UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 4, 2022

CANDEL THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-40629	52-2214851
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

117 Kendrick St., Suite 450 Needham, MA	02494
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 916-5445

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	**CADL**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 4, 2022, Candel Therapeutics, Inc. held an investor presentation via live webcast in which it presented initial data on CAN-2409 in a phase 2 clinical trial, which showed cytotoxic T Cell response and disease control in patients with non-small cell lung cancer. The investor presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K are furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Investor Presentation dated June 4, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

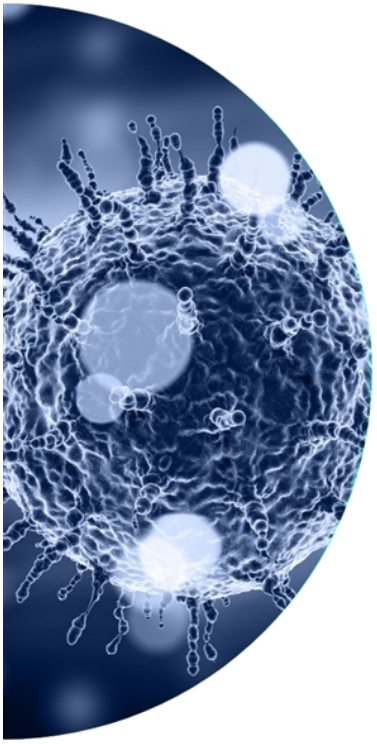
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Candel Therapeutics, Inc.

Date: June 6, 2022

By: /s/ Paul Peter Tak
Paul Peter Tak, M.D., Ph.D., FMedSci
President and Chief Executive Officer

Exhibit 99.1



CANDEL THERAPEUTICS

Breakfast Event during ASCO 2022 Annual Meeting

(NASDAQ: CADL)

Tipping the balance in favor of the immune system to fight cancer

Paul Peter Tak, MD, PhD, FMedSci

President and Chief Executive Officer
Candel Therapeutics, Needham, MA

CANDEL THERAPEUTICS

Forward-Looking Statements

This Presentation contains forward-looking statements and information. All statements other than statements of historical facts contained in this Presentation, including express or implied statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market size, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "target," "seek," "predict," "potential," "continue" or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market size, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Presentation include, but are not limited to, statements about: the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; our ability to efficiently discover and develop product candidates; our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project; our ability to obtain and maintain regulatory approval of our product candidates; our ability to compete with companies currently marketing or engaged in the development of treatments that our product candidates are designed to target; our reliance on third parties to conduct our clinical trials and to manufacture drug substance for use in our clinical trials; the size and growth potential of the markets for our product candidates and our ability to serve those markets; the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; our ability to obtain and maintain adequate intellectual property rights; our estimates of our future expenses, revenue, capital requirements or our need for or ability to obtain additional financing; the potential benefits of strategic collaboration agreements, our ability to enter into additional strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise; our financial performance; developments and projections relating to our competitors or our industry; the effects of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies or current and future clinical trials. We caution the recipient not to place considerable reliance on the forward-looking statements contained in this Presentation. The forward-looking statements in this Presentation speak only as of the date of this document, and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above.

Certain information contained in this Presentation relates to or is based on estimates, projections and other information concerning the Company's industry, its business and the markets for its programs and product candidates and studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this Presentation involves a number of assumptions and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not verified by any independent source.

These forward-looking statements are based on the beliefs of our management, as well as assumptions made by and information currently available to us. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. If such assumptions do not fully materialize or prove incorrect, the events or circumstances referred to in the forward-looking statements may not occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations, except as required by law. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Additional risks and uncertainties that could affect our business are included under the caption "Risk Factors" in our most recent report filed with the Securities and Exchange Commission.

Candel overview: Oncolytic viral immunotherapies

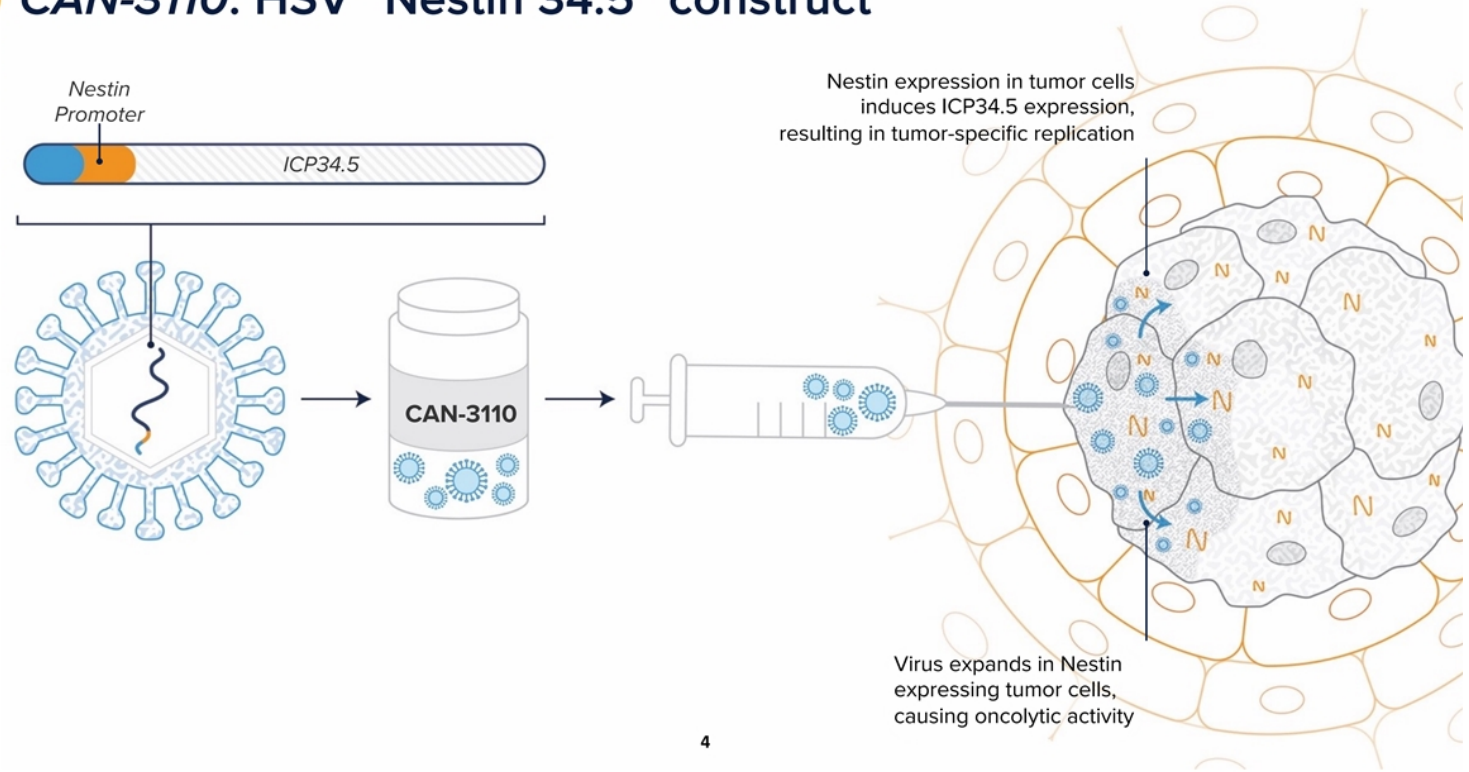
Two clinical stage investigational medicines and an innovative discovery platform

- CAN-3110
  - Engineered, replication-competent herpes simplex virus with tumor-specificity
  - Ongoing phase 1 clinical trial in recurrent HGG
  - Potential for expansion of indications

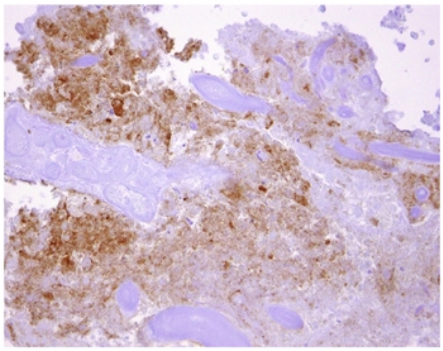
- CAN-2409
  - Engineered, non-replicating adenoviral gene construct encoding HSV-thymidine kinase
  - Ongoing clinical trials in NSCLC, high-grade glioma (HGG), pancreatic cancer, and prostate cancer
  - Pipeline in a product

- enLIGHTEN™ Discovery Platform based on HSV technology

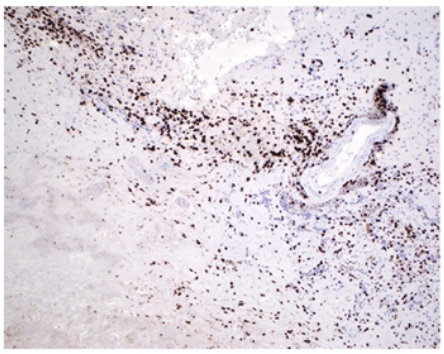
CAN-3110: HSV “Nestin 34.5” construct



Oncolytic HSV infection and CD8+ T cell infiltration after CAN-3110 treatment in patients with recurrent high-grade glioma



HSV1 antigen 6 weeks after injection of $1x10^6$ pfu
1.79×10^6 copies of viral DNA/mg
2.97×10^5 copies of viral RNA transcript (ICP22)/mg



Infiltration by CD8+ cytotoxic T cells
(tumor infiltrating lymphocytes)

Post-treatment tissue (available in 18 patients) demonstrates persistence of HSV antigen and CD8+ T cell infiltrates
T cell receptor repertoire, transcriptomics, and single cell RNA sequencing analyses are ongoing

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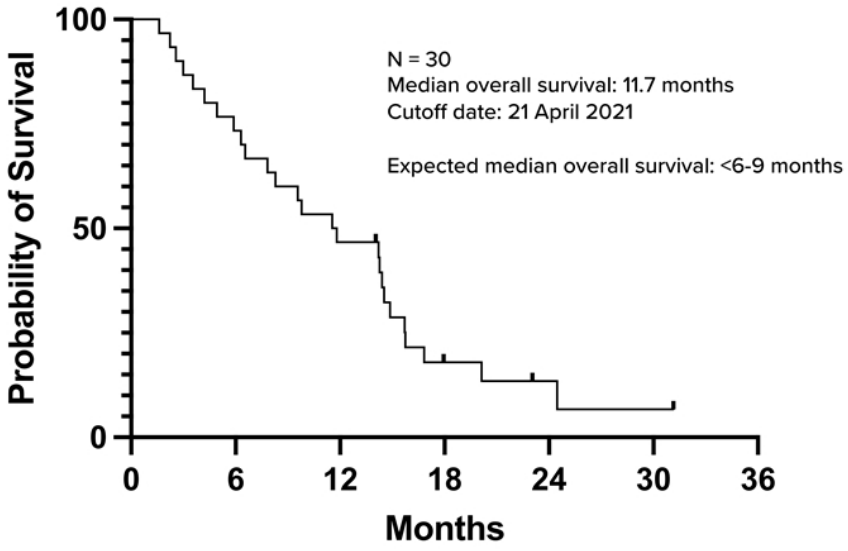
EA Chiocca et al. Oral presentation. ASCO June 2021
New data: Q4 2022

Survival in ongoing phase 1b clinical trial after single dose of CAN-3110 in recurrent high-grade glioma



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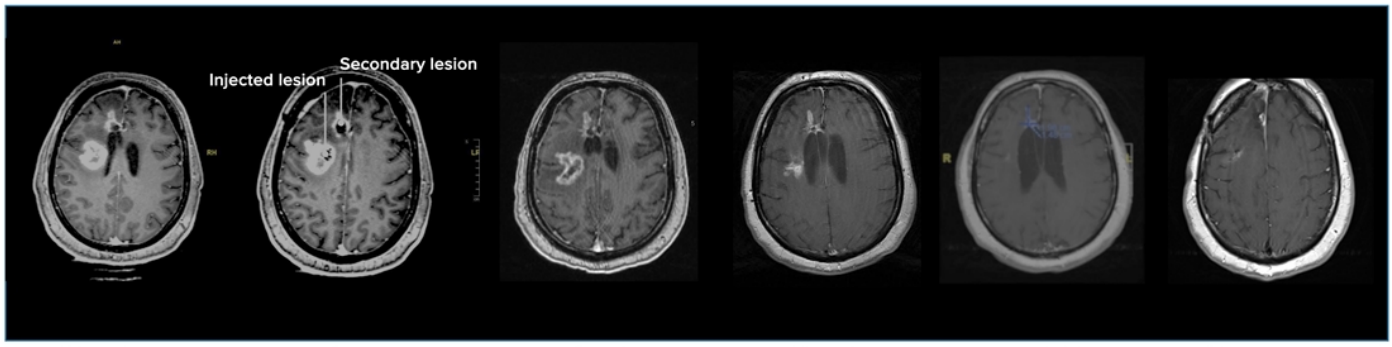
Single agent activity of CAN-3110 in recurrent HGG patient with abscopal effect



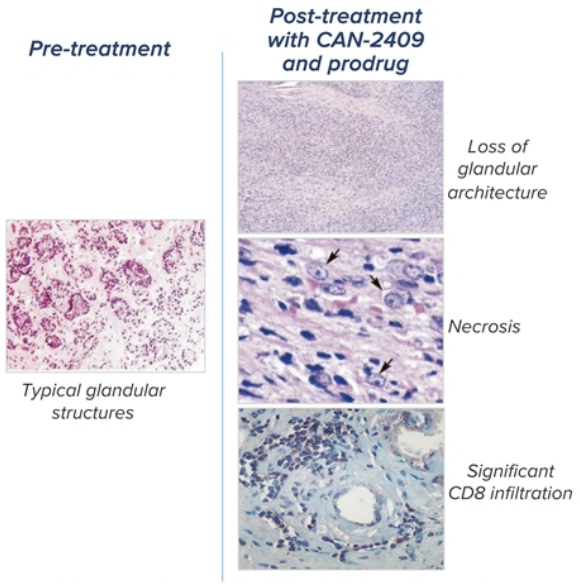
Baseline	Day 0	Day 56	Day 111	Day 168	Day 280
	Black hole within tumor image is injection site 10^6 PFU dose	Reduction in contrast area with no additional treatment	Patient back to work		

56 YOM, IDH wild-type, MGMT partially methylated, right frontal mesial lesion initially treated with gross total resection, chemoradiation. Recurrences at two sites.

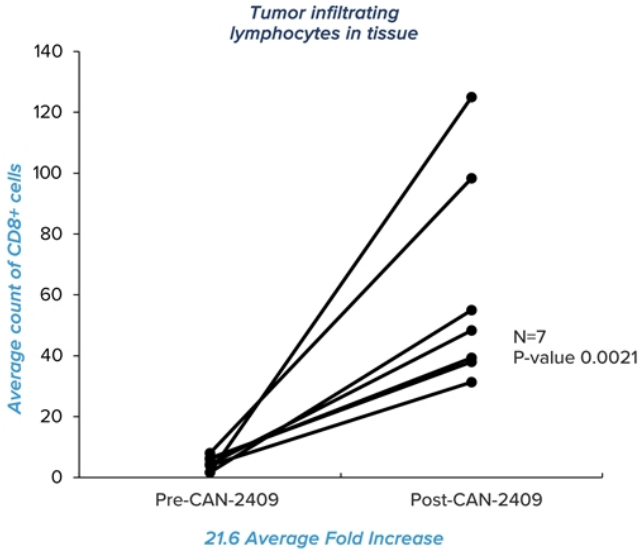
Clinical effect on injected tumor and uninjected tumor

CAN-2409 treatment: Induction of CD8+ tumor-infiltrating lymphocytes in prostate cancer and pancreatic cancer

PROSTATE CANCER PH 1/2 STUDY

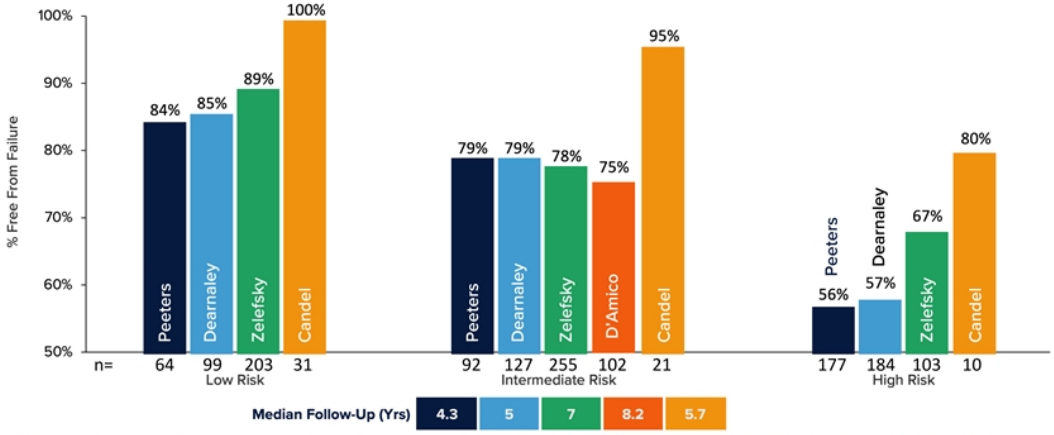


PANCREATIC CANCER PH 1/2 STUDY



Clinical evidence supports ongoing clinical trials of CAN-2409 in prostate cancer and pancreatic cancer

Completed phase 2 trial of CAN-2409 shows consistently improved freedom from failure rates in newly diagnosed, localized prostate cancer



- Pathological complete response (pCR) observed in 93% of the biopsies available at 2yrs (37%-73% in control populations)
- Low risk patients achieved PSA < 2ng/ml in 77% of CAN-2409 treated patients versus 58% in control populations
- Significant increase in activated CD8+ T cells compared to baseline (p=0.0003)

Clinical evidence supports ongoing phase 3 clinical trial of CAN-2409 in combination with SoC as first line treatment

Failure was measured from the start date of treatment until the date of treatment failure defined as clinical failure or biochemical failure, whichever first, according to the Phoenix ASTRO consensus (Nadir +2)

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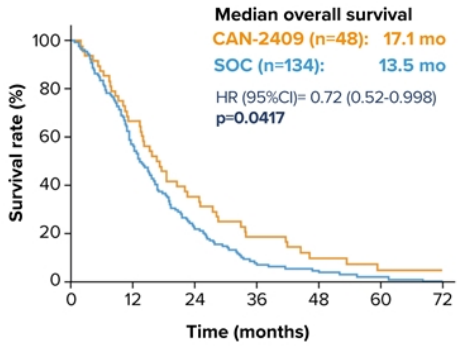
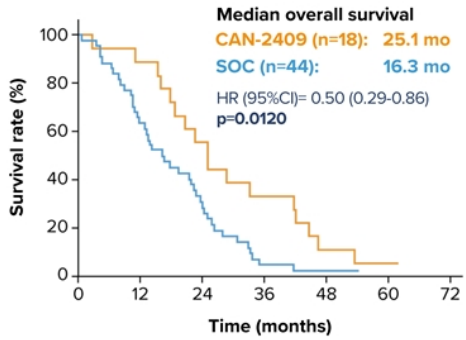
Significant survival benefit after CAN-2409 treatment in HGG

Compared to contemporary controls fulfilling the same inclusion and exclusion criteria

All patients: All high-grade glioma, All resection extent



Prespecified subgroup: glioblastoma with gross total resection

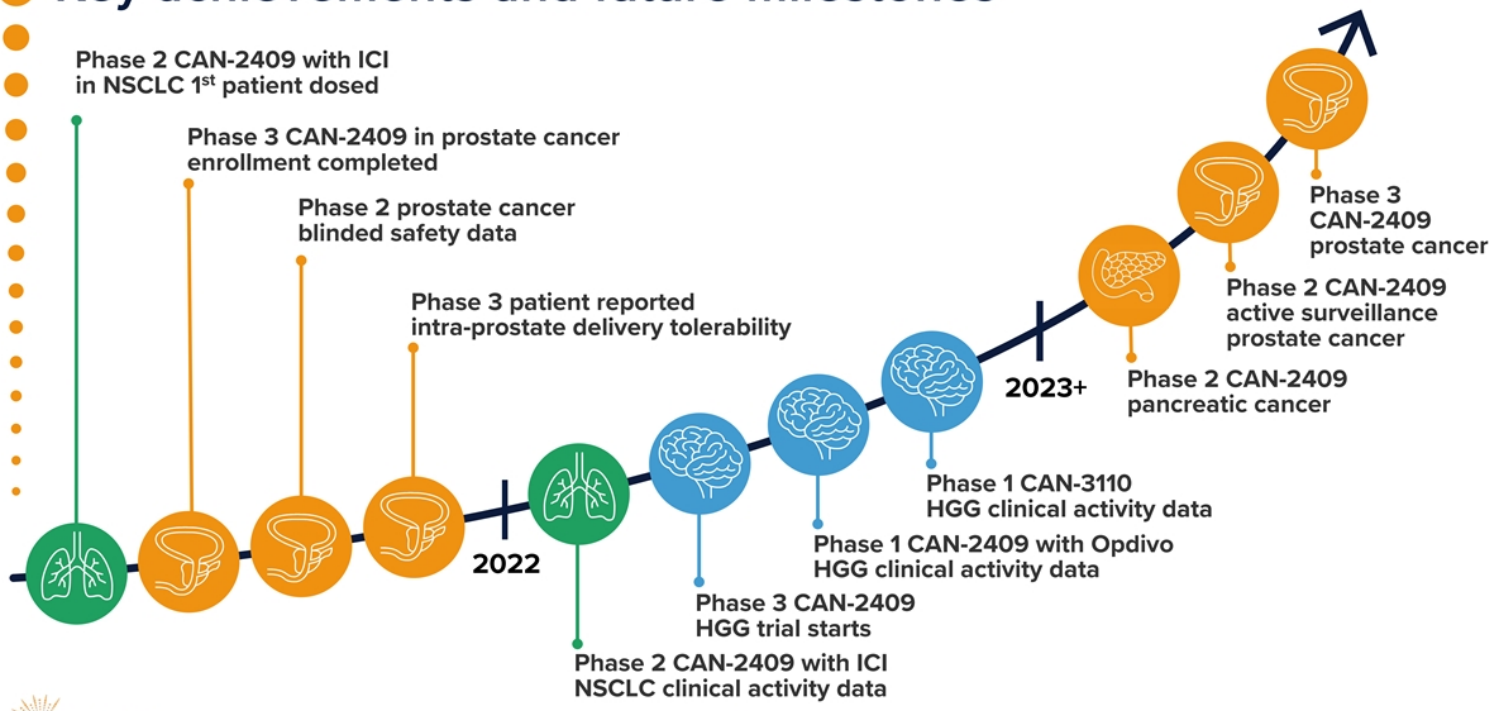


54% Relative improvement
(8.8 mo median survival benefit)

Clinical evidence supports adaptive phase 3 clinical trial of CAN-2409 in high-grade glioma patients undergoing Gross Total Resection and standard of care chemoradiation (reviewed with FDA)

Results have also been confirmed by comparison to independent control cohort matched for known prognostic factors

Key achievements and future milestones



CANDEL THERAPEUTICS

Leadership team with decades of experience in oncology, immunology, and drug development

Paul-Peter Tak, M.D., Ph.D., FMedSci
President & Chief Executive Officer

Nathan Caffo
Chief Business Officer

Christopher Matheny, Pharm.D., Ph.D.
Vice President, Development Leader

Seshu Tyagarajan, Ph.D., RAC
Chief Technical and Development Officer

Francesca Barone, M.D., Ph.D.
Chief Scientific Officer

John Canepa
Chief Financial Officer

Susan Stewart, J.D.
Chief Regulatory Officer

Research Advisory Board of premier thought leaders

James Allison, Ph.D.
Chair of the Department of Immunology
MD Anderson Cancer Center
Director of the Parker Institute for Cancer Research
2018 Nobel Recipient

Edward Benz, M.D.
President and CEO Emeritus
Dana-Farber Cancer Institute

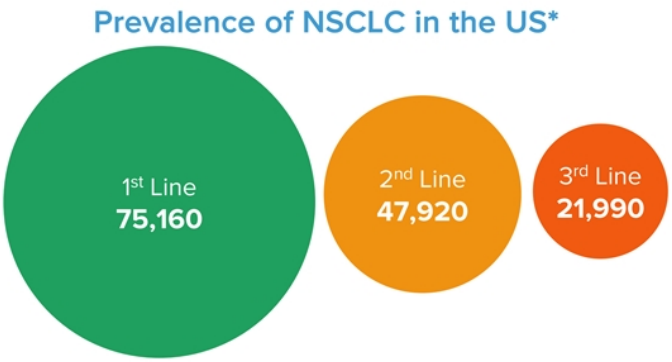
Henry Brem, M.D.
Director, Department of Neurosurgery
Professor of Neurosurgery
Johns Hopkins University

Roy Herbst, M.D., Ph.D.
Chief of Medical Oncology
Yale Cancer Center

Philip Kantoff, M.D.
Former Chair, Department of Medicine
Memorial Sloan Kettering Cancer Center

Padmanee Sharma, M.D., Ph.D.
Professor of Genitourinary Medical Oncology and Immunology
MD Anderson Cancer Center

Non-small cell lung cancer opportunity for CAN-2409



- Patients treated with immune checkpoint inhibitors often combined with chemotherapy as 1st line treatment
- Median overall survival 22 months
- < 40% of patients survive > 30 months
- Opportunity to improve response by teaching the immune system how to recognize the cancer cells

Target label for CAN-2409: Indicated as adjunct to standard-of-care immune checkpoint inhibitor treatment (+/- chemotherapy) in stage III / IV NSCLC patients not responding to first-line or later ICI treatment#

* Decision Resources Group 2020
\# Market research and interviews with 13 KOLs (8 US and 5EU) Dec. 2020

First report from a phase 2 clinical trial of CAN-2409 in inadequate responders to immune checkpoint inhibitors for stage III/IV NSCLC

Daniel Sterman, MD

Thomas and Suzanne Murphy Professor of Pulmonary and Critical Care Medicine, at the New York University Grossman School of Medicine, and Director of the Division of Pulmonary, Critical Care, and Sleep Medicine, and Director of the Multidisciplinary Pulmonary Oncology Program at NYU Langone Health

Conflict of interest disclosure: Nothing to disclose

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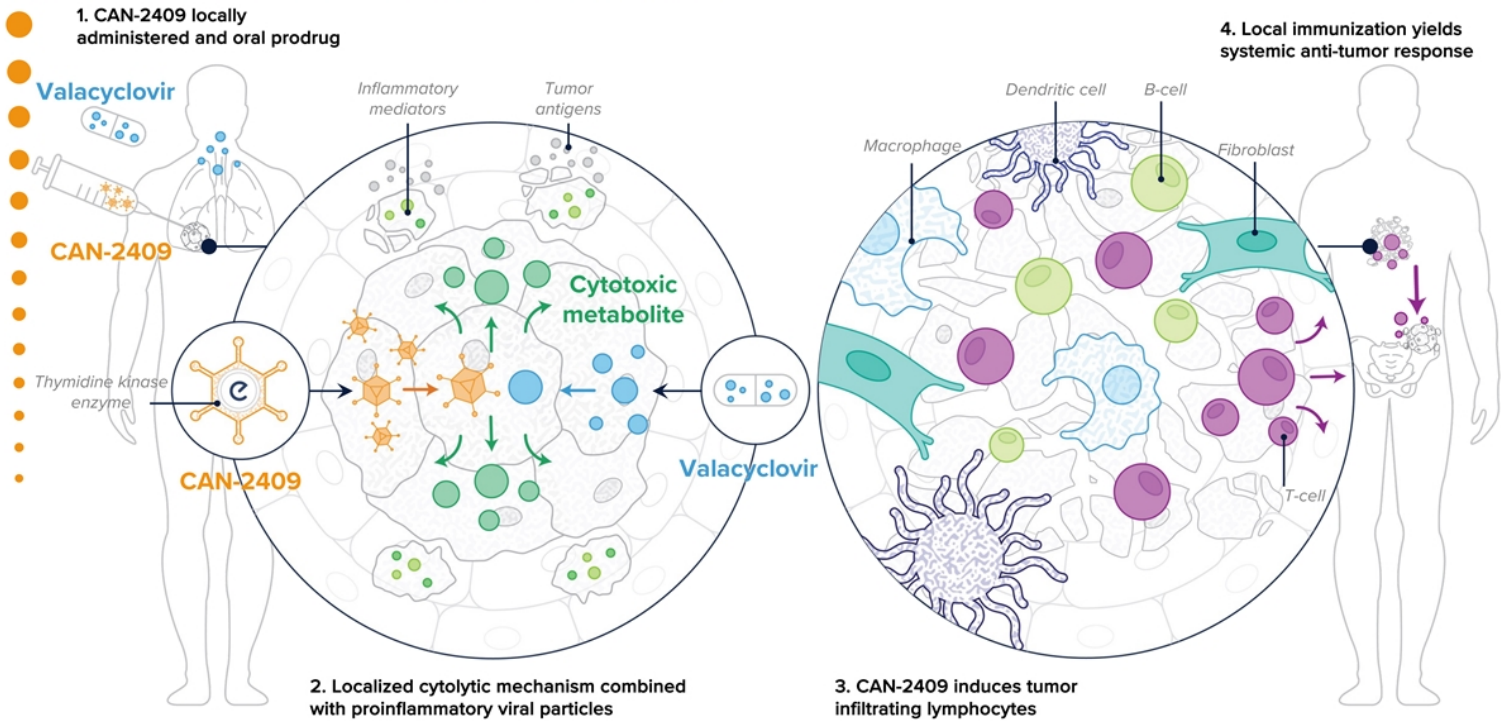
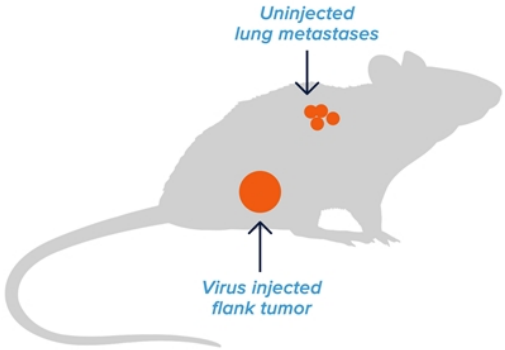
CAN-2409: Mechanism of action



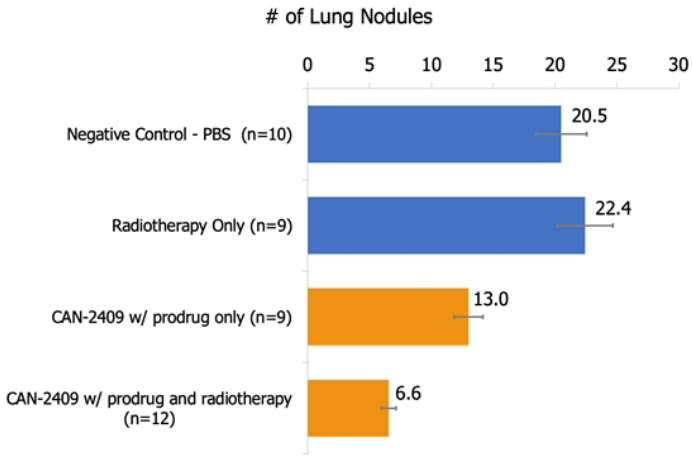
CAN-2409 teaches the immune system how to fight cancer in injected tumor and uninjected metastases



Mice receive one of four treatment regimens

1. PBS
2. Radiotherapy
3. CAN-2409 with prodrug
4. CAN-2409 with prodrug plus radiotherapy

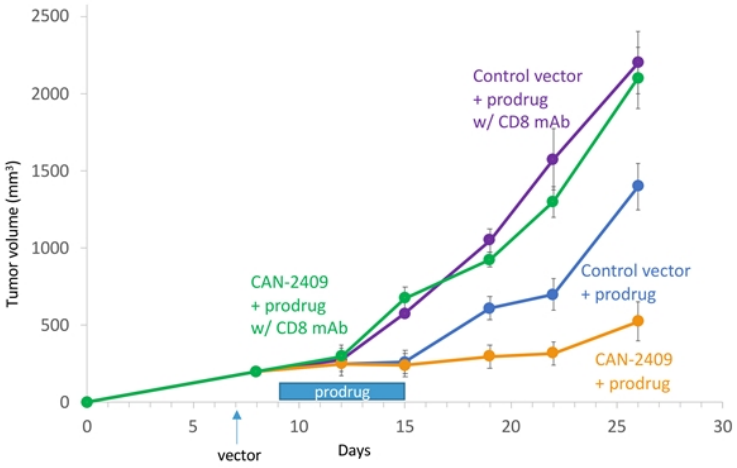
Decrease in uninjected lung metastases

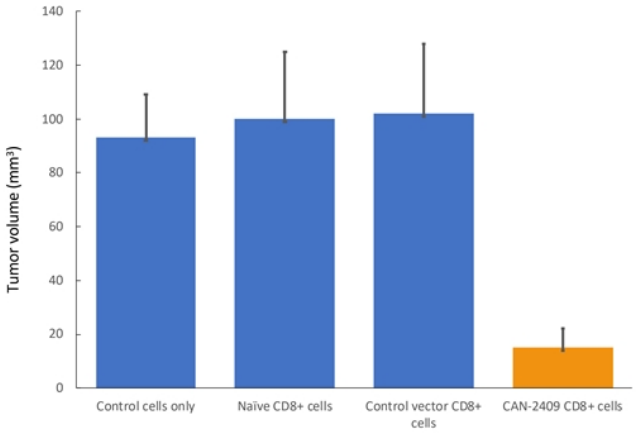


Model of prostate cancer: RM-1 cells in C57BL/6 mice

Chhikara M et al. Mol Ther 2001; 3:536-42

Response to CAN-2409 is dependent on CD8+ T cells and transferable in mouse models of cancer





Depletion of CD8+ cells eliminated effect

Esophageal cancer model (AKR) flank tumors in C57Bl/6 mice (n = 8 per group)

CD8+ cells from 'cured' mice administered CAN-2409 protected naïve mice from tumor challenge

Winn Assay: Lung cancer model (TC-1) flank tumors in C57Bl/6 mice (n = 5 per group)

Predina JD et al. J Hematol Oncol 2012; 5:34

Phase 1 mechanistic trial in resectable NSCLC: Safety and feasibility of intratumoral administration of CAN-2409

Evidence of monotherapy activity both via biomarkers and clinical response

Newly diagnosed stage I-III suspected operable NSCLC

N=12 completing treatment and surgical resection

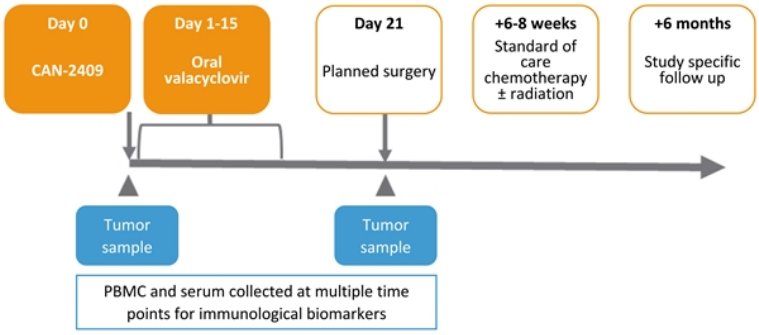
CAN-2409 and valacyclovir (one course)

3+3 dose escalation

Injected into tumor during SoC staging procedure (endobronchial or direct injection)

No other therapy

CAN-2409 dose levels:
2.5×10^{11}, 5×10^{11}, 1×10^{12} VP

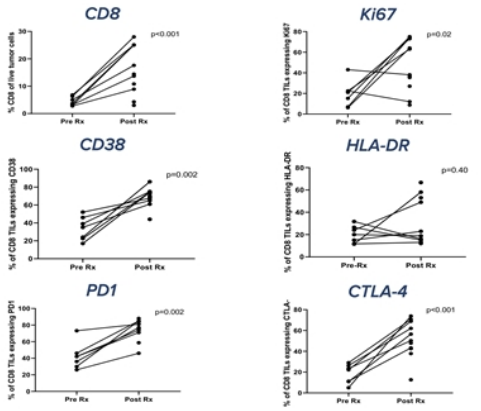


Principal investigators:
Dr S Singhal (UPenn) and Dr S Albelda (UPenn)

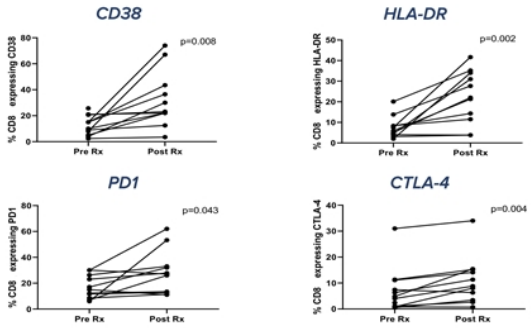
CAN-2409 stimulates local and systemic CD8+ T-cell response in patients with NSCLC

Non-small cell lung cancer Ph 1 study (n=12)

TISSUE



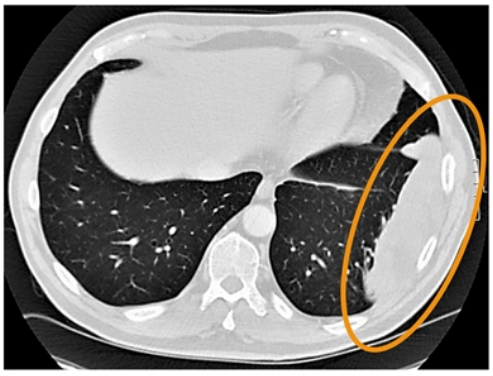
PERIPHERAL BLOOD



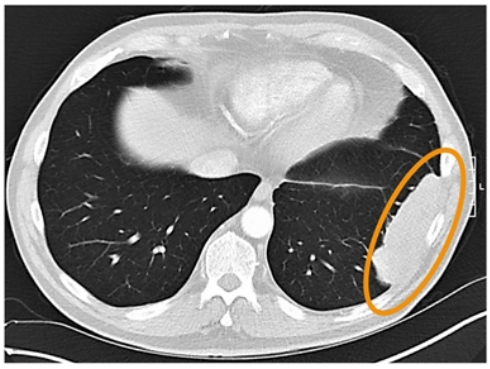
Predina JD et al. Mol Ther 2020; 29:1-13

Monotherapy activity of CAN-2409 in NSCLC

70 yr old male with a 14.8 cm stage IIIA sarcomatoid carcinoma



Day 0
Tumor Dimensions: 148 x 40 x 82 mm



Day 22
Tumor Dimensions: 100 x 34 x 75 mm

10^{12} vp dose

Nearly 50% decrease in tumor volume* at 3 weeks after CAN-2409 monotherapy

Predina JD et al. Mol Ther 2020; 29:1-13

* $\pi/6$ x L x W x H

Current, ongoing phase 2 clinical trial of CAN-2409 in combination with ICI in stage III/IV NSCLC

Stage III/IV Non-resectable NSCLC with inadequate response to ICI

N=96 (32 per cohort)

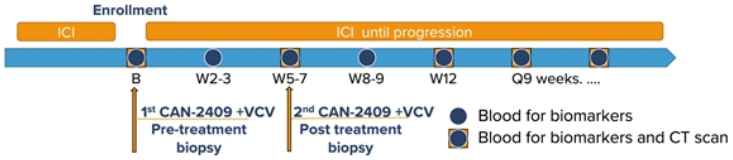
CAN-2409 and valacyclovir (2 courses)

with standard of care: Anti-PD-1/PD-L1 +/- chemotherapy

- Cohort 1: Stable Disease (>18 wks ICI)
- Cohort 2: Progressive Disease (>18 wks ICI)
- Cohort 3: Refractory Disease (>9 wks ICI)

Primary Endpoints
- Response by RECIST Criteria
- Safety

Secondary Endpoints
- Overall survival
- Progression free survival
- Quality of life
- Immunological biomarkers
- Response by iRECIST and itRECIST (Exploratory)



ASCO 2022 Annual Meeting
Abstract # 9037
Poster session June 6, 2022 8:00-11:00 CDT

Demographics

35 patients enrolled between October 2020 and April 2022

Age	Years
Median (range)	69 (43-88)
Sex	n (%)
Male	20 (57)
Female	15 (43)
Race	n (%)
White/Caucasian	30 (86)
Black/African American	3 (9)
Smoking History	n (%)
Never	4 (11)
Former or current	28 (80); 3 (9)
ECOG Status at Enrollment	n (%)
0 or 1	14 (40); 21 (60)

Data cutoff was April 20, 2022

Most frequent treatment-related adverse events

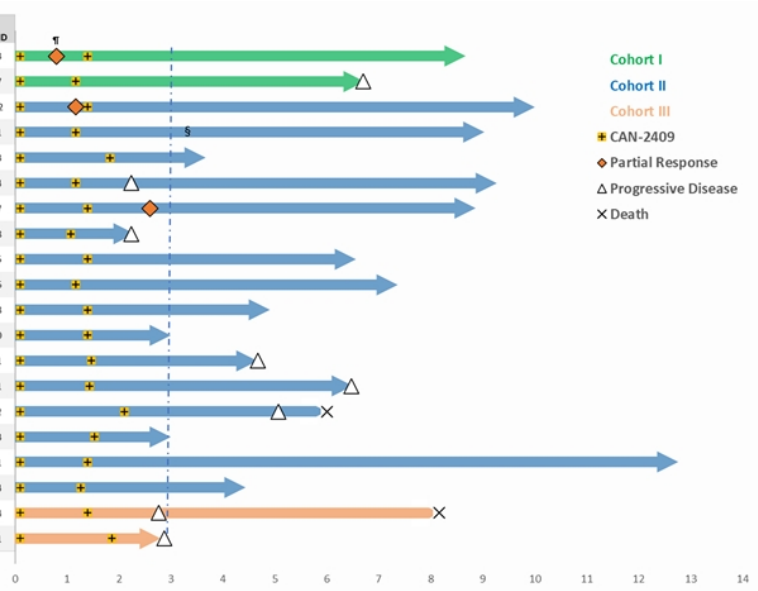
Generally, CAN-2409 was shown to be well tolerated with no Grade 4 and few Grade 3 events

SOC/Adverse Event (>10%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Total patients (n=35)
General disorders and administration site conditions				
Chills	4 (11)			4 (11)
Fatigue	8 (22)	4 (11)		12 (33)
Injection site reaction	4 (11)			4 (11)
Pyrexia	6 (17)		2 (6)	7 (20)
Investigations				
Blood creatinine increased	4 (11)	1 (3)		4 (11)

Swimmer plot for all evaluable patients

20 patients received 2 courses of CAN-2409 with valacyclovir and were evaluable at 12 weeks

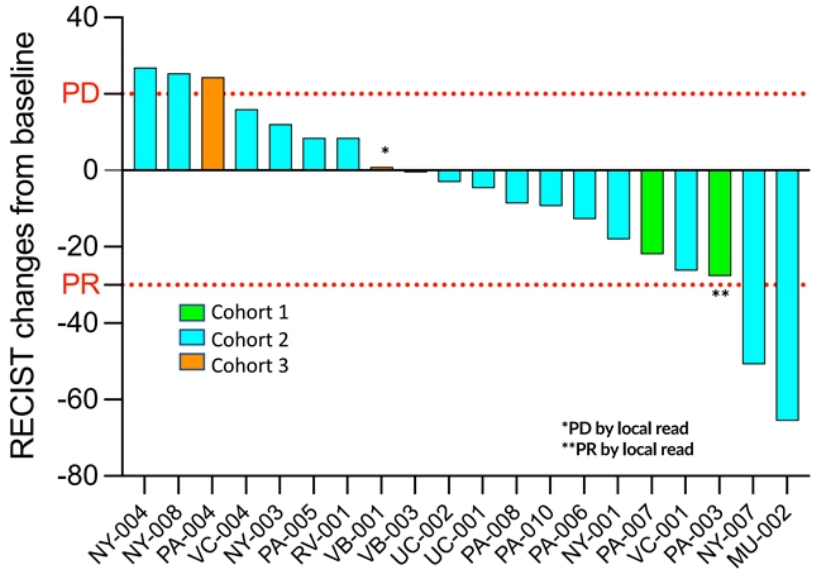
Stage*	Histology	PD-L1	TMB	ICI‡	Time on ICI (months) ‖	Patient ID
III	NonSQ	< 1%	NA	Pembro +	15.5	PA-003
IV	NonSQ	< 1%	NA	Pembro +	5.0	PA-007
IV	NonSQ	NA	32.5	Pembro	16.6	MU-002
IV	NonSQ	1 - 49%	15.0	Pembro	7.0	NY-001
IV	NonSQ	1 - 49%	11.0	Nivo	12.1	NY-003
IV	NonSQ	>= 50%	19.0	Pembro	11.7	NY-004
IV	NonSQ	< 1%	13.0	Nivo	16.2	NY-007
IV	Sq	1 - 49%	4.0	Pembro +	10.3	NY-008
IV	NonSQ	< 1%	NA	Pembro +	19.1	PA-005
IV	NonSQ	< 1%	NA	Pembro +	8.2	PA-006
IV	Non-SQ	< 1%	NA	Pembro	11.1	PA-008
IV	Non-SQ	< 1%	NA	Pembro +	11.8	PA-010
III	NonSQ	1 - 49%	NA	Nivo	38.4	RV-001
IV	NonSQ	1 - 49%	Na	Pembro	13.0	UC-001
IV	NonSQ	1 - 49%	0.0	Pembro	16.6	UC-002
III	NonSQ	1 - 49%	1.6	Pembro	10.8	VB-003
III	NonSQ	< 1%	9.0	Pembro +	5.4	VC-001
IV	NonSQ	1 - 49%	5.0	Pembro +	5.4	VC-004
IV	Sq	< 1%	NA	Pembro +	4.2	PA-004
IV	Sq	1 - 49%	3.7	Pembro	10.7	VB-001



* Stage: at time of enrollment to study
‡ SOC ICI: at enrollment to study. + Chemotherapy = pemetrexed
‖ Time on SOC ICI prior to Study Enrollment: Initiation of ICI to first CAN-2409 injection
¶ PR by local read
§ Irradiation included target lesion, no longer RECIST evaluable

Radiographic best responses for all evaluable patients

Majority of patients experienced reduction in tumor burden



PR= partial response; PD= progressive disease

Encouraging clinical responses

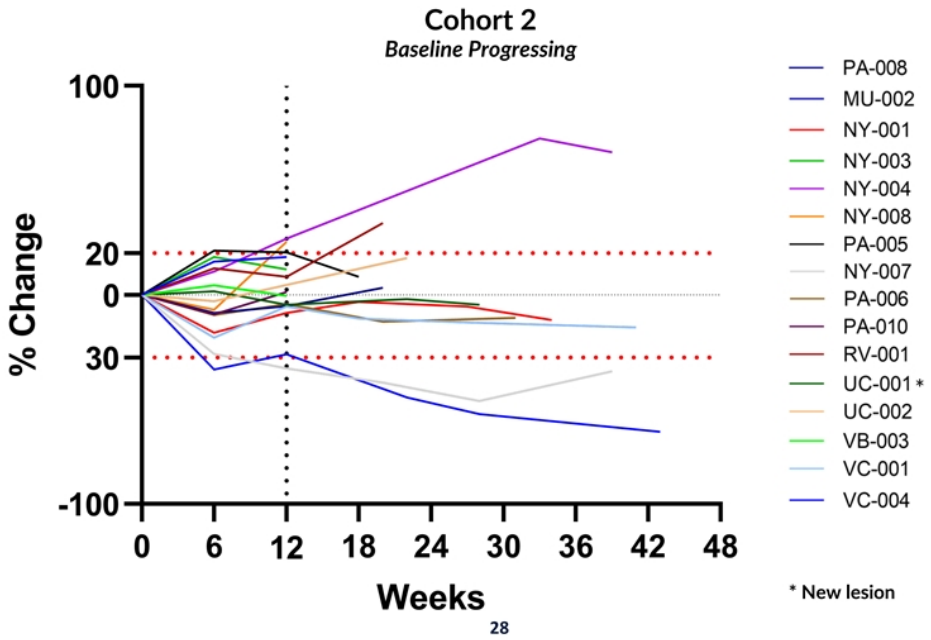
Disease control rate in cohort 2 of 87.5% in patients who were progressing at trial entry

Cohort	Completed 12-week treatment	PR	SD	PD	DCR	DoR for PR (w)	DoR for SD (w)
1	2	1**	1	0	50%	24.1+	26.9
2	16	2	12	2	87.5%	26.7-37.9+	5.4+ - 50.4+
3	2	0	0	2*	0%	n/a	n/a

PR= partial response; SD= stable disease; PD= progressive disease;
DCR = disease control rate
DoR PR= weeks from PR to progression; DoR SD=weeks from SD to progression
+ongoing response
*PD by local read; **PR by local read

Spider plot of cohort 2 suggests durable and stable response

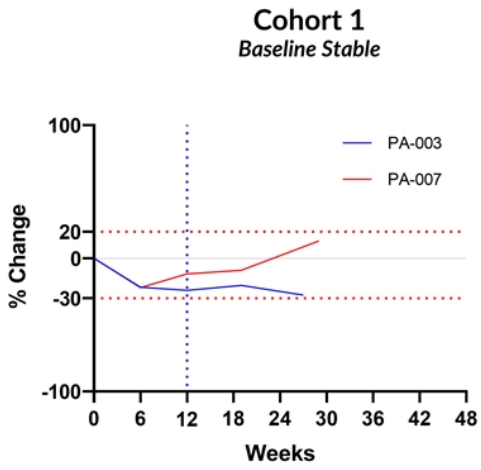
CAN-2409 led to disease stabilization in most patients who were progressing at entry

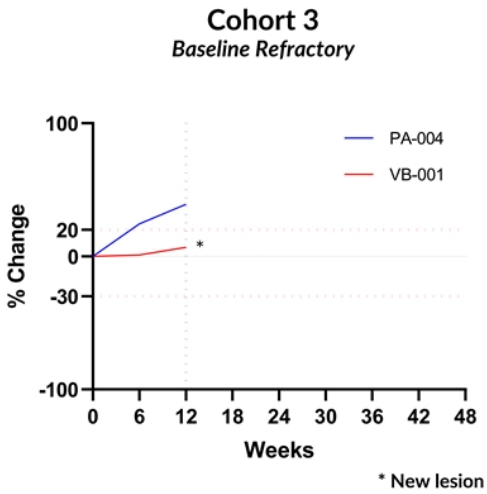


Limited patient numbers in cohorts 1 and 3

Cohort 1: challenging recruitment because stable disease in NSCLC was considered acceptable by treating physician

Cohort 3: patients were often too ill to get to the 2nd CAN-2409 administration



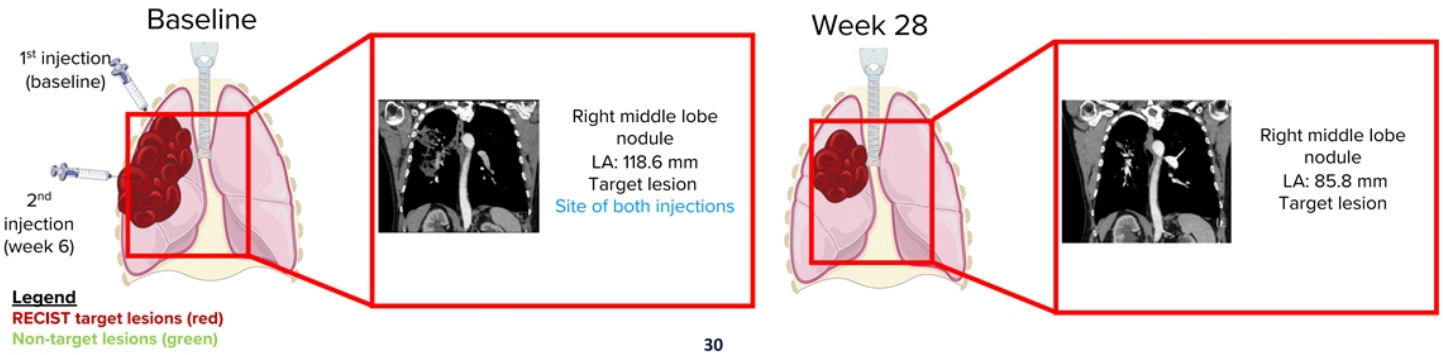


Patient with partial response defined by local read in extended lung lesion and consolidation

PA-003 (Cohort 1)
73M, Stage III Non-SQ
PD-L1<1%
Diagnosed Jan'20
Started pembro + carbo + pemetrexed Feb'20, pembro + pemetrexed cont. from Jun'20 through trial

PR by local read

Schematics to show general lesion injection orientation; not to scale
LN = lymph node; LA = long axis; SA = short axis

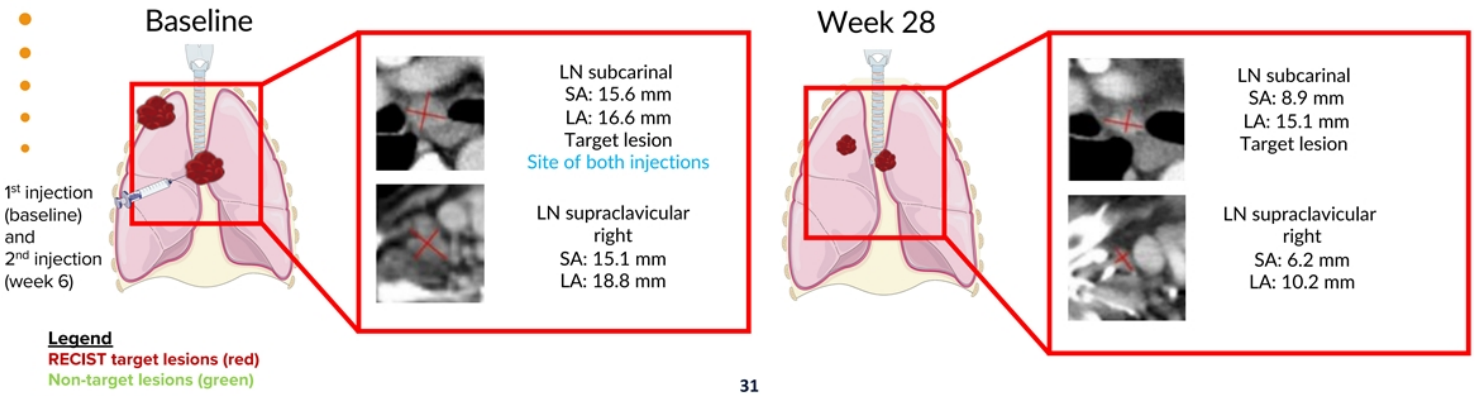


Patient with partial response and evidence of abscopal effect

NY-007 (Cohort 2)
74M, Stage IV Non-SQ
PD-L1 <1%
Diagnosed Feb'19
cisplatin/etoposide Feb'19 to Jul'19, nivolumab monotherapy from Sep'19 thru trial

PR by local and central read

Schematics to show general lesion injection orientation; not to scale
LN = lymph node; LA = long axis; SA = short axis



Legend
RECIST target lesions (red)
Non-target lesions (green)

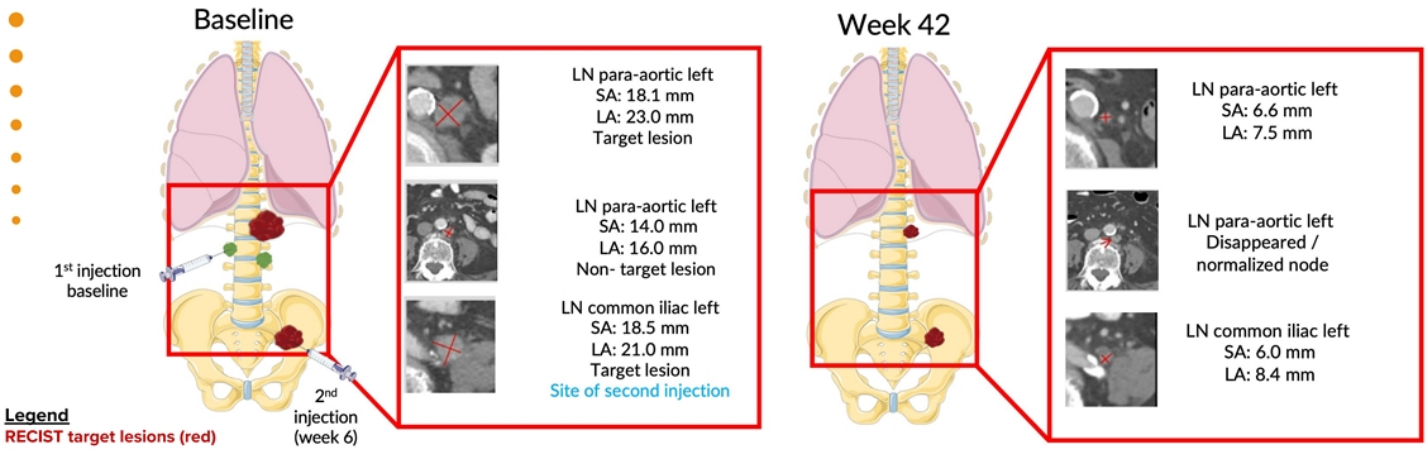
Patient with partial response and evidence of abscopal effect

MU-002 (Cohort 2)

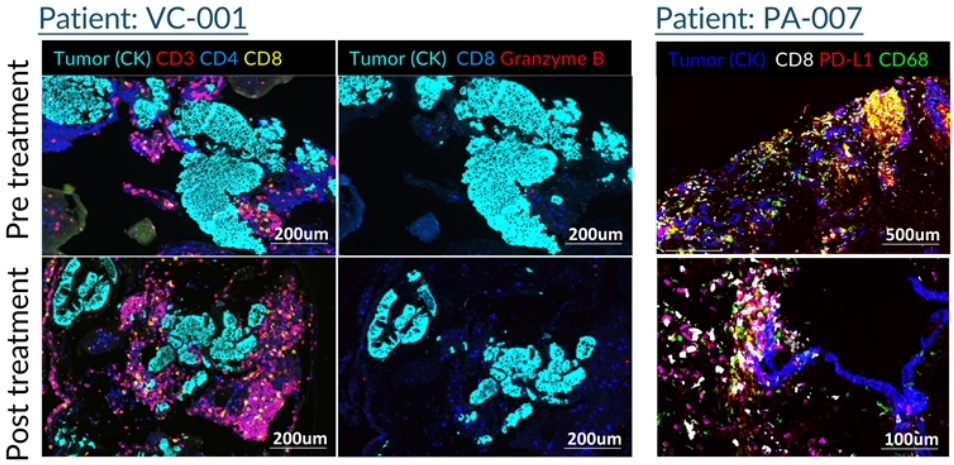
69F, Stage III 2013, Stage IV 2019; Non-SQ; PD-L1 unknown; Started pembro monotherapy Jan'20 through trial

PR by local and central read

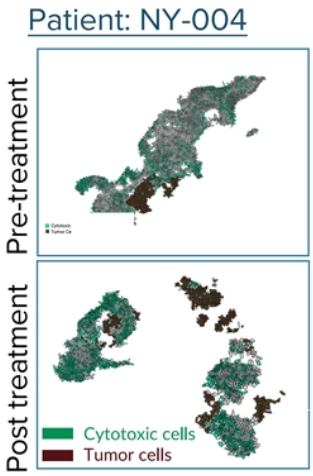
Schematics to show general lesion injection orientation; not to scale
LN = lymph node; LA = long axis; SA = short axis



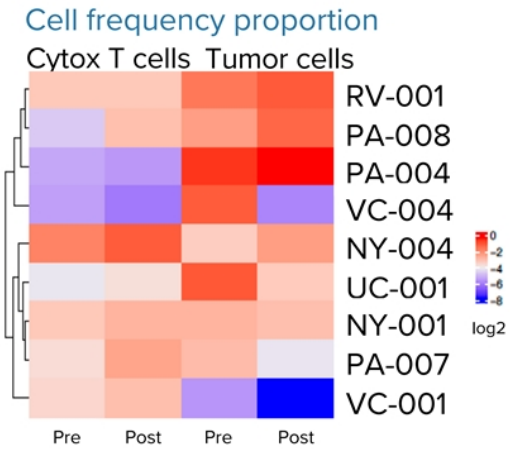
CAN-2409 increases immune cell infiltration in post-treatment tumor biopsies



Frequency analysis demonstrates enrichment in cytotoxic T cells

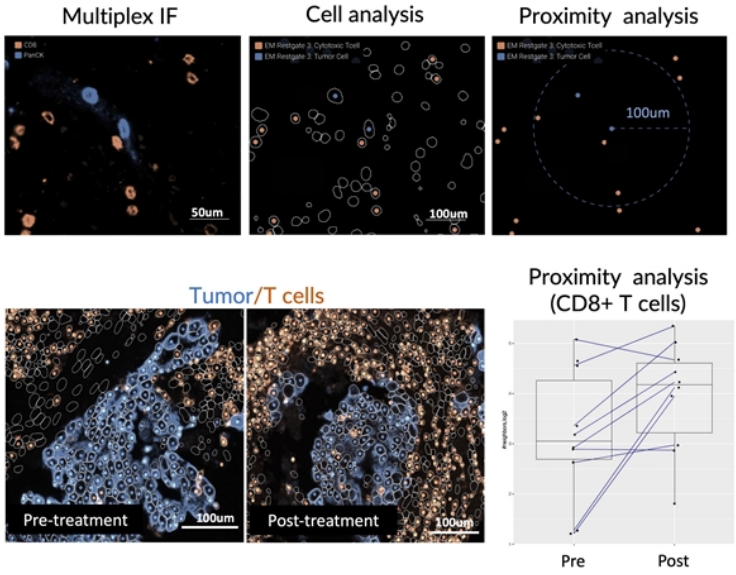


Vorenoi diagram illustrating frequency analysis methodology for patient NY-004 in pre- and post-treatment samples



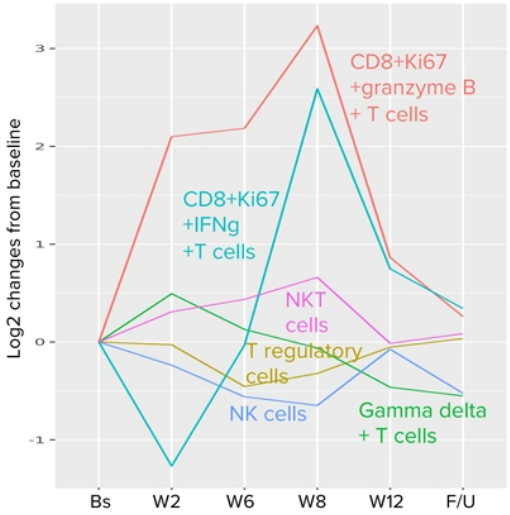
Heat map summarizing frequency data for paired biopsy samples for 9 eligible patients

Increased aggregation of cytotoxic T cells in post treatment biopsies



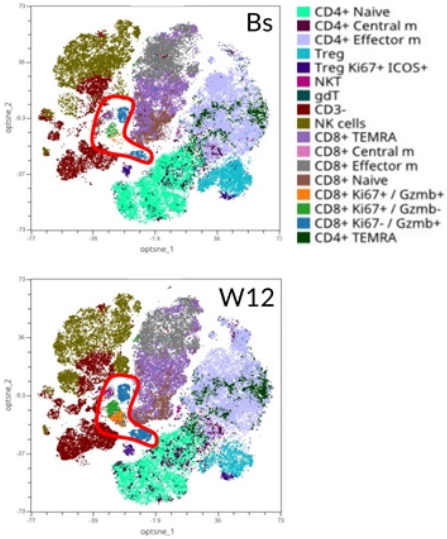
Proximity analysis was applied to immunofluorescence (IF) stained samples to evaluate number of CD8+ cytotoxic cells within a distance of 100um radius from tumor cells. Significant difference was observed in post treatment samples (paired patient data represented p=0.0149 t-test).

CAN-2409 increases circulating cytotoxic T cells and decreases circulating T regulatory cells



Flow cytometry quantitation of cytotoxic cells and T regulatory cells; average values for subpopulations at specific time points from 14 patients' PBMCs

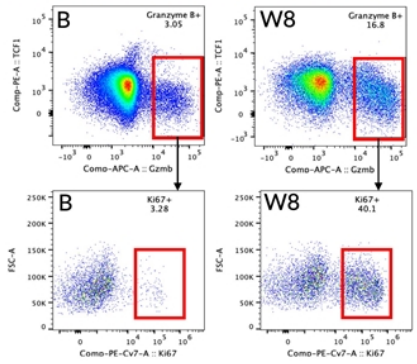
Patient: NY-007



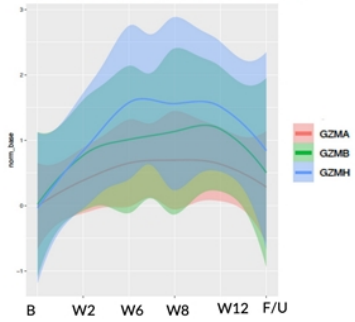
t-SNE plot representing patient MU-002 at baseline and 12 w demonstrating changes in the T cells and NK subpopulations (red outline)

CAN-2409 induces an increase in circulating CD8+Ki67+granzyme B+ T cells associated with elevated soluble granzyme A, B, and H levels

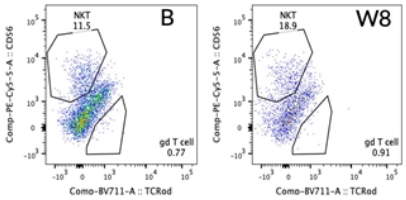
Increase in granzyme B+Ki67+CD8 T cells



Soluble granzyme A, B and H increase over time

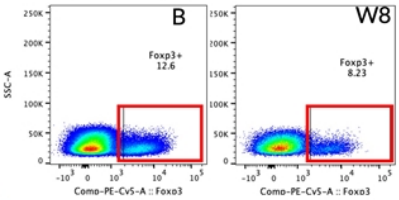


Post treatment increase in NK- T cells



Post treatment reduction in T-reg

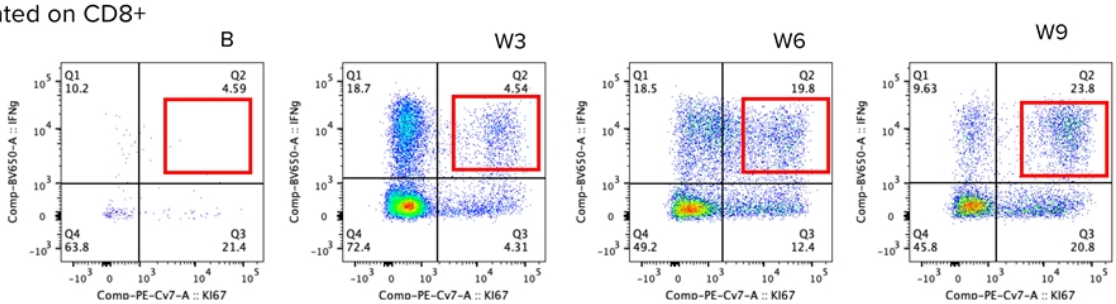
Gated on CD4



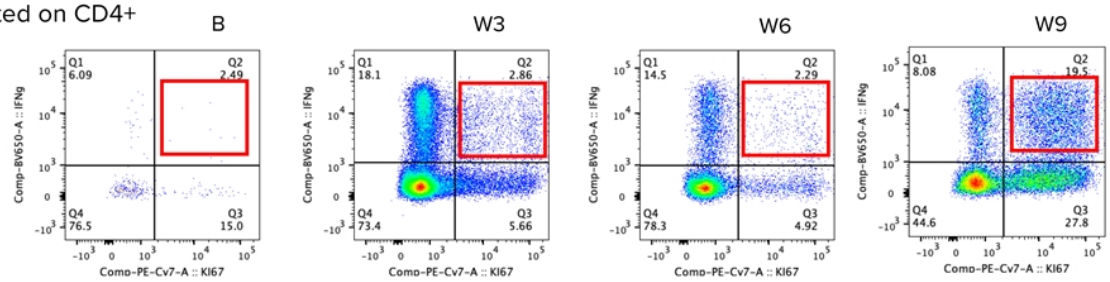
CAN-2409 induces a systemic increase in proliferating CD8+ and CD4+ IFNɣ producing effector cells

Patient: PA-003

Gated on CD8+



Gated on CD4+



Biomarker analysis summary

Biomarker data consistent with hypothesized mechanism of action

- Post treatment tumor biopsies:
  - Increased infiltration of cytotoxic T cells
  - Increased T cell aggregation in proximity to tumor cells
- Post treatment peripheral blood samples:
  - Increased actively proliferating, granzyme B positive T cells
  - Increased actively proliferating, CD4+ and CD8+ IFNɣ+ T cells
  - Increased levels of soluble granzymes A, B, and H

Summary of data from ongoing phase 2 clinical trial:

- Experimental treatment with CAN-2409 plus valacyclovir in patients with advanced NSCLC and an inadequate response to first-line ICI (±chemo) who continued ICI treatment appears to be generally well tolerated

- Encouraging preliminary activity in the first 20 evaluable patients at 12 weeks post-treatment:
  - Evidence for disease regression in both injected and uninjected lesions
  - In Cohort 2 (patients who entered the study with progressive disease), a DCR of 87.5% with durable disease stabilization ongoing in 10 out of 16 patients
  - Partial Response in 3 patients
  - Increased infiltration by cytotoxic T cells in the tumor microenvironment associated with increased levels of soluble granzymes A, B, and H as well as granzyme B positive T cells in the peripheral blood

- These data are consistent with the hypothesis that CAN-2409 induces immunization against tumor antigens in the injected tumor and uninjected metastases

Perspective on clinical trial of CAN-2409 and anti-PD-1 in patients with NSCLC and inadequate response to anti-PD-1 agents

Roy Herbst, MD, PhD

Ensign Professor of Medicine (Medical Oncology) and Professor of Pharmacology at Yale School of Medicine
Chief of Medical Oncology at the Yale Cancer Center and Smilow Cancer Hospital

Conflict of interest disclosure: Member of Candel's Research Advisory Board

CANDEL THERAPEUTICS

Key Findings

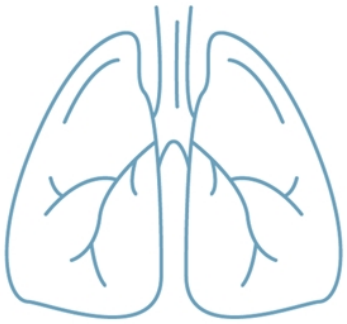
- Experimental treatment with CAN-2409 plus valacyclovir in patients with advanced NSCLC and an inadequate response to first-line ICI (±chemo) who continued ICI treatment appears to be well tolerated

- Encouraging preliminary activity in the first 20 evaluable patients at 12 weeks post-treatment:
  - Evidence for disease regression in both injected and uninjected lesions
  - In Cohort 2 (patients who entered the study with progressive disease), a DCR of 87.5% with durable disease stabilization ongoing in 10 out of 16 patients
  - PR in 3 patients
  - Increased infiltration by cytotoxic T cells in the tumor microenvironment associated with increased levels of soluble granzymes A, B, and H as well as granzyme B positive T cells in the peripheral blood

- These data are consistent with the hypothesis that CAN-2409 induces immunization against tumor antigens in the injected tumor and uninjected metastases

NSCLC landscape

Experience in treating NSCLC



Current treatment paradigm

Q&A

Q&A

- How important is achieving stable disease in NSCLC patients?
- What has been the response rate in PD-1 progressing patients treated beyond progression with anti-PD-1 or other agents?
- What is your view of the monotherapy data for CAN-2409?
- How quickly did patients experience tumor shrinkage? PRs?
- Do you think you might get better response rates by retreating patients with CAN-2409?
- Do you think CAN-2409 has a unique opportunity in low PD-L1 tumors?