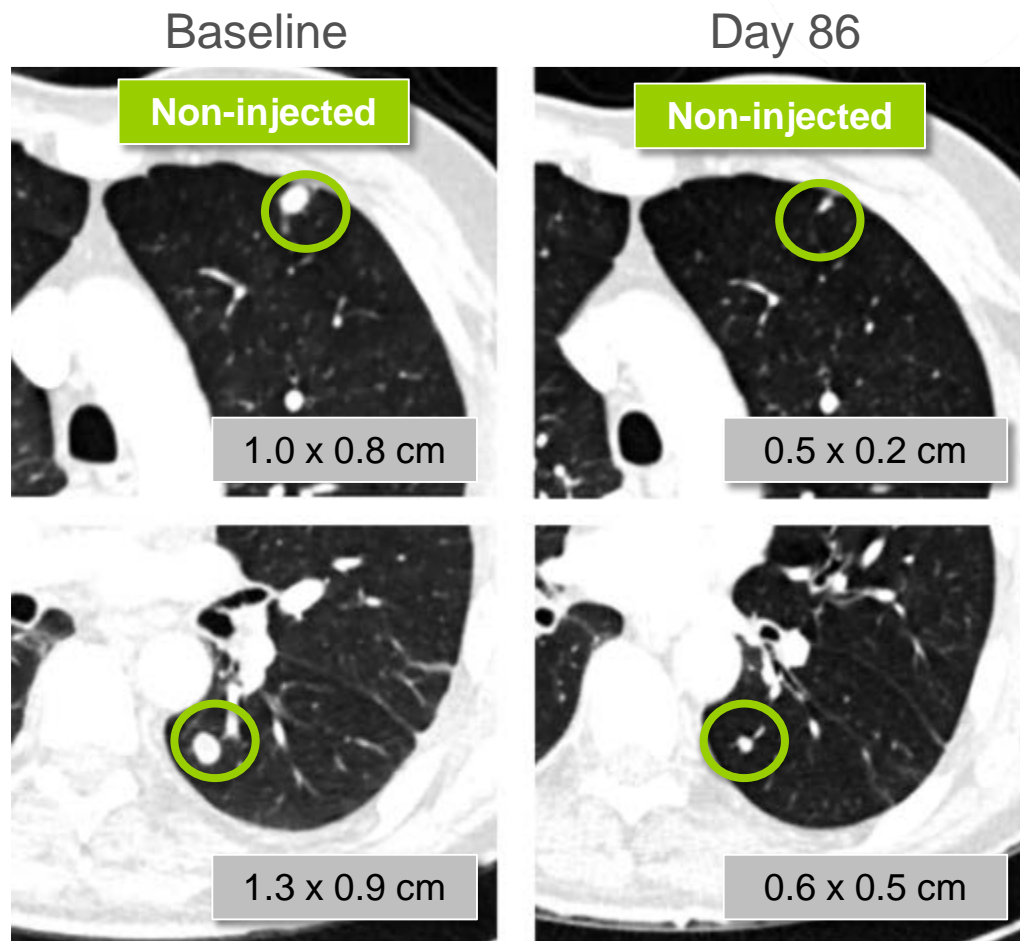
Male with metastatic melanoma to the leg. Injection in leg lesions.

CALM Phase 2 Trial:

Non-injected Distant Visceral Lesion Response



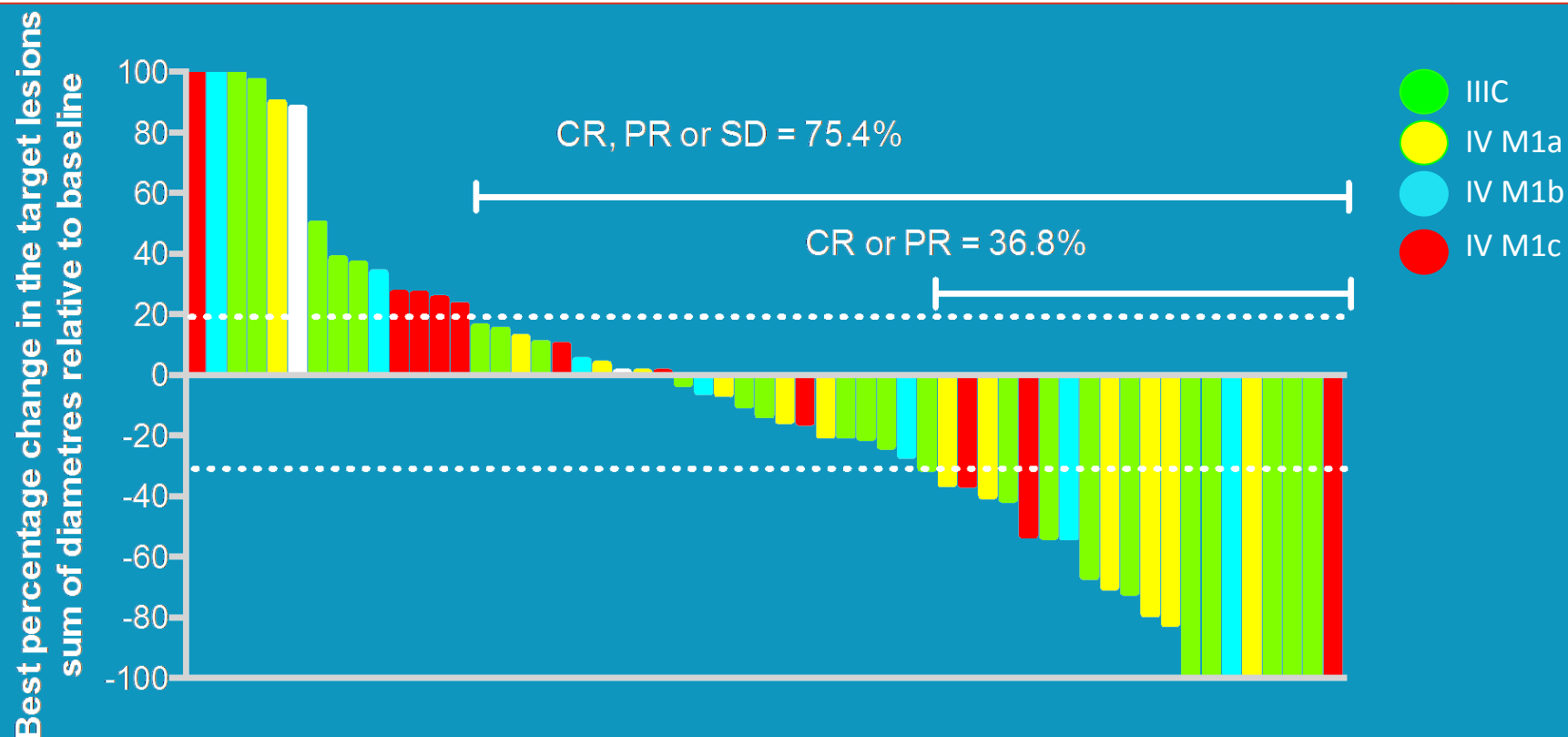
Male with metastatic melanoma to left neck and lungs. Injection in left neck.



CALM Phase 2 Trial:

Best Percentage Changes in Target Lesions

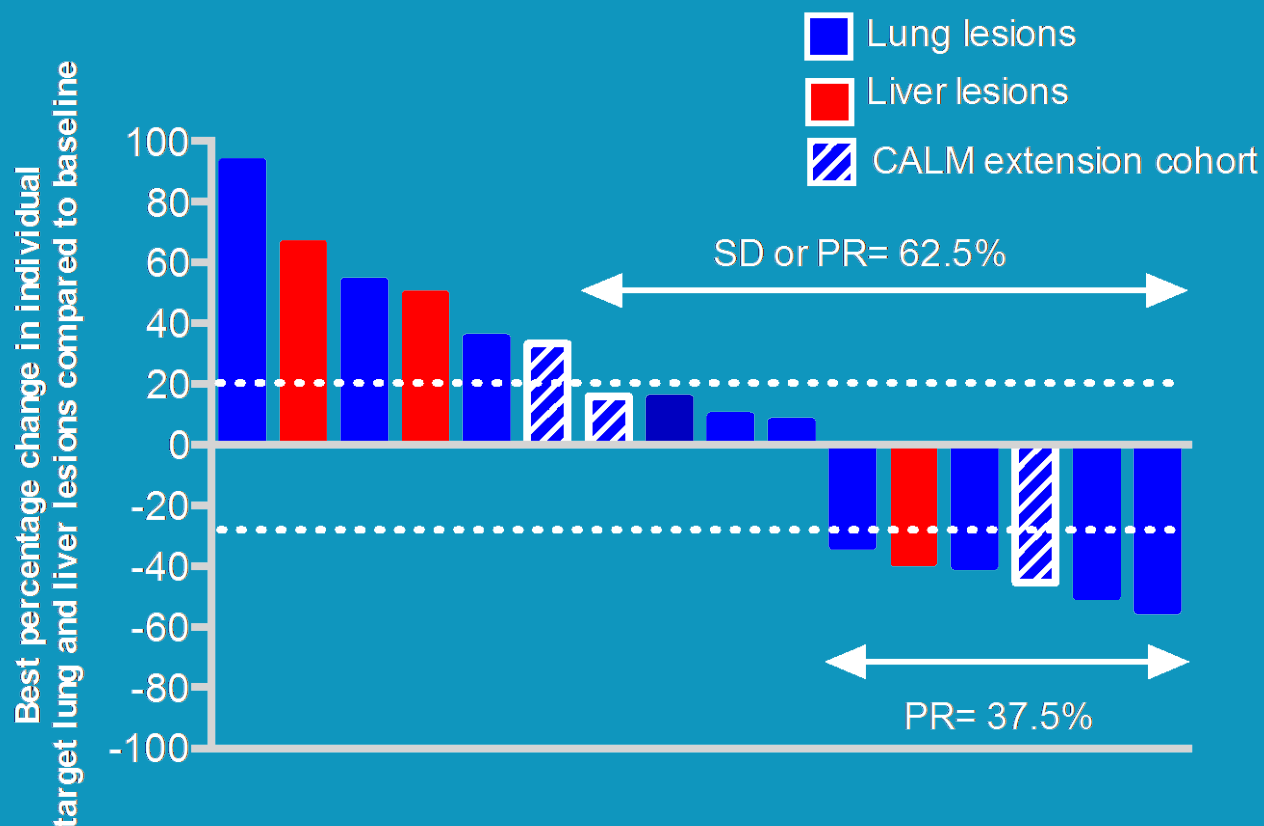
14



• Analysis excludes patients satisfying protocol criteria but not on study long enough for 6 week tumor response assessment;
CR=Complete response, PR= Partial response, SD= Stable disease and PD= Progressive disease

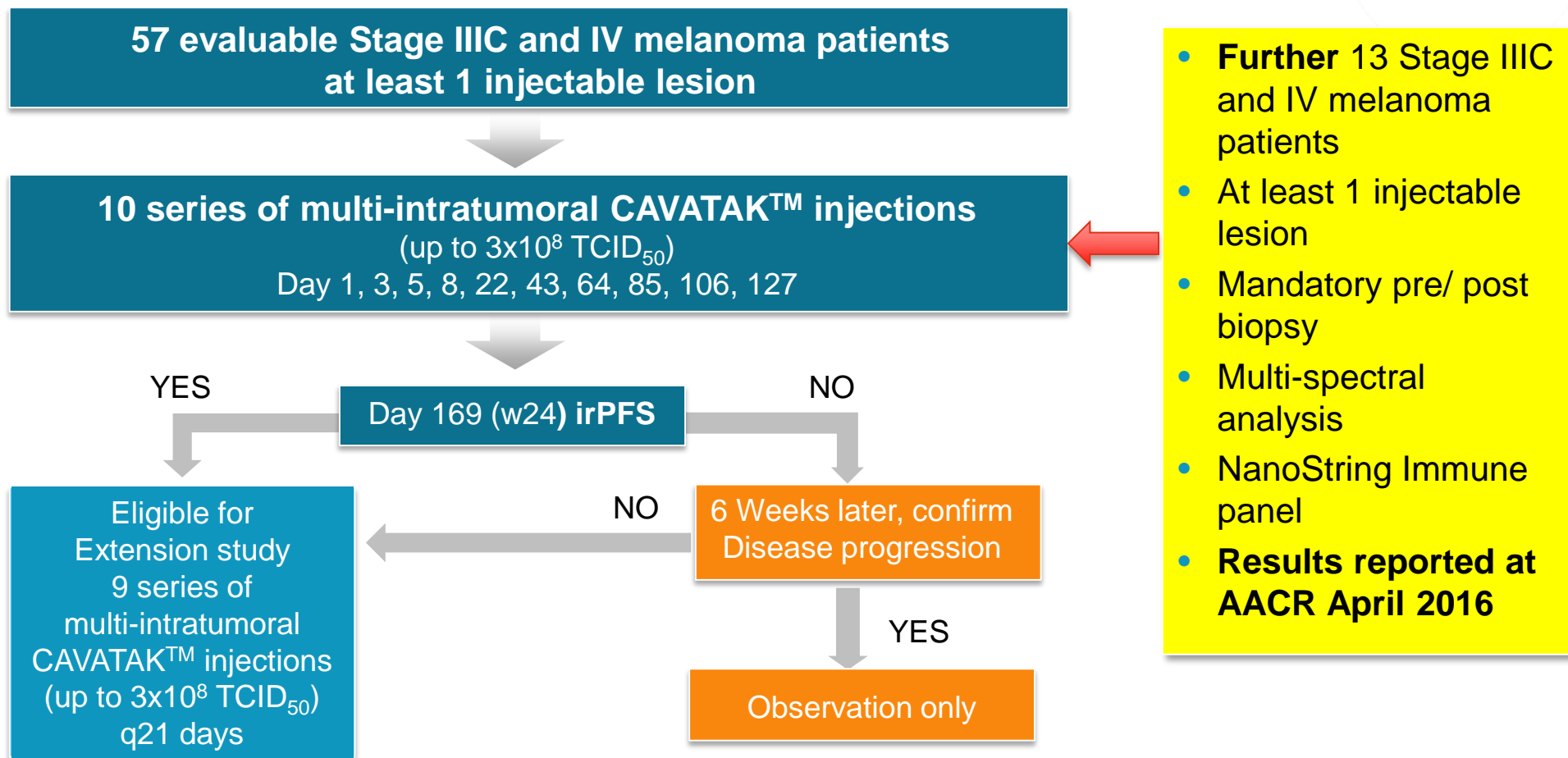
CALM Phase 2 Trial:

Best Percentage Change in Non-injected Target Lung and Liver Lesions



CALM Phase 2 Trial: Extension Cohort (Biopsy Study) Overview

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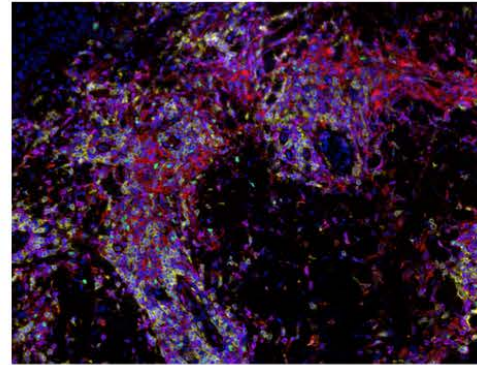
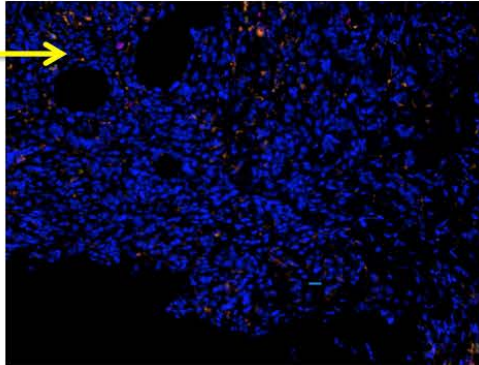


CALM Phase 2 Trial: Extension Cohort (Biopsy Study) – When Checkpoint Inhibitors Fail

Pt 04-015

Day 0 (pre-treatment)

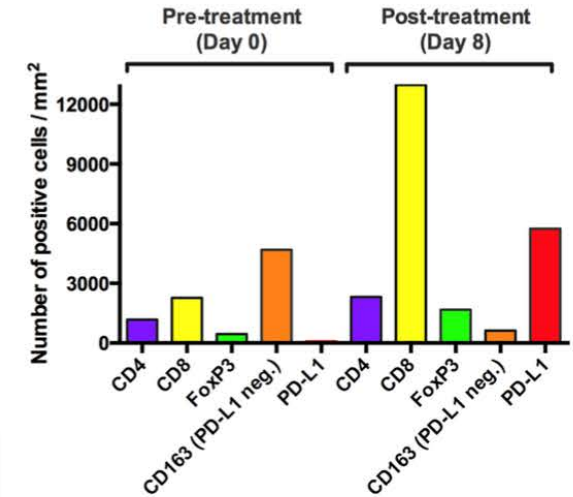
Day 8 (post-treatment)



- Female: Stage IIIC with melanoma to legs
- Prior treatment with ipilimumab and pembrolizumab

■ PD-L1
■ CD3
■ CD8
■ FoxP3
■ CD163
■ DAPI

Partial Response in both patients



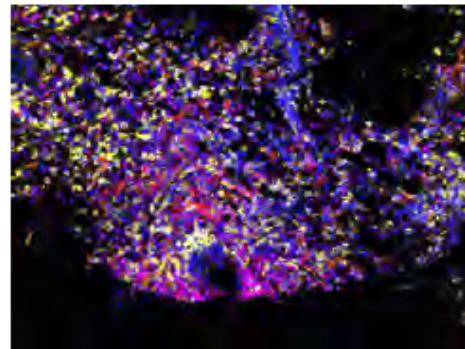
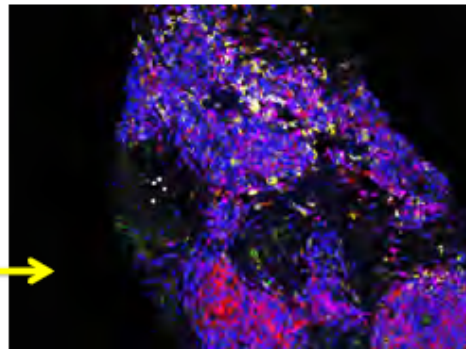
Pt 03-044

Day 0 (pre-treatment)

Day 8 (post-treatment)



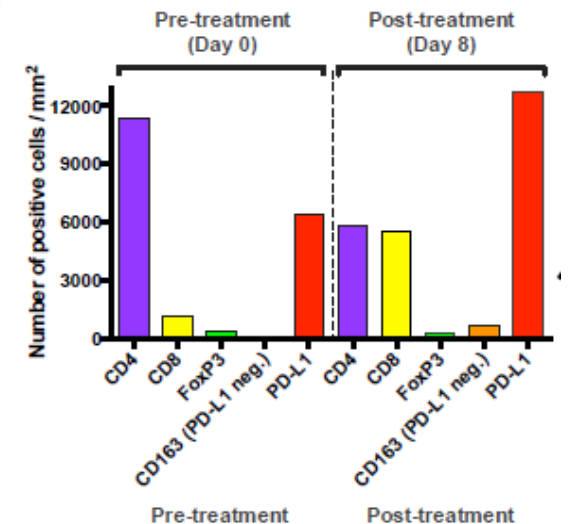
Injected



- Female: Stage IIIC with melanoma to back
- Prior treatment with ipilimumab and talimogene laherparepvec

Day 0

Day 8



CALM Phase 2 Trial: Results and Future Directions

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- Successful study with primary endpoint achieved
- Significantly exceeded secondary endpoints
 - Overall response rate of 28%
 - Durable response in 21% patients
- Activity in non-injected distant lesions, including lung and liver metastases



Extension Trial

- Overall response rate of 31%
- CAVATAK-induced changes in the tumor:
 - Increases in immune cell infiltrates
 - Up-regulation of PD-L1 and other checkpoint molecules
- Observations suggest combination with checkpoint inhibitors may result in enhanced anti-tumor activity



CLINICAL TRIAL PROGRESS

Combination Therapy Studies



CAVATAK™ Combined with Checkpoint Inhibitors

- Preclinical checkpoint inhibitor / CAVATAK combination studies:
 - Well tolerated
 - Significant anti-tumor activity demonstrated
- Checkpoint inhibitors active in cancers that are also targets for CAVATAK, including melanoma, lung and bladder
- CAVATAK combination clinical trials with approved checkpoint inhibitors underway
- Potential for CAVATAK in combination with future checkpoint inhibitors targeting LAG-3, TIM-3, IDO (in development by big pharma)

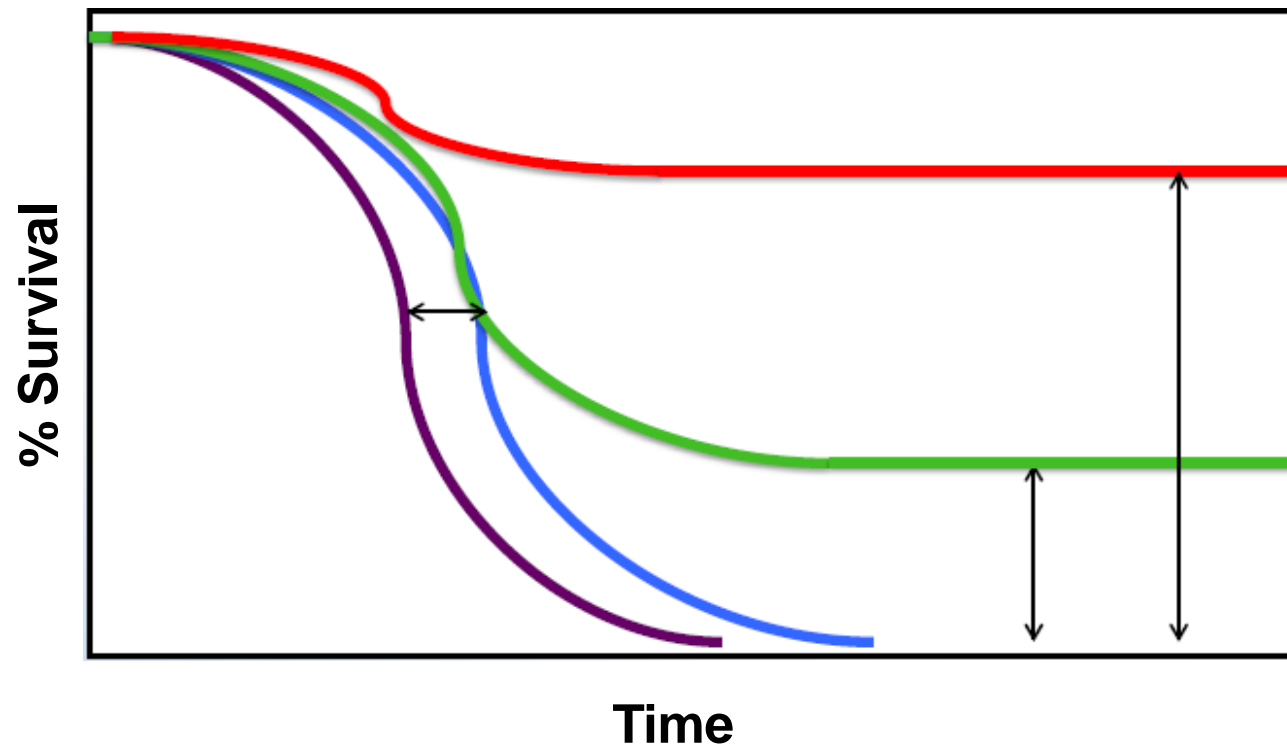
Checkpoint inhibitors:

- Anti-PD-1 mAb approved in USA (e.g. Merck - KEYTRUDA® and BMS - OPDIVO™) in late stage melanoma and lung cancer patients.
- Merck, Astra Zeneca, BMS and Roche have anti-PD-1 / PD-L1 mAb in development in a range of cancer types.

Anti-CTLA4 mAb approved globally (BMS - YERVOY™) in melanoma.

Checkpoint Inhibitors:

Room to Improve Through Combination with New Therapies



- Control
- Conventional Therapy
- Checkpoint Inhibitor Therapy (eg anti-CTLA4)
- Future Combinations with Checkpoint Inhibitors

Big Pharma focused on improving activity of the checkpoint inhibitors through combination therapy

Goal: To enhance survival with manageable toxicity through combination with CAVATAK

Melanoma - Next Steps in Clinical Development

CAVATAK in combination with checkpoint inhibitors being evaluated in late-stage melanoma patients

Intralesional

- MITCI Phase 1b Trial: CAVATAK / anti-CTLA-4 (YERVOY™)
- CAPRA Phase 1b Trial: CAVATAK / anti-PD-1 (KEYTRUDA®)

Intravenous

- Study in planning stage

“The observation of CAVATAK-induced immune cell infiltration within the tumor, combined with the encouraging results seen in the CALM trial, point to CAVATAK as an investigational agent with real promise in combination with checkpoint inhibitors such as anti-CTLA-4 (YERVOY™) and/or anti-PD-1 (KEYTRUDA®).”

Dr Robert Andtbacka - Huntsman Cancer Institute

“ I am eager to explore the combination of CAVATAK and KEYTRUDA® in human trials. Although KEYTRUDA® and other checkpoint inhibitors represent a major advance in the treatment of melanoma, there is great interest in the potential of oncolytic viruses such as CAVATAK to improve upon these outcomes in patients with melanoma.”

Dr Howard Kaufman – Rutgers Cancer Institute



CLINICAL TRIAL PROGRESS

MITCI Phase 1b Study



CAVATAK™ - MITCI Phase 1b Study

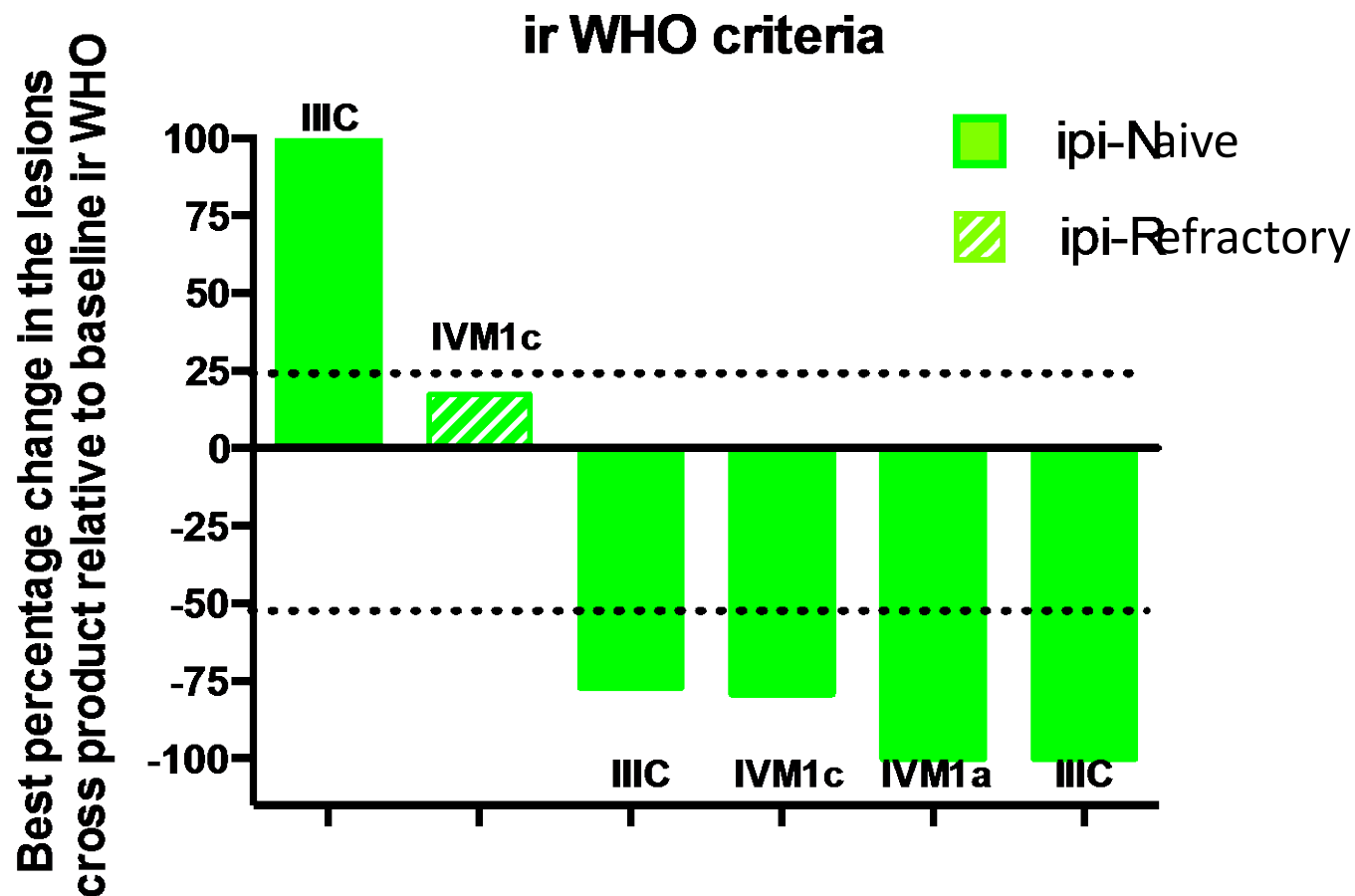
MELANOMA INTRA-TUMORAL CAVATAK AND IPILIMUMAB

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- Phase 1b company-sponsored open label study at 4 US sites
- Intralesional CAVATAK and YERVOY™ (ipilimumab)
- Primary Objective:
 - Evaluate safety and tolerability (assessed by incidence of dose-limiting toxicities)
- Secondary Objective:
 - Determine objective response rate
- 26 patients with late-stage melanoma (stage IIIC/ IV)
- Lead investigator: Dr Brendan Curti MD, Providence Cancer Center, Portland
- Treatment with CAVATAK on days 1, 3, 5 and 8; both agents co-administered on days 22, 43, 64 and 85
- Patients with clinical benefit can continue for up to one year

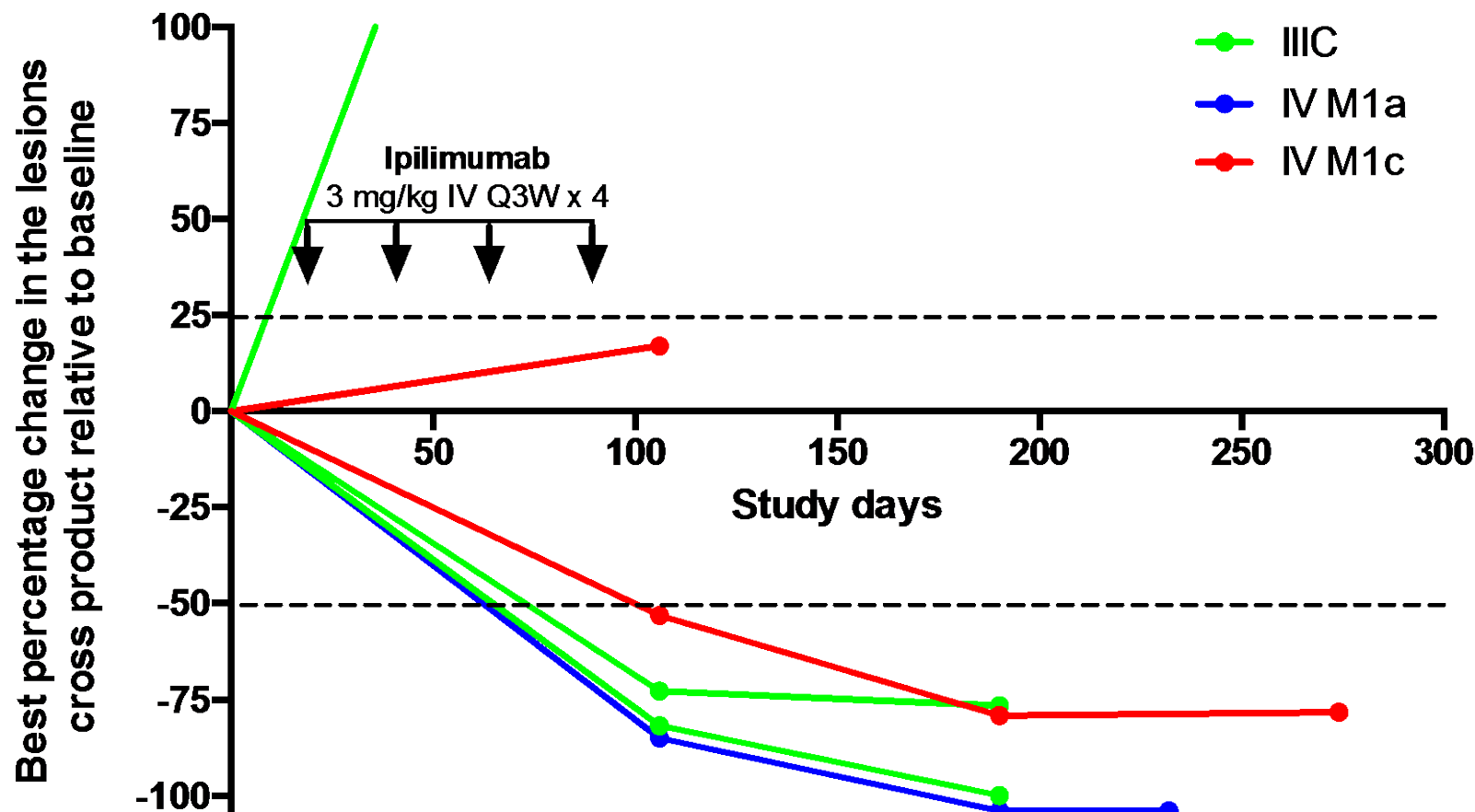
CAVATAK™ - MITCI Phase 1b: Early Results - Best Overall Response

25



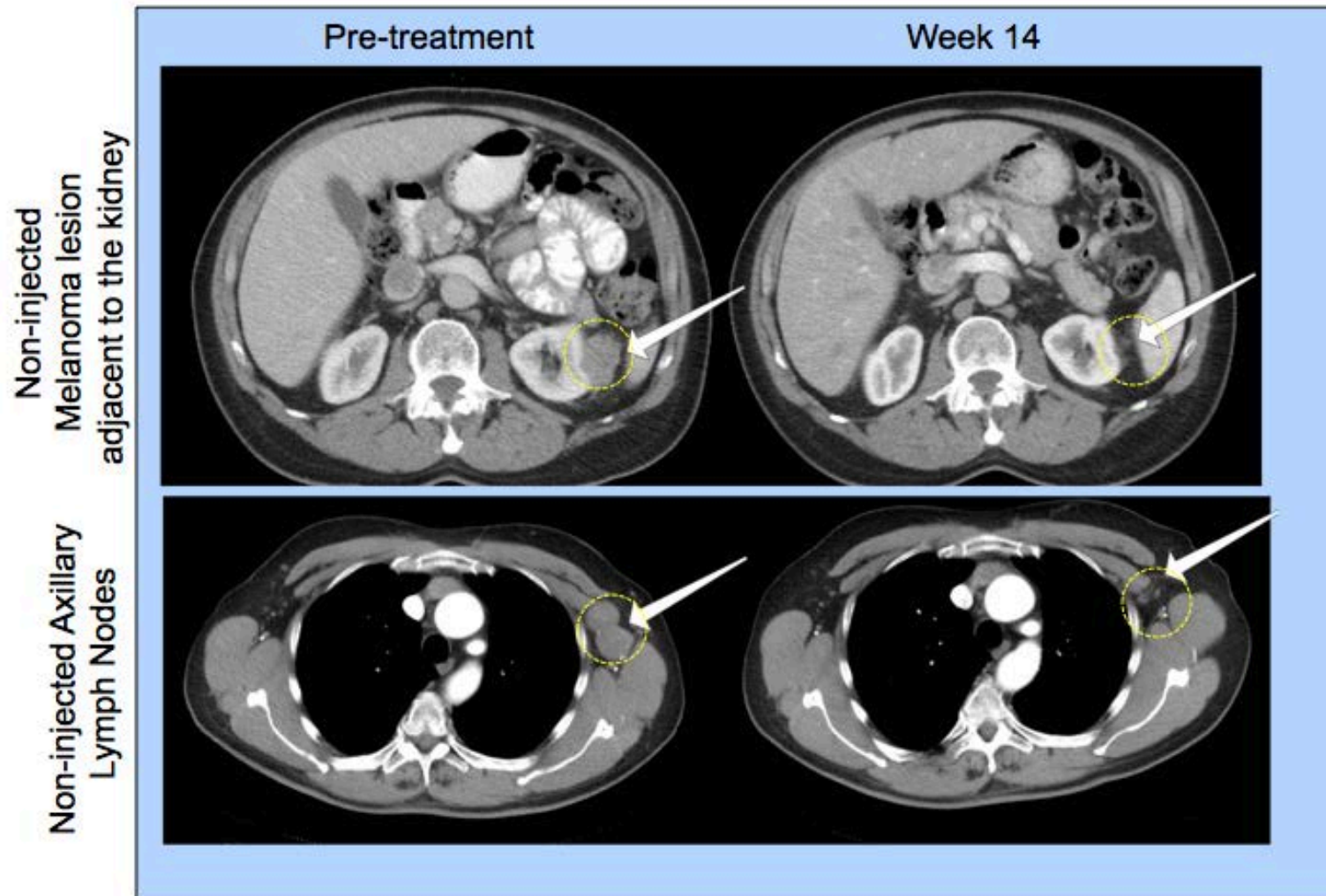
CAVATAK™ - MITCI Phase 1b: Early Results - Response by Cancer Stage

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CAVATAK™ - MITCI Phase 1b Study:

Partial Tumor Response Stage IV M1c (Pt 13-12003)*



CAVATAK™ - MITCI Phase 1b Study:

Complete Tumor Response Stage IIIC (Pt 13-5001)

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Baseline



One month



Three months



Six months

CAVATAK™ - MITCI Phase 1b Study:

Current MITCI Data and Other Key Published Studies

	Ipilimumab and Pembrolizumab (Phase 3)*	Ipilimumab and TVEC (Phase 1b)	Ipilimumab and CAVATAK (Phase 1b)
Number of patients	314	18	11
Stage of Disease	IIIC-IV	IIIB-IV	IIIC-IV
Best Overall Response Rate	57.6%	50% [¶]	66.7% (80% [¶])
Disease Control Rate	70.8%	73%	83.3% [#]
Grade 3 + Drug related Adverse Events (%)	55%	32%	9%

References at: <http://www.viralytics.com/our-pipeline/scientific-presentations/scientific-presentations-2016/>

[¶] Ipilimumab naïve patients

[#] 6 patients evaluable for tumor assessment

CAVATAK™ - MITCI Phase 1b Study:

Preliminary Results and Outlook

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- CAVATAK / YERVOY combination well tolerated and displays antitumor activity in both local and systemic disease
- Safety:
 - No dose-limiting toxicities reported
 - One Grade 3 (YERVOY-related) fatigue adverse event
- Efficacy:
 - 4 out of 5 of YERVOY-naïve patients demonstrated a confirmed overall response, with 2 complete responses and 2 partial responses in preliminary results
 - Preliminary results better than monotherapy – CAVATAK: 28% and monotherapy YERVOY: ~11%
 - Preliminary but encouraging results, compared to published data about other YERVOY combinations
- Acceleration of enrolment underway
- Further update second half 2016

Potential to lead to a pivotal study



CLINICAL TRIAL PROGRESS

CAPRA Phase 1b Study



CAVATAK™ - CAPRA Phase 1b Study

CAVATAK AND PEMBROLIZUMAB in ADVANCED MELANOMA

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- Phase 1b company-sponsored open label study
- Intralesional CAVATAK and KEYTRUDA® (pembrolizumab)
- Primary objective:
 - Safety and tolerability by incidence of dose-limiting toxicities
- Secondary objective:
 - Efficacy measured by immune-related progression-free survival at 12 months, response and survival
 - 30 patients with late-stage melanoma (stage IIIC/ IV)
- Lead investigator: Dr Howard Kaufman MD FACS, Rutgers Cancer Institute of New Jersey, New Brunswick
- CAVATAK on Days 1, 3, 5 and 8; KEYTRUDA starting on Day 8, both given at three-weekly intervals for up to 2 years (maximum of 19 total injections)

Potential to lead to a pivotal study



CLINICAL TRIAL PROGRESS

STORM Phase 1 Study

Part A – Monotherapy

Part B – KEYTRUDA combination ‘Keynote-200’



Multi-dose Intravenous CAVATAK™ — STORM Phase 1 Study: (SYSTEMIC TREATMENT OF RESISTANT MALIGNANCIES)

VLA-009A (Monotherapy)

18 subjects with advanced melanoma, prostate, NSCLC or bladder cancer with <1:16 anti-CAVATAK serum antibodies

IV infusions of CAVATAK in 100 mL saline over 30 min on Day 1,3,5,21,43,64,85,106,127,158

Cohort 1
Any cancer
 1×10^8 TCID₅₀
n=3

Cohort 2
Any cancer
 3×10^8 TCID₅₀
n=3

Cohort 3
 1×10^9 TCID₅₀
Mandatory lesion biopsy (Day 8)
Melanoma, NSCLC, Bladder
And Prostate cancer n=3 each

VLA-009B / KEYNOTE-200 (Combination with KEYTRUDA)

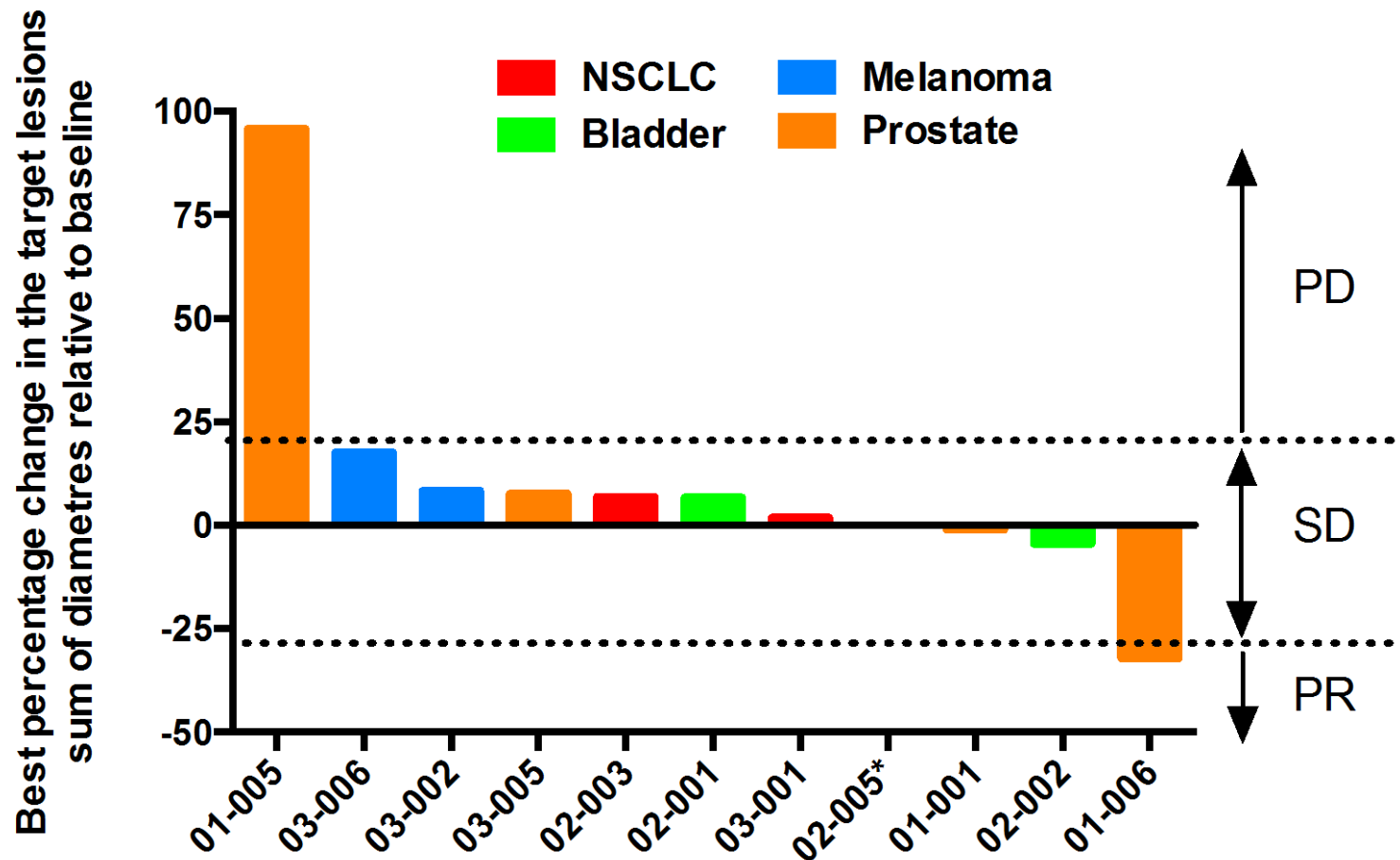
Cohort 1
NSCLC or Bladder cancer
CAVATAK (1×10^8 TCID₅₀)
+ Keytruda
n=3

Cohort 2
NSCLC or Bladder cancer
CAVATAK (3×10^8 TCID₅₀)
+ Keytruda
n=3

Cohort 3: Expansion
NSCLC or Bladder cancer
CAVATAK (1×10^9 TCID₅₀)
+ Keytruda
~n=80

STORM Phase 1 Study - Part A: Best Percentage Change in Target Lesions

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*, No lesion assessment available

STORM Phase 1 Study - Part A:

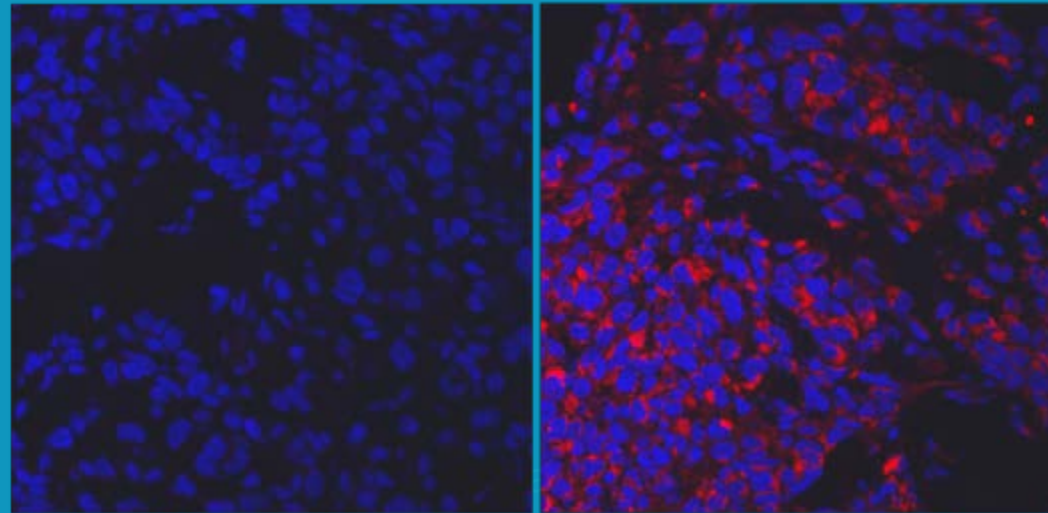
CAVATAK Tumor Targeting: Biopsy Viral Protein Staining (day 8): Cohort 3

36

Control

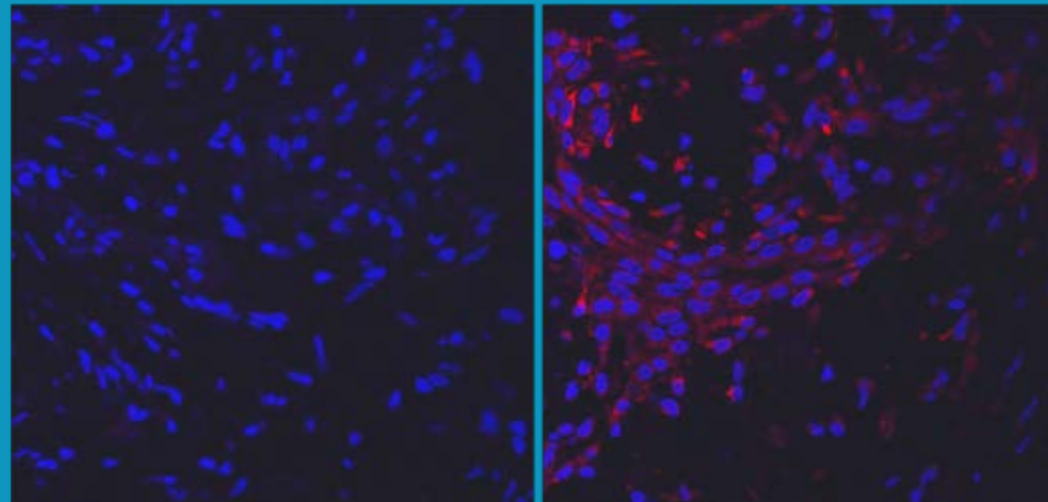
Anti-enterovirus

Pt 02-005



CAVATAK present in melanoma cells after intravenous delivery

Pt 03-006



 Nucleus

 Cytoplasmic CAVATAK viral proteins

STORM Phase 1 Study - Part A: Preliminary Results

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- Part A – 18 patients planned
 - Advanced melanoma, prostate, lung and metastatic bladder cancers
- Well tolerated in first 17 patients (including 3rd cohort)
- Encouraging preliminary results with anticancer activity in some individual lesions
- Signs of possible secondary tumor specific viral replication in some patients
- Evidence of tumor targeting with all 3 melanoma patients in Cohort 3 displaying CAVATAK replication in tumor biopsies
- Several patients have shown disease stabilization, with 1 of 5 patients in cohort 3 displaying a confirmed partial response (RECIST 1.1)

Cancer Type	Rank *	Estimated New Cases in the US in 2016 *
Breast	1 st	249,260
Lung	2 nd	224,390
Prostate	3 rd	180,890
Colorectal	4 th	134,490
Bladder	5 th	76,960
Melanoma	6 th	76,380

* USA National Cancer Institute, 2016

**Potential to
significantly broaden
applications and
expand partnering
discussions**

STORM Phase 1 Study - Part B / Keynote-200:

CAVATAK/ Merck's KEYTRUDA® Combination

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- Phase 1b study in progress; collaboration with Merck
- Combination of intravenous CAVATAK / KEYTRUDA in late-stage cancer patients (~ 80 patients)
 - Non-small cell lung cancer
 - Metastatic bladder cancer
- ~10 sites in the US and UK
- Primary objective:
 - Safety and tolerability
- Secondary objective:
 - Efficacy

“We believe that there may be potential benefit in combining CAVATAK with our anti-PD-1 therapy, KEYTRUDA – which have different, yet complementary approaches to engaging the immune system to fight cancer –and look forward to seeing results from this study.”

Dr Eric Rubin, Vice President and
Therapeutic Area Head, Oncology
Early-stage Development, MSD
Research Laboratories

 **Potential to lead to a pivotal study**



CLINICAL TRIAL PROGRESS

CANON Phase 1 Study



CAVATAK™ — CANON Phase 1 Study:

(CAVATAK in NON-MUSCLE INVASIVE BLADDER CANCER)

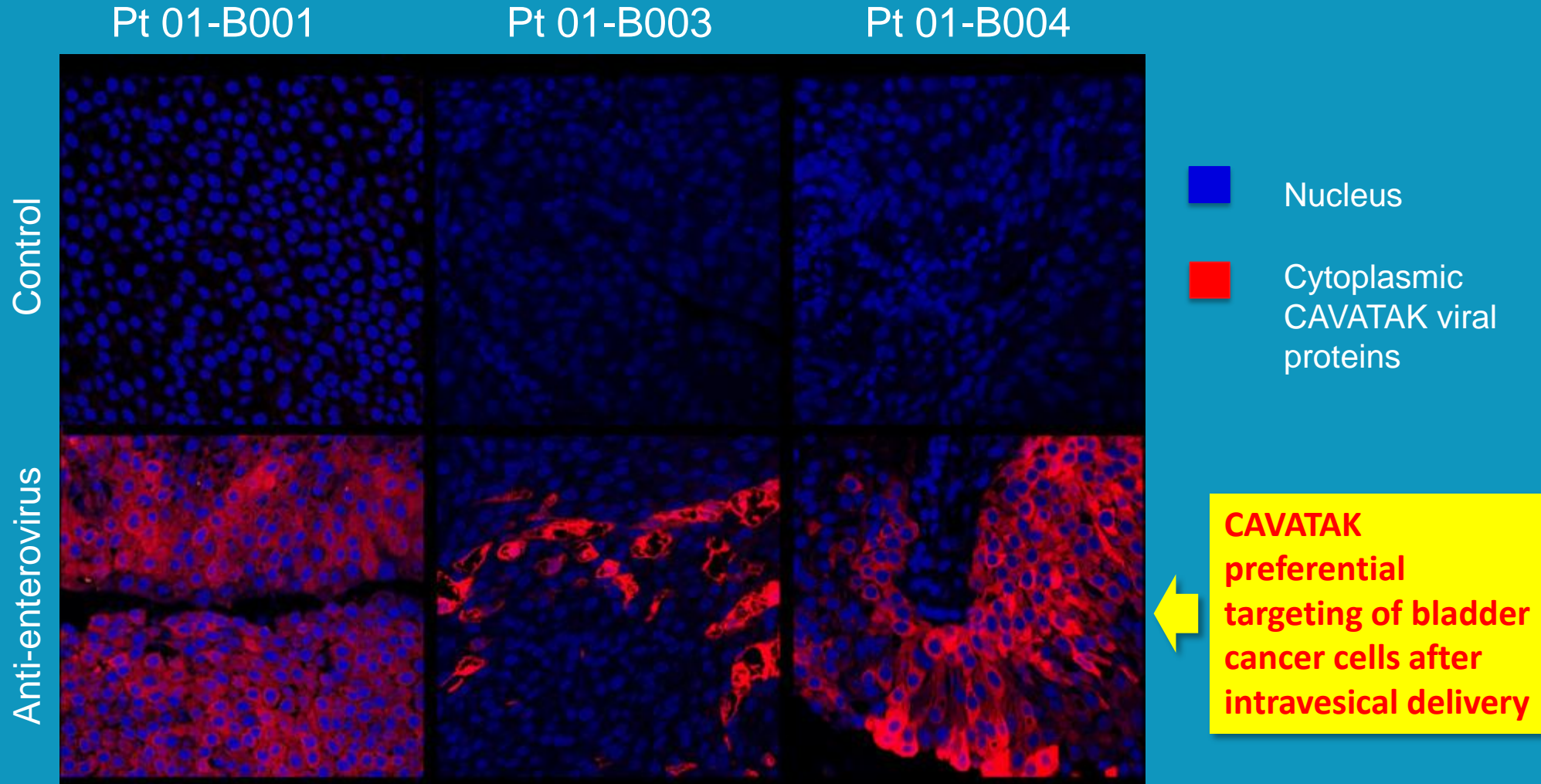
- Common cancer - high unmet need, no recent advances
- Standard of care includes toxic chemotherapies
- CAVATAK active in preclinical studies
- Study to assess intravesicular CAVATAK in neo-adjuvant, frontline setting:
 - Evaluating safety and tolerability of CAVATAK given alone and in combination with the standard chemotherapy, mitomycin C
 - Evaluating biopsies, blood and urine samples for viral replication
 - Examining the pharmacodynamics of CAVATAK and documenting evidence of anti-tumor activity
- Enrollment complete, 16 patients in 2 stages at Royal Surrey Hospital, UK

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Melanoma	6 th	76,380

* USA National Cancer Institute, 2016

CAVATAK™ — CANON Phase 1 Study:

Intralesional CAVATAK Viral Protein in Transurethral Resection Tissue; Cohort 1: 1×10^8 TCID₅₀



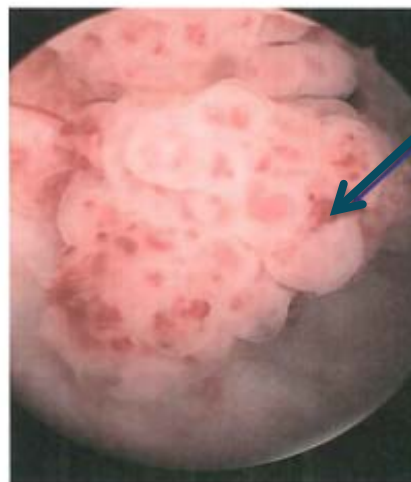
CAVATAK™ — CANON Phase 1 Study: Tumor Response Pre-and Post CAVATAK

**Cohort 1:
Pt 01-B001**

Pre-treatment

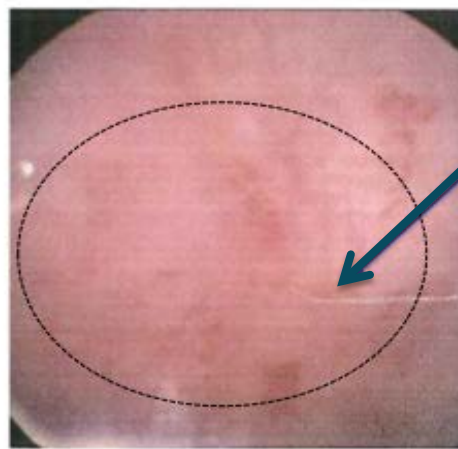
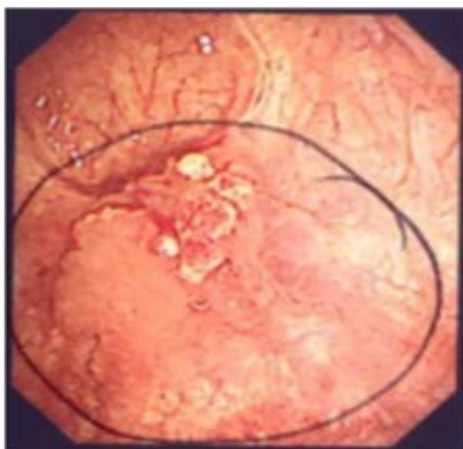


Post-treatment Day 8



**Surface
hemorrhage and
elimination of the
tumor**

**Cohort 3:
Pt 01-B008**




**Complete clinical
response
(confirmed by
histopathology)**

CAVATAK™ — CANON Phase 1 Study: Preliminary Results and Next Steps

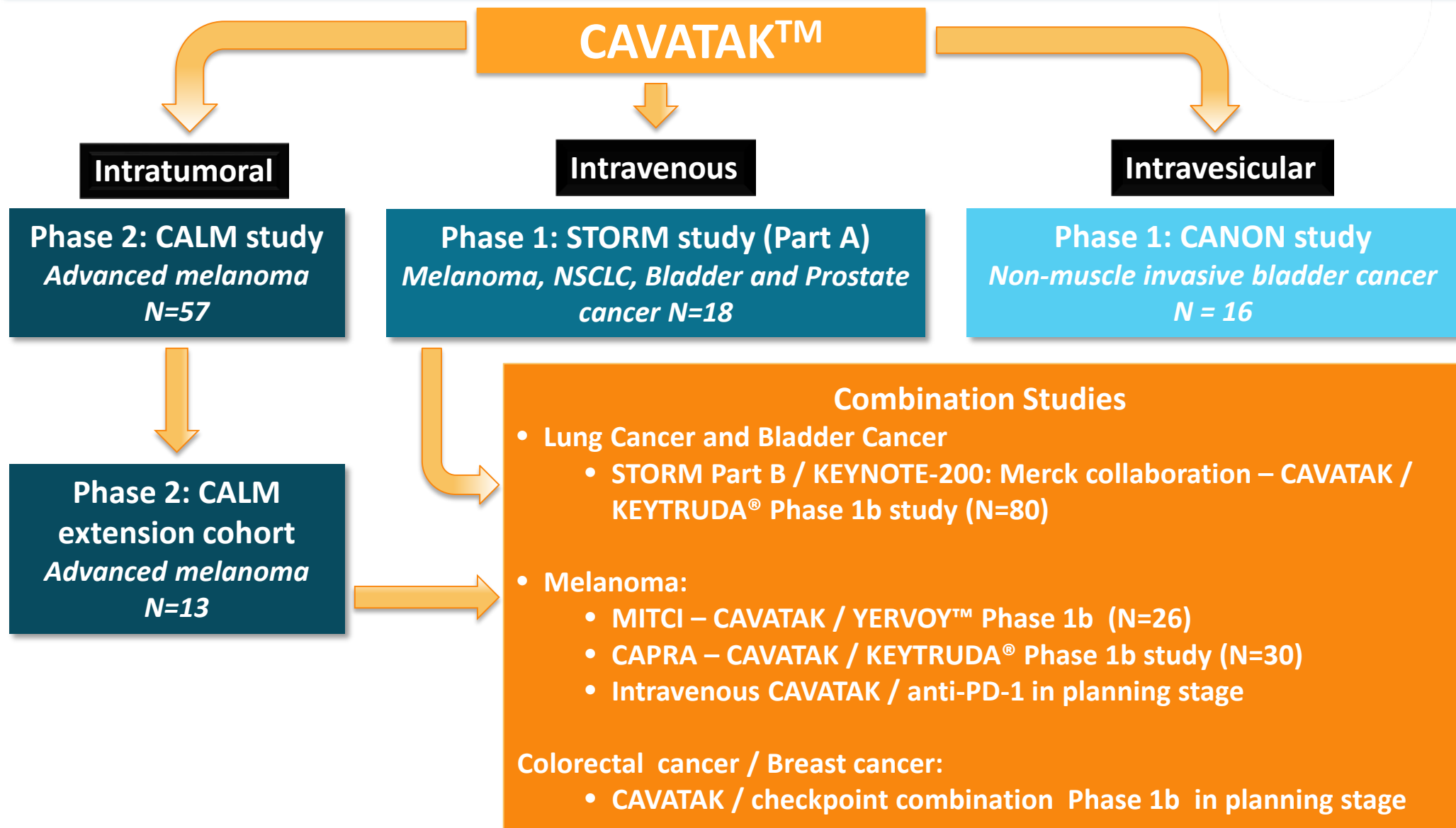
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- Intravesicular administration of CAVATAK as monotherapy generally well tolerated - no Grade 2, 3 or 4 CAVATAK-related AE's
- Evidence of tumor targeting with viral replication
- Complete response in one of the first 3 patients at the highest dose
- Potential to generate strong local *and* systemic antitumor immune response
- Commercial opportunity in neoadjuvant setting - prior to transurethral resection of tumor *or* in combination with checkpoint inhibitors

 **Potential to broaden partnering discussions**

SUMMARY





Deep Clinical Development Experience

Dr Darren Shafren
*Chief Scientific Officer,
 inventor of CAVATAK™*

25 years' experience in
 oncolytic virotherapy and
 cancer cell interactions

Dr Leonard Post
Director

Biomarin CSO
 formerly Onyx, Biovex

Extensive experience including
 Nexavar™ from IND through
 FDA approval for kidney cancer

Dr Robert Andtbacka
*CALM Phase 2
 Principal Investigator*

MITCI Phase 1b Investigator

Huntsman Cancer Institute,
 University of Utah

Dr Keith Flaherty
Scientific Advisory Board

Massachusetts General
 Hospital Cancer Center

**Professor Howard
 Kaufman**
*CALM Phase 2 Investigator
 CAPRA Phase 1b Principal
 Investigator*

Rutgers Cancer Institute
 Rutgers, The State University of
 New Jersey

President Society for
 Immunotherapy of Cancer

Professor Hardev Pandha
*STORM and CANON trial
 Principal Investigator*

University of Surrey, UK

Dr Brendan Curti
*CALM Phase 2 Investigator
 MITCI Phase 1b Principal
 Investigator*

Providence Cancer Center
 Portland, USA

Dr Mark Faries
*MITCI Phase 1b
 Investigator*

John Wayne Cancer Institute,
 Los Angeles, USA

A Strong Record of Achievements

Initiate CAPRA (KEYTRUDA® combination) Phase 1b study in melanoma patients

Achieved

Complete Merck collaboration clinical trial agreement

Achieved

Present interim results first stage of STORM Phase 1 study (Part A)

Achieved

Report interim results CANON Phase 1 bladder cancer study

Achieved

Present final results of extension cohort in CALM study

Achieved

Report interim results MITCI (YERVOY™ combination) Phase 1b study in melanoma patients

Achieved

Initiate STORM Part B/Keynote-200 KEYTRUDA combination in lung and bladder patients

Achieved

Compelling Near-Term Value Builders

- CAVATAK™ - strong potential in a range of cancer types
- Collaborators include leading oncologists in US and UK
- Investment by leading global specialist funds
- CALM Phase 2 study – impressive results
- MITCI YERVOY™ combination trial – encouraging data in first 11 patients
- CAPRA KEYTRUDA® combination trial underway
- CANON bladder cancer trial – promising activity and well tolerated
- STORM trial in solid cancers – encouraging initial results
- STORM/KEYNOTE-200 Phase 1b Merck collaboration trial to assess CAVATAK / KEYTRUDA® in lung and bladder cancer patients – underway
- Updates from ongoing open label trials at oncology conferences in 2016
- Growing body of data to drive partnering discussions and shareholder value
- Recent high-value transactions in cancer immunotherapy

Strong pharma company interest in combination strategies

Viralytics corporate strategy to build value through to licensing or partnering transaction



Thank You



Dr Malcolm McColl
Managing Director

Email: malcolm.mccoll@viralytics.com
Web: www.viralytics.com

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