

**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): December 5, 2025

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

Delaware (State or Other Jurisdiction of Incorporation)	001-40629 (Commission File Number)	52-2214851 (IRS Employer Identification No.)
117 Kendrick St., Suite 450 Needham, MA (Address of Principal Executive Offices)		02494 (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 December 5, 2025, Candel Therapeutics, Inc. (the “Company”) will host a virtual Research and Development (“R&D”) Day from 11:00 am – 1:45 pm ET. The event will provide an extensive overview of the Company’s viral immunotherapy approach and oncology-focused pipeline.

A copy of the presentation to be shown at the R&D Day is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein. The presentation will also be available on the investor relations section of the Company’s website at <https://ir.candeltx.com/>. Information contained on the Company’s website is not incorporated by reference into this Current Report on Form 8-K, and you should not consider any information on, or that can be accessed from, the Company’s website as part of 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 on Form 8-K, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	R&D Day Presentation dated December 5, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

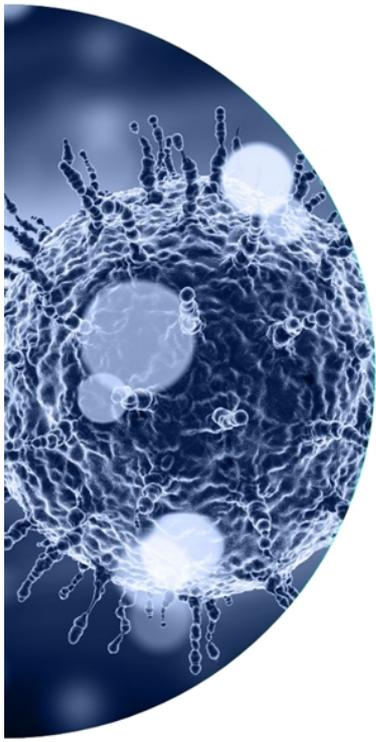
SIGNATURES

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 hereunto duly authorized.

Candel Therapeutics, Inc.

Date: December 5, 2025

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



RESEARCH & DEVELOPMENT DAY



Virtual Event | December 5, 2025

NASDAQ: CADL

Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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; the therapeutic benefit of our programs, including the potential for our programs to extend patient survival; 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; our ability to continue as a going concern, 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; and developments and projections relating to our competitors or our industry. 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; 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 been 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 Form 10-Q filed with the Securities and Exchange Commission on November 13, 2025.



Candel at a glance



- CAN-2409 (aglitimagene besadenovec): Off-the-shelf pan-solid tumor therapy, individualized anticancer immune response
 - Positive phase 3 randomized placebo-controlled clinical trial in localized, intermediate- to high-risk prostate cancer
 - Positive overall survival data from randomized phase 2a clinical trial of CAN-2409 in borderline resectable pancreatic cancer
 - Positive overall survival data from randomized phase 2a clinical trial of CAN-2409 in therapy-resistant non-small cell lung cancer
 - FDA Regenerative Medicine Advanced Therapy (RMAT) designation in prostate cancer, Fast Track designation in NSCLC, pancreatic cancer, and prostate cancer. Orphan Drug designation in pancreatic cancer
 - "Pipeline in a product" strategy advancing multiple programs in several large indications



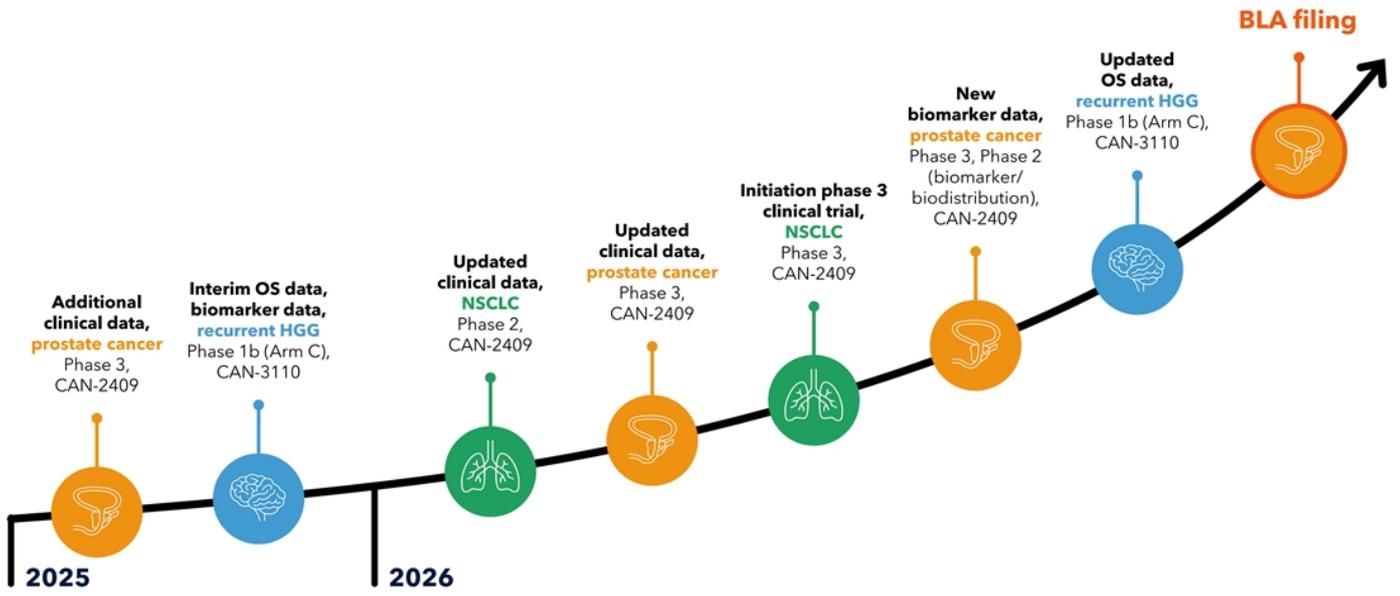
- CAN-3110 (linoserpaturev): Oncolytic HSV-1 designed for tumor-specific replication
 - Proof of concept in patients with recurrent high-grade glioma, published in Nature and Science Translational Medicine
 - Fast Track designation, Orphan Drug designation
 - Opportunity for creation of "pipeline in a product" by expansion into indications beyond brain cancers



- Corporate highlights
 - Experienced Executive Team and strong scientific support from high-profile Research Advisory Board
 - Cash and cash equivalents of \$87.0 million as of September 30, 2025; expected runway into Q1 2027
 - Entered into a term loan facility of up to \$130 million in October 2025
 - IP protection: CAN-2409 (2034, method of use); CAN-3110 (2036, composition of matter); 12 years data exclusivity
 - Low-cost manufacturing
 - Precommercialization activities underway to support potential post approval commercial launch of CAN-2409



Key achievements and anticipated future milestones in clinical programs 2025-2026



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



Paul Peter Tak, MD, PhD, FMedSci

President & Chief Executive Officer



Charles Schoch, MBA, MSA

Chief Financial Officer



Francesca Barone, MD, PhD

Chief Scientific Officer



Garrett Nichols, MD, MS

Chief Medical Officer



Seshu Tyagarajan, PhD, RAC

Chief Technical and Development Officer



Susan Stewart, JD

Chief Regulatory Officer



Research Advisory Board of premier thought leaders



James Allison, PhD

Chair of the Department of Immunology, MD Anderson Cancer Center

*Director of the Parker Institute for Cancer Research
2018 Nobel Recipient*



Edward Benz, MD

President and CEO Emeritus Dana-Farber Cancer Institute



Henry Brem, MD

*Director, Department of Neurosurgery
Professor of Neurosurgery
Johns Hopkins University*



Roy Herbst, MD, PhD

*Chief of Medical Oncology
Yale Cancer Center*



Elizabeth M. Jaffee, MD

*Deputy Director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and
Co-Director of the Gastrointestinal Cancers Program*



Carl H. June, MD

Richard W. Vaque Professor in Immunotherapy, Perelman School of Medicine, University of Pennsylvania



Philip Kantoff, MD

Former Chair, Department of Medicine, Memorial Sloan Kettering Cancer Center



Gary Nabel, MD, PhD

*Chief Innovation Officer of OPKO and President/CEO of ModeX Therapeutics
Former CSO Sanofi*



Bali Pulendran, PhD

Violetta L. Horton Professor at Stanford University School of Medicine and Director of the Institute for Immunity, Transplantation and Infection at Stanford University



Padmanee Sharma, MD, PhD

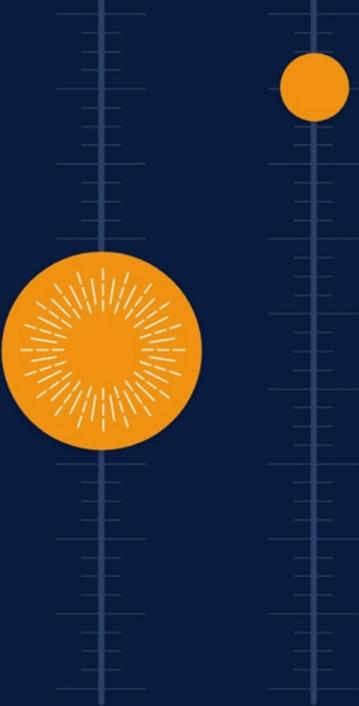
Professor of Genitourinary Medical Oncology and Immunology, MD Anderson Cancer Center



R&D Day 2025: Agenda

1	Introduction to Candel Therapeutics	11:00-11:10 AM
2	Immuno-oncology: The Next Wave of Innovation	11:10-11:40 AM
3	CAN-2409 for Newly Diagnosed Localized Prostate Cancer	11:40-12:10 PM
4	Road Map to Biologics License Application (BLA)	12:10-12:30 PM
5	Pre-Commercialization Road Map	12:30-12:50 PM
6	CAN-2409 for Immune Checkpoint Inhibitor Refractory Non-Small Cell Lung Cancer	12:50-1:15 PM
7	CAN-3110 for Recurrent Glioblastoma	1:15-1:30 PM
8	Analyst Management Q&A/Closing	1:30-2:00 PM





IMMUNO-ONCOLOGY: THE NEXT WAVE OF INNOVATION

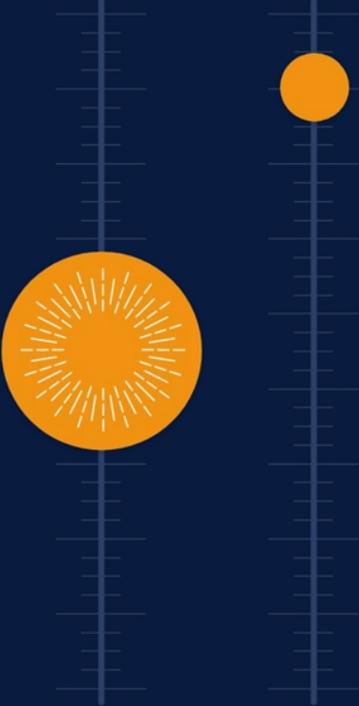


James P. Allison, PhD, Nobel Laureate, Regental Professor and Chair of Immunology, and Founding Director of Scientific Programs for the James P. Allison Institute at the University of Texas MD Anderson Cancer Center

Carl H. June, MD, Richard W. Vague Professor in Immunotherapy and Director, Center for Cellular Immunotherapies and Parker Institute for Cancer Therapy, Perelman School of Medicine, University of Pennsylvania

Padmanee Sharma, MD, PhD, Professor of Genitourinary Medical Oncology and Immunology, and Director of Scientific Programs for the James P. Allison Institute at the University of Texas MD Anderson Cancer Center

Moderator: Yigal Nochomovitz, PhD, Citi Group



CAN-2409 FOR NEWLY DIAGNOSED LOCALIZED PROSTATE CANCER



Glen Gejerman, MD, Co-chief of Urologic Oncology, Hackensack University Medical Center

Philip Kantoff, MD, Former Chair Department of Medicine, Memorial Sloan Kettering Cancer Center, CEO, Convergent Therapeutics

Garrett Nichols, MD, MS, Candel's Chief Medical Officer

Ron Tutrone, MD, National Director of Clinical Research, United Urology

Moderator: Oliver McCammon, LifeSci Capital

Candel is addressing a clear unmet patient need

The U.S. prostate cancer opportunity for CAN-2409

Localized Prostate Incidence



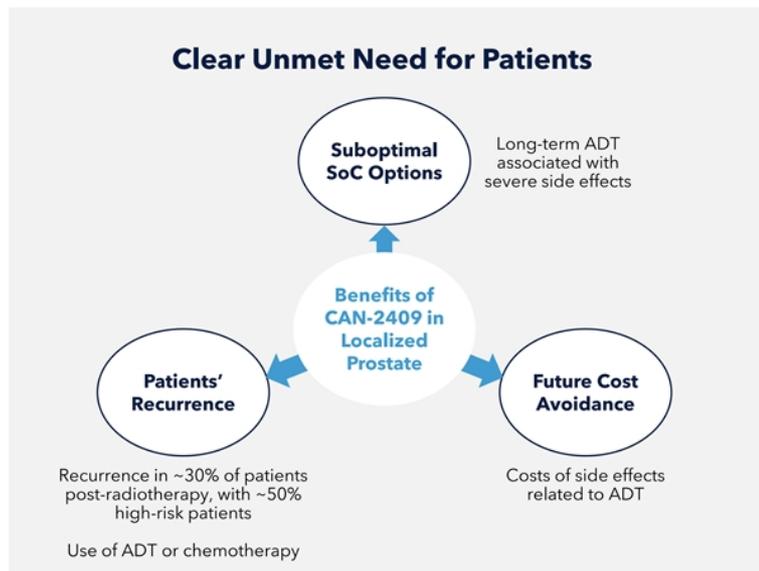
Patients Currently Receiving Radiotherapy

~65K (~43%)

Illustrative Range of Existing Prostate Approved Therapies

~\$150-\$250K

Clear Unmet Need for Patients



Source: Globe Life Sciences (May 2025).



Target Product Profile for CAN-2409 in intermediate- to high-risk, localized prostate cancer

"Off-the-shelf" viral immunotherapy product designed to elicit a broad, potent immune response against solid tumors

Planned Indication

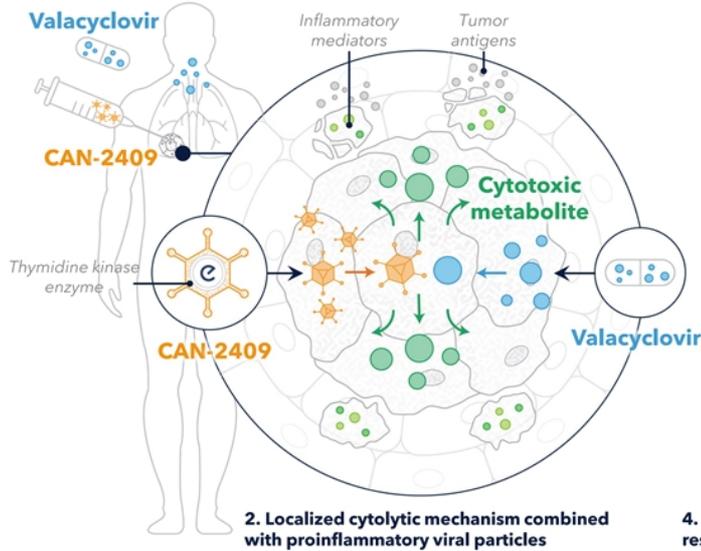
- Planned indication in newly diagnosed localized prostate cancer in patients with intermediate- to high-risk disease in conjunction with radiotherapy to prevent prostate cancer recurrence
 - NCCN* defined intermediate (at least one of: PSA 10-20 ng/mL, Gleason score of 7, stage T2b/T2c) or patients with a single high-risk characteristic (one of: PSA >20 ng/mL, Gleason score 8-10, stage T3a)

Administration

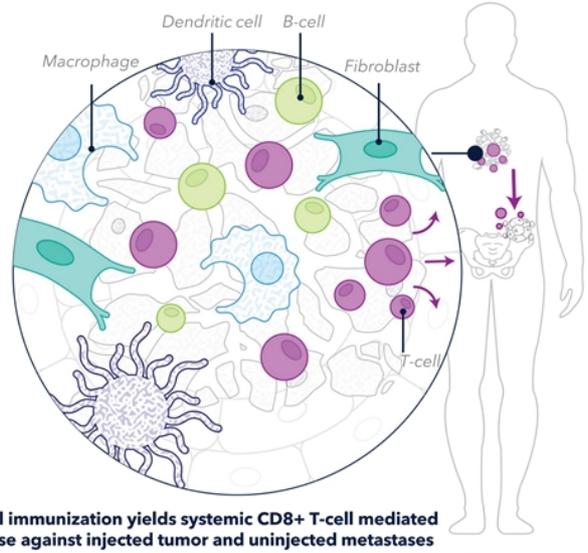
- Administered in combination with SoC external beam radiotherapy (EBRT) ± short course of ADT (<6 months)
- 3 courses of intraprostatic injections: 2 mL total volume (2-6 weeks apart)
 - Each administration is performed in outpatient clinic (~20 minutes)
 - 14 days of valacyclovir orally following each injection course

CAN-2409: Mechanism of action

1. CAN-2409 locally administered combined with oral prodrug



3. CAN-2409 induces CD8+ cytotoxic T cells



CAN-2409 is an investigational product and its mechanism of action in humans has not been definitively established. This depiction of the CAN-2409 mechanism of action is based on preclinical data and observations in clinical studies to date.

Phase 3 Clinical trial of CAN-2409 in patients with newly diagnosed, intermediate- to high-risk, localized prostate cancer

NCT01436968



Conducted under agreement with FDA under Special Protocol Assessment

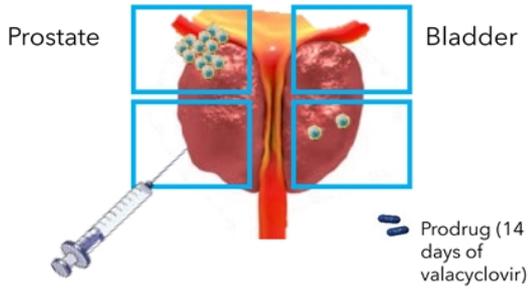
Randomized stratified by the National Comprehensive Cancer Network (NCCN) guideline risk group and planned short-course ADT (androgen deprivation therapy). *Defined as local (biopsy), regional or metastatic disease, or death due to any cause.



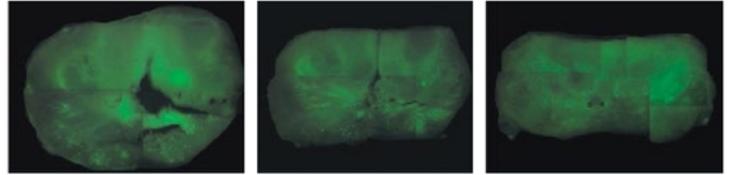
DeWeese TL et al. 2025 ASCO Annual Meeting; May 28, 2025; Chicago, IL. *J Clin Oncol.* 2025;43(16)(suppl):Abstract 5000

CAN-2409 is delivered in a routine and well-tolerated outpatient procedure

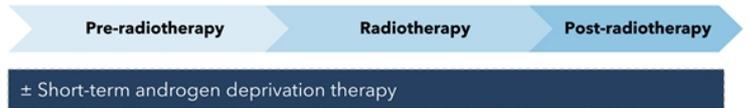
Standard urologic injection procedure



- Ultrasound-guided injection (transrectal or transperineal)¹
- Performed by urologists or radiation oncologists in outpatient clinic
- A total volume of 2 mL, 0.5 mL in each of 4 quadrants of the prostate using a 20-G to 22-G needle



Images of fluorescently labeled adenoviral vector in freshly resected prostate, demonstrating homogeneous distribution throughout the organ after 4 injections of virus (0.5 mL) in each prostate quadrant²

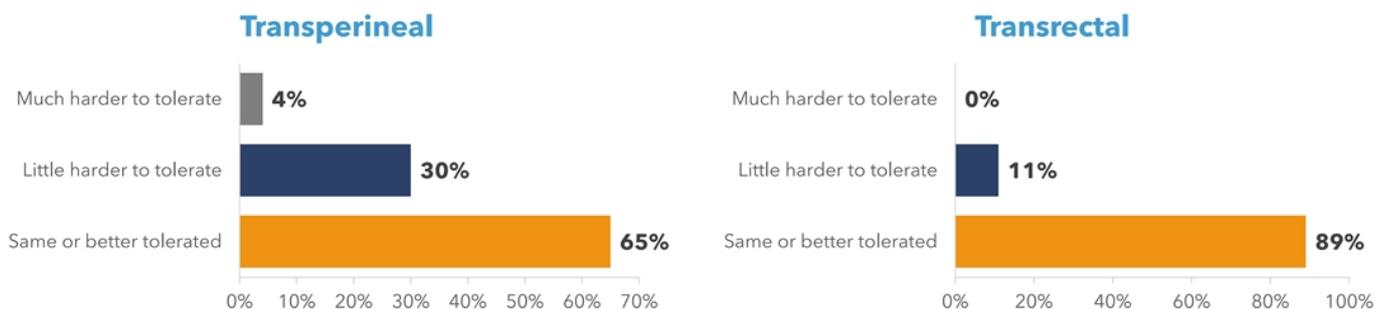


1. Aguilar L. 28th Annual Prostate Cancer Foundation, Scientific Retreat, October 2021;
2. Rojas-Martinez A et al. *Cancer Gene Ther.* 2013;20:642-9.

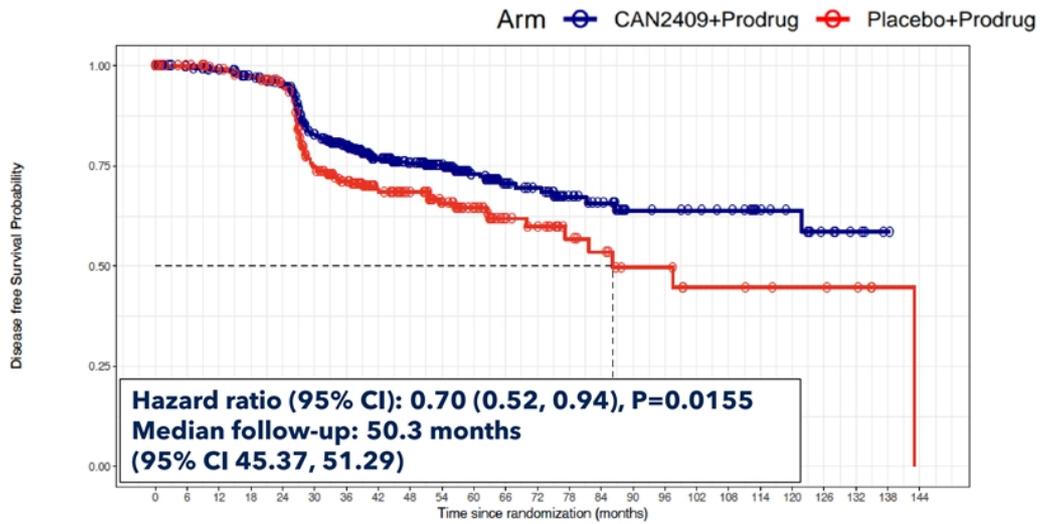
Most patients tolerate intraprostatic injection the same or better than prostate biopsy

Patient questionnaire substudy (n=32)

In total >2000 intraprostatic injections
(40% transperineal; 56% transrectal; 4% not reported)
"How did you tolerate the study procedure compared to a prostate biopsy?"



CAN-2409 significantly improved disease-free survival (DFS) in newly diagnosed, intermediate- to high-risk prostate cancer

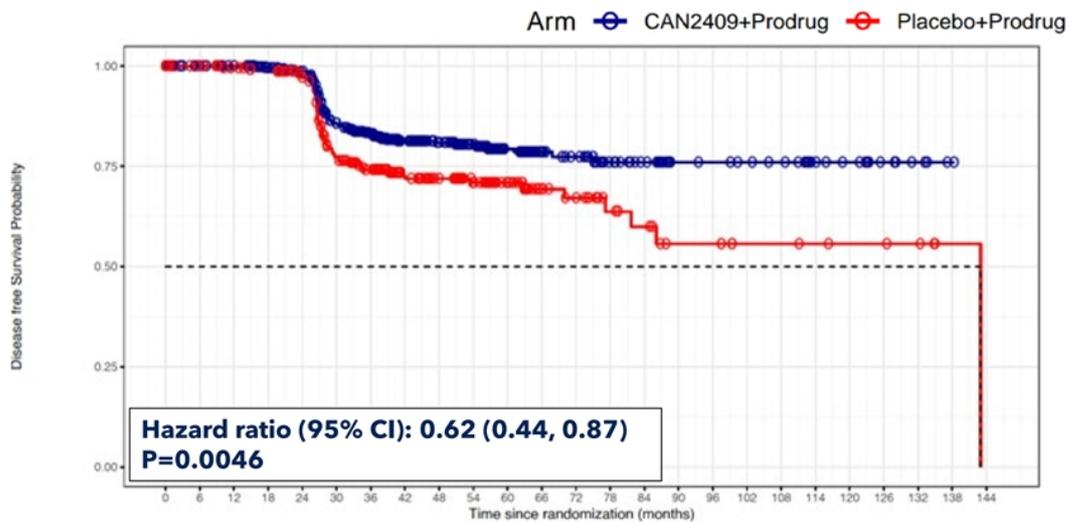


CAN-2409 results in **30% risk reduction in disease recurrence** (includes death from any cause) compared to Standard of Care (ITT,* n=745).



*Intent to treat population.
DeWeese TL et al. 2025 ASCO Annual Meeting; May 28, 2025; Chicago, IL. *J Clin Oncol.* 2025;43(16_suppl):Abstract 5000.

CAN-2409 significantly improved prostate cancer-specific DFS



38% reduction in risk for prostate cancer-specific disease recurrence (ITT,* n=745)



*Intent to treat population.
DeWeese TL et al. 2025 ASCO Annual Meeting; May 28, 2025; Chicago, IL. J Clin Oncol. 2025;43(16_suppl):Abstract 5000

CAN-2409: Other key secondary endpoints

- **Significant increase in the proportion of patients achieving a prostate-specific antigen (PSA) nadir of <0.2 ng/mL in the treatment arm compared with placebo arm**
 - 67.1% vs 58.6%, respectively ($P=0.0164$)
- **As expected¹, overall survival was similar by treatment arm in this time frame (median follow-up 50 months)**
 - Only 2 deaths due to prostate cancer (one CAN-2409, one placebo)
 - 50 patients died due to other causes, unrelated to treatment

CAN-2409 significantly improved the rate of pathological complete response in 2-year biopsies compared with the placebo control arm

Pathological complete response was observed in 80.4% of the biopsies available at 2 years in the CAN-2409 arm compared with 63.6% in the placebo arm

	CAN-2409	Placebo
Total	214	99
Negative	172 (80.4%)*	63 (63.6%)
Positive	42 (19.6%)	36 (36.4%)

***Significant difference between arms, chi-square test $P=0.0015$.**

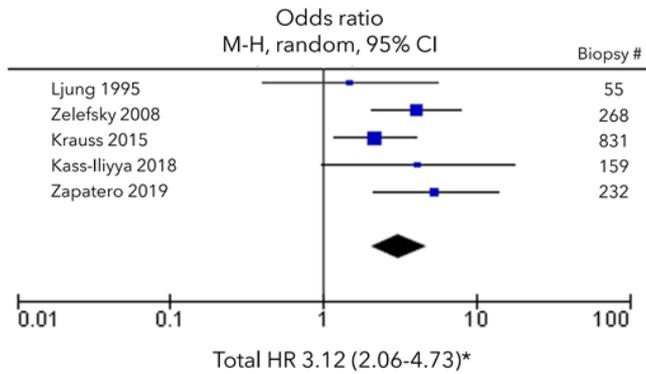
- 451 post-treatment biopsies centrally reviewed by at least 2 blinded independent readers
- 313 post-treatment biopsies available for review for the 2-year histologic analysis

Positive biopsies ≥ 2 years after radiotherapy are predictive of metastases and cancer-related mortality after long-term follow-up

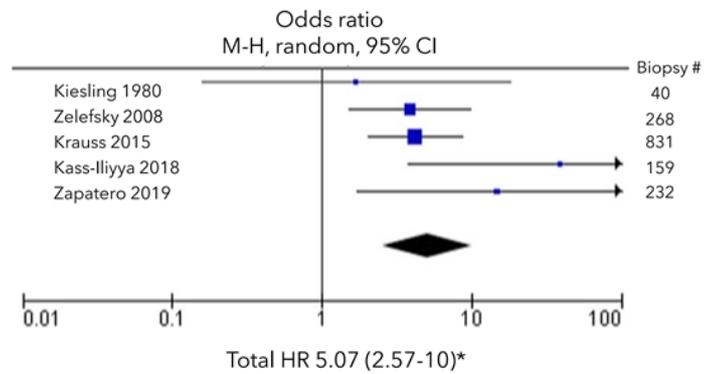
Patients with a positive prostate biopsy ≥ 2 years after radiotherapy because of localized cancer had:

- 10-fold higher odds of developing biochemical failure ($P < 0.00001$)
- 3-fold higher odds of developing distant metastasis ($P < 0.00001$)
- 5-fold higher odds of dying from their prostate cancer ($P < 0.00001$)

Risk of Developing Distant Metastasis



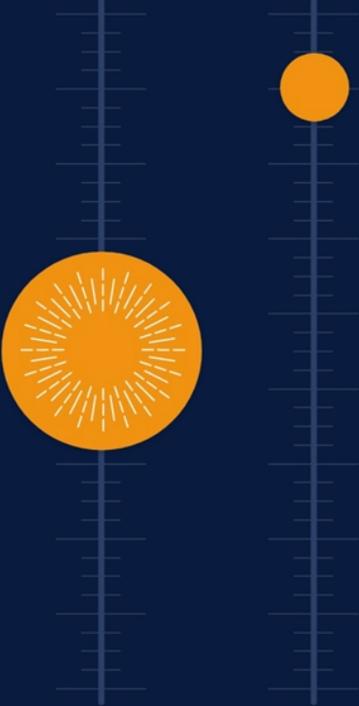
Risk of Prostate Cancer Mortality



*Weighted risk across studies, represented forest plots for metastasis-free survival and cancer mortality. Singh S et al. *Prostate Cancer Prostatic Dis.* 2021;24:612-622.

Phase 3 clinical trial of CAN-2409 in intermediate- to high-risk, localized prostate cancer: primary endpoint achieved, supported by secondary endpoints

Trial Design	<ul style="list-style-type: none">745-patient randomized trial with treatment arm + placebo arm, focused on disease-free survival (DFS) primary endpoint and multiple secondary endpoints
Primary Endpoint	<ul style="list-style-type: none">Statistically significant and clinically meaningful improvement in DFS for CAN-2409 plus radiation therapy vs radiation therapy alone. Hazard ratio 0.70, $P=0.0155$ in the intent to treat (ITT) analysis; median follow-up time of 50.3 months
Secondary and Supplemental Endpoints	<ul style="list-style-type: none">Significant effect on prostate cancer-specific DFS. Hazard ratio 0.62, $P=0.0046$Significant increase in the proportion of patients achieving a prostate-specific antigen (PSA) nadir of <0.2 ng/mL in the treatment arm compared to the placebo: 67.1% vs 58.6%, $P=0.0164$Central, blinded evaluation of post-treatment biopsies: pathological complete response rate of 80.4% in the CAN-2409 treatment arm vs 63.6% in the placebo control arm 2 years post-radiation ($P=0.0015$)
Safety	<ul style="list-style-type: none">Compelling safety profile, with lower incidence of serious adverse events (SAEs) and treatment-related SAEs in active arm vs control (5.8% vs 7.3% and 1.7% vs 2.2%, respectively)



CAN-2409 FOR NEWLY DIAGNOSED LOCALIZED PROSTATE CANCER



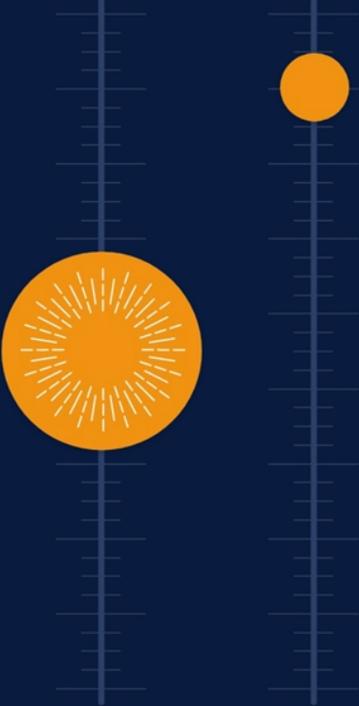
Glen Gejerman, MD, Co-chief of Urologic Oncology, Hackensack University Medical Center

Philip Kantoff, MD, Former Chair Department of Medicine, Memorial Sloan Kettering Cancer Center, CEO, Convergent Therapeutics

Garrett Nichols, MD, MS, Candel's Chief Medical Officer

Ron Tutrone, MD, National Director of Clinical Research, United Urology

Moderator: Oliver McCammon, LifeSci Capital



ROAD MAP TO BIOLOGICS LICENSE APPLICATION (BLA)



Susan Stewart, JD LLM, Candel's Chief Regulatory Officer

Seshu Tyagarajan, PhD, Candel's Chief Technical and Development Officer

Moderator: Andres Maldonado, PhD, H.C. Wainwright & Co.

BLA strategy

BLA on track for submission to FDA in Q4 2026

- Fast Track and RMAT designations granted



- iPSP pediatric waiver granted

- Priority Review eligible

- Expedited Review: Potential for additional reduced review timeline by 1+ more months

- Rolling Review eligible

- Small business fee waiver request

Regenerative Medicine Advanced Therapy (RMAT)

- All Fast Track designation features
- All Breakthrough Therapy designation features:
 - FDA actions to expedite development and review (e.g. 'Expedited Review')
 - Rolling review
 - Expedited review
 - Potential accelerated Approval on surrogate/intermediate endpoints
 - Organizational commitment involving senior managers
 - All meetings are now Type A or Type B

FDA interactions 2025



Prostate

- RCA Specification/Assay, Type D
- RMAT designation granted
- Tox and Biodistribution/Shedding Study Proposal, Type D
- Comparability Proposal, Type D



Lung

- EOP2/pre-Ph3 meeting, Type B

Interactions with FDA about CAN-2409 in prostate cancer

- ✓ **RMAT designation granted, allowing for frequent meetings**
- ✓ **FDA aligned with approach to setting RCA specification**
- ✓ **FDA aligned with proposed nonclinical toxicology package and clinical biodistribution/shedding study**
- ✓ **FDA aligned with the analytical approach for comparability**
- ✓ **Discussions regarding BLA submission ongoing (eg, data sets for rolling submission)**

Interactions with FDA about CAN-2409 in NSCLC

FDA alignment with:

Single preclinical toxicology study:

Species (mouse); RoA (IV);
prodrug (ip ganciclovir)

Clinical biodistribution and shedding plan

Proposed phase 3 registration study

Contribution of the agents
requirement noted–July 2025
FDA Guidance issued

“We tentatively agree that the primary evidence from the proposed phase 3 registrational study, if successful, when supported by confirmatory evidence from the phase 2 clinical trial, could demonstrate substantial evidence of effectiveness (SEE) to support a supplemental BLA submission and review.”



MANUFACTURING UPDATE

Technical operations (CMC) critical successes, to date



GMP1 run successful



Assay qualification and validation on track



DP fills successful



RCA assay development is complete



GMP2 run ongoing currently



FDA meeting on RCA and Comparability were productive



Master cell bank (MCB) and working cell bank (WCB) have been vialled, testing ongoing



Clear road map and alignment for executing analytical comparability



Commercial viral bank (VB) has been vialled, testing ongoing



Aligned with FDA on PPQ strategy



Potency assay has been qualified (ahead of schedule), validation ongoing

CAN-2409: Anticipated CMC timelines with FDA interactions

■ Completed
■ Planned



CMC progress

Manufacturing	<ul style="list-style-type: none">○ 4 large-scale runs + 2 midscale runs (3 × 200L runs completed, 2 × 50L runs completed, 1 × 200L run ongoing)○ 2 DP fills completed, 3 DP fills scheduled for December/January○ Master cell bank and working cell bank vialled, testing ongoing○ Commercial viral bank vialled, testing ongoing
PPQ	<ul style="list-style-type: none">○ All activities on track○ Small-scale model complete○ Master Validation Plan ongoing○ Process characterization ongoing
Analytical	<ul style="list-style-type: none">○ Assay qualification and assay validation on track○ Analytical comparability plan aligned○ Comparability protocol draft ongoing
Other critical work streams	<ul style="list-style-type: none">○ Supply chain & launch readiness○ Shipping validation and stability studies○ Extractables and leachables assessment○ PAI Readiness

CMC scale-up on track to support regulatory filings and anticipated launch

2023	<ul style="list-style-type: none">✓ Process development and scale-up from 3L to 50L to 200L✓ Type C Meeting with FDA re: CMC
2024	<ul style="list-style-type: none">✓ 200L ENG run
1H 2025	<ul style="list-style-type: none">✓ Type C Meeting with FDA re: RCA✓ 200L GMP run for commercial viral bank generation
2H 2025	<ul style="list-style-type: none">✓ Type D meeting with FDA re: comparability□ 200L GMP run with commercial viral bank and commercial cell bank; final commercial production process
2026	<ul style="list-style-type: none">□ 3×200L PPQ runs to be used for PPQ validation and comparability testing. PPQ and comparability data to be filed in support of the BLA

Key areas of progress

- ✓ Alignment on analytical comparability plan for BLA
- ✓ No additional clinical/non-clinical studies to support comparability/BLA currently anticipated to be necessary
- ✓ Agreement on RCA strategy
- ✓ Allowed to pool materials from prior processes without further testing to generate acceptance criteria for comparability protocol

✓ Completed



ENG=engineering; GMP=good manufacturing practice; PPQ=process performance qualification; RCA=replication-competent adenovirus

SAFC (Millipore Sigma/Candel's CDMO) manufacturing update

All activities
on track

Small-scale model
qualification is complete

Process
characterization
and PPQ readiness
is ongoing

Showing a collaborative
approach to ensure readiness
for meeting BLA timelines

Very engaged team

Increased cadence
of meetings

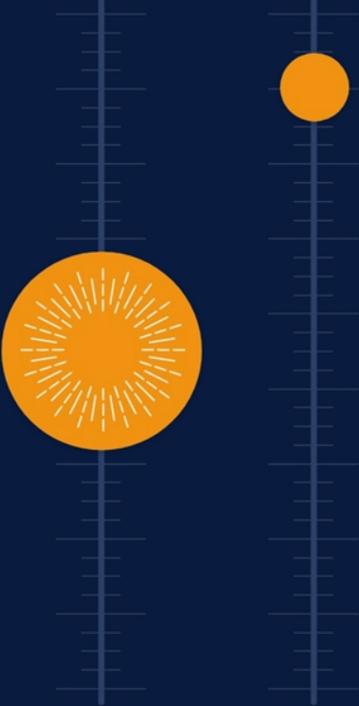
Hired extra resources to
ensure smooth progress

Committed to maintain
PPQ timelines

They continue to be a
good partner for Candel

Candel has
person-in-plant
at SAFC for
critical activities





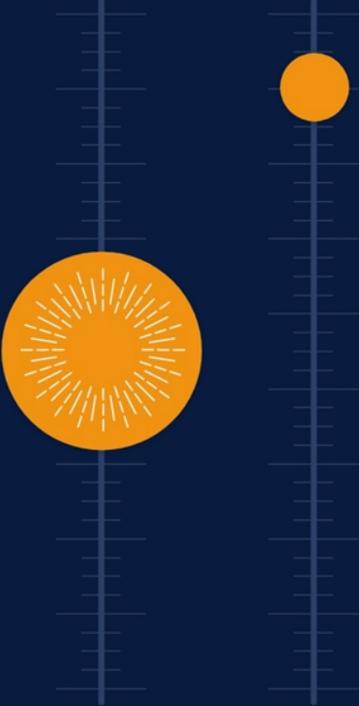
ROAD MAP TO BIOLOGICS LICENSE APPLICATION (BLA)



Susan Stewart, JD LLM, Candel's Chief Regulatory Officer

Seshu Tyagarajan, PhD, Candel's Chief Technical and Development Officer

Moderator: Andres Maldonado, PhD, H.C. Wainwright & Co.



PRE-COMMERCIALIZATION ROAD MAP



Jonathon Mitchell, MSc, Partner, Globe Life Sciences

Jacqueline Poot, President, IDEA Pharma

Paul Peter Tak, MD, PhD, FMedSci, Candel's President and CEO

Moderator: Andres Maldonado, PhD, H.C. Wainwright & Co.

Benefits of Candel's pre-commercialization model

1

EXTENSIVE COMMERCIALIZATION EXPERIENCE IN ONCOLOGY



2

MARKET-LEADING PRICING AND MARKET ACCESS CAPABILITIES TO MAXIMIZE VALUE



3

EXPERTISE TO DEFINE CRITICAL STRATEGIES & OPERATIONAL LEVERS TO ENSURE SUCCESS



4

FLEXIBILITY, SHARED RISK, AND POTENTIAL LAUNCH COST REDUCTIONS



Comprehensive commercial work streams for CAN-2409 in prostate cancer

12- to 18-month commercial road map

Strategic Goals

Go-to-Market
Ensure a seamless, data-driven commercialization strategy to maximize uptake at launch

Stakeholder Engagement
Build early advocacy with KOLs, HCPs, and patient organizations to drive awareness, education, and adoption

Market Access
Secure broad and rapid payer coverage by demonstrating compelling clinical and economic value

Key Activities

Activities underway today

- Strategic road map and positioning
- Scientific publications and conferences
- Pricing and reimbursement (P&R) assessments

Planned pre-launch activities

- Onboard field-force
- KOL/patient advocacy/ omnichannel engagement
- Core value dossier and budget impact model for payer engagement
- Coverage and formulary access

At launch

- HCP/account engagement execution
- Speaker medical education program
- Monitor and address barriers to access
- Track KPIs; optimize commercial strategy

BLA submission is expected in Q4 2026.



KOL=key opinion leader; HCPs=healthcare providers; KPIs=key performance indicators.

For patients electing to undergo radical therapy, achieving cure was consistently identified as the primary goal of treatment

Goals of Treatment

1

Cure

Primary goal among >95% of physicians interviewed



Preservation of quality of life

Second priority

"If you were going to rank these, cure is probably the top, and it's going to be competing with quality of life ... I want to live as long as I can, but I want that amount of time that I'm here to be as high quality as possible. It's the quality versus quantity argument."


KOL - US, Rad

"The goal is the same for surgery and for radiation, which is to control the disease and to have a PSA value which goes down to zero. The purpose if you undergo or undertake these kind of treatment modalities is to cure."


KOL - FRA, Uro

"I think the top two goals patients have are cure and preserving quality of life. Cure is usually number one. Preserving quality of life is a very close second."

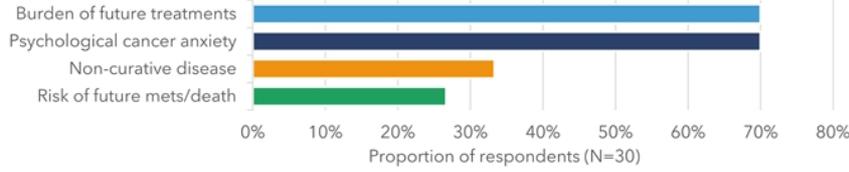

KOL - US, Rad



Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025. Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

Significant patient burden associated with recurrence, while unmet need for a novel adjunct therapy to improve outcomes was consistently described by physicians and KOLs as "high" or "very high"

Factors Contributing to Burden of Recurrence



"The impact is pretty profound. It's very high. Once they fail primary therapy they're going to have to think about alternatives, and it's usually systemic in nature. They will have to commit to a lifelong treatment plan and associated side effects."

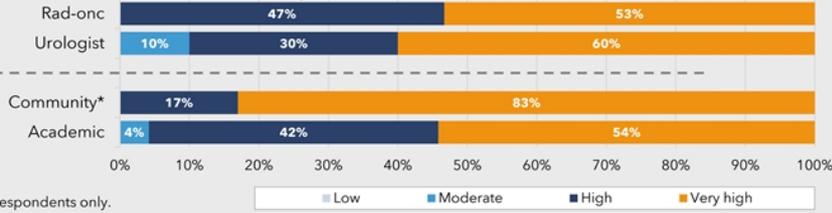


Community - US, Uro

Clear Need for Novel Adjunct



Perceived Need for Novel Adjunct to Radical Therapy in Int./High-Risk Localised Prostate Cancer

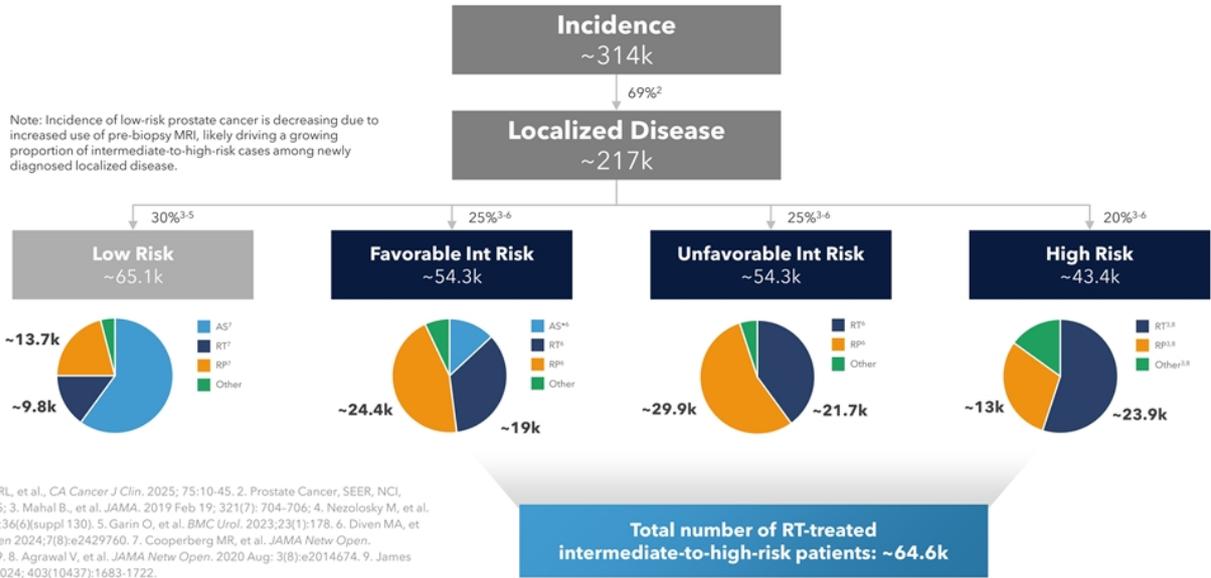


Key Areas to Address



Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025. Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

Substantial (and growing) addressable market opportunity in intermediate- to high-risk, localized prostate cancer - 65,000 patients undergoing RT each year in the US



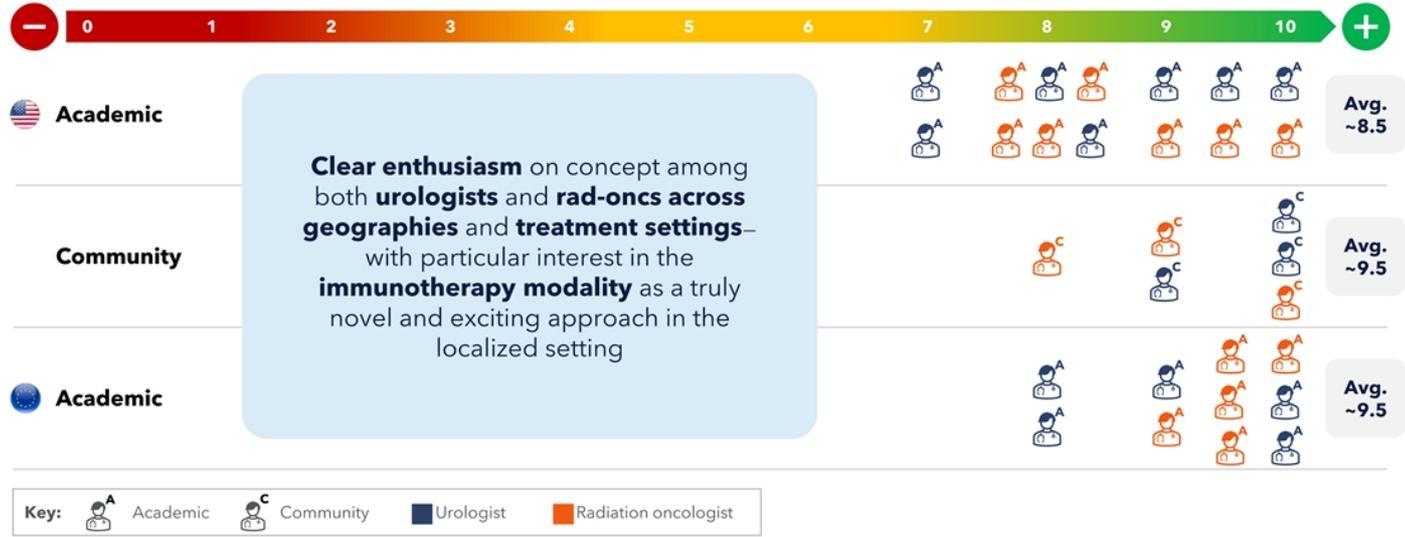
Sources: 1. Siegel RL, et al., *CA Cancer J Clin.* 2025; 75:10-45. 2. Prostate Cancer, SEER, NCI, accessed Mar 2025; 3. Mahal B., et al. *JAMA.* 2019 Feb 19; 321(7): 704-706; 4. Nezelosky M, et al. *J Clin Oncol.* 2018;36(6)(suppl 130). 5. Garin O, et al. *BMC Urol.* 2023;23(1):178. 6. Diven MA, et al. *JAMA Netw Open* 2024;7(8):e2429760. 7. Cooperberg MR, et al. *JAMA Netw Open.* 2023;6(3):e231439. 8. Agrawal V, et al. *JAMA Netw Open.* 2020 Aug; 3(8):e2014674. 9. James ND, et al. *Lancet.* 2024; 403(10437):1683-1722.



Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025. Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

The CAN-2409 product concept generated enthusiasm and excitement among interviewed physicians—with a consistently positive response across customer segments

Physician Interest/Excitement in Product Concept (N=30)



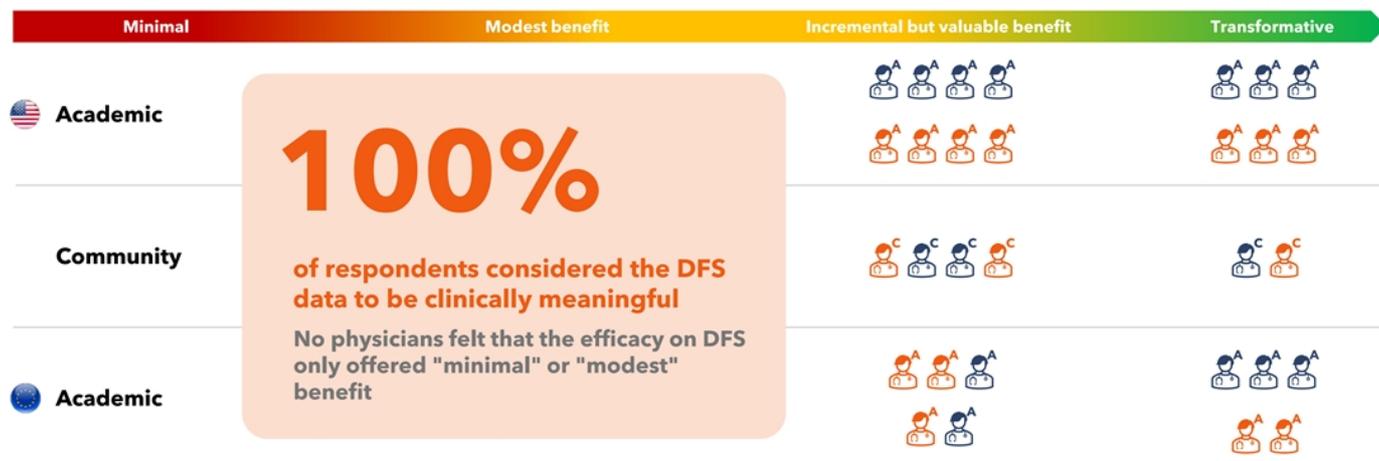
Clear enthusiasm on concept among both **urologists** and **rad-oncs** across **geographies** and **treatment settings**—with particular interest in the **immunotherapy modality** as a truly novel and exciting approach in the localized setting



Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025. Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

100% of interviewed physicians considered the DFS primary endpoint data to be clinically meaningful-and roughly 50% viewed it to be transformative

Physician Views on Strength & Clinical Meaningfulness of DFS Primary Endpoint Data (N=30)



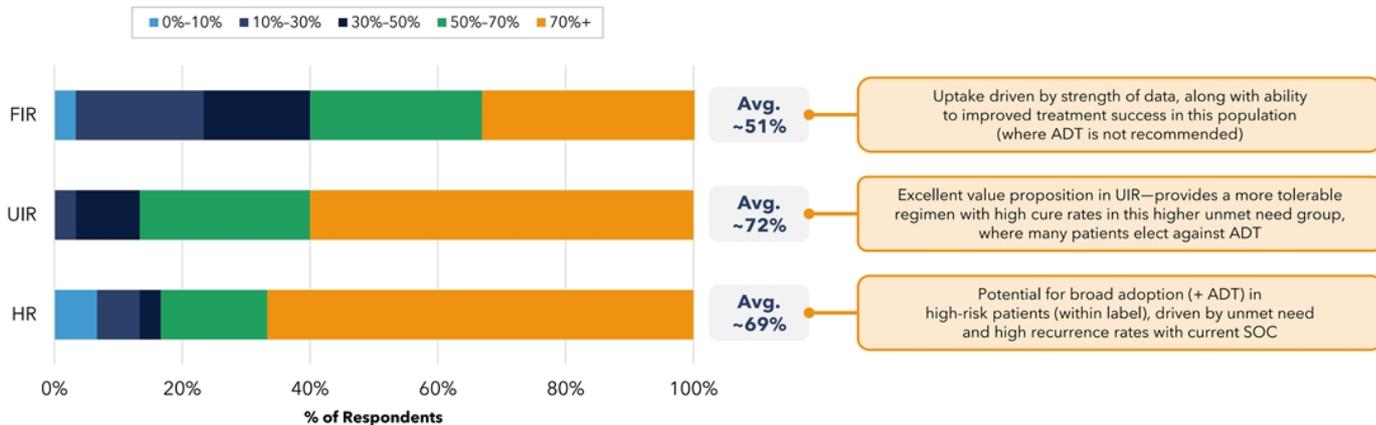
Key: Academic Community Urologist Radiation oncologist



Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025. Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

Physician feedback suggests potential for strong uptake of CAN-2409 across risk groups, and adoption of the product as a standard of care in patients receiving RT

Physician Anticipated Uptake of CAN-2409 in Their Practice (in Patients Receiving RT) * (N=30)



*Assuming no major reimbursement/market access barriers.
FIR=favorable intermediate risk; HR=high risk; UIR=unfavorable intermediate risk.



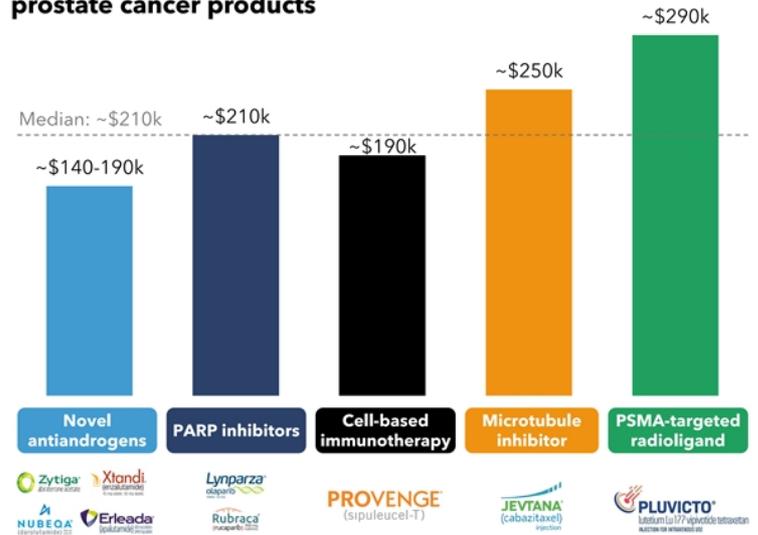
Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025.
Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

Benchmarks and payer feedback support an illustrative pricing range for CAN-2409 in localized prostate cancer

Payer study findings

- **Phase 3 results resonate with payers and purchasers**—30% improvement in disease-free survival (DFS) and 38% improvement in prostate cancer-specific DFS viewed as clinically meaningful
 - Trial size and design seen as appropriate
- **Payers receptive to attractive price points**, in line with annualized costs of other prostate cancer therapies without significant access restrictions, based on CAN-2409's clinical value
- **Payers generally demonstrate minimal price sensitivity** if the product is included in NCCN guidelines—if is recommended (Category 1 or 2A) it will be covered regardless of price

Annual wholesale acquisition cost (WAC) for selected prostate cancer products



Note: Prices assume continuous treatment on annual basis except Provenge and Pluvicto, which are one-time treatments.

Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025.

Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.



CAN-2409 is positioned to succeed in early localized prostate cancer

High Unmet Need

Significant Market Opportunity

Candel's Unique Value Proposition

CAN-2409: Off-the-shelf pan-solid tumor therapy, individualized anticancer immune response

- Positive Phase 3 randomized placebo-controlled clinical trial in localized, intermediate-to-high-risk prostate cancer
- Disease-free survival as primary endpoint was a key element of the Special Protocol Assessment (SPA) agreement with the FDA
- FDA Regenerative Medicine Advanced Therapy (RMAT) designation in prostate cancer, Fast Track designation in NSCLC, pancreatic cancer, and prostate cancer. Orphan Drug designation in pancreatic cancer
- "Pipeline in a product" strategy advancing multiple programs in several large indications
- IP protection: CAN-2409 (2034, method of use); 12 years data exclusivity
- Low-cost manufacturing
- Pre-commercialization activities underway to support potential post-approval commercial launch of CAN-2409



Our commercial strategy is anchored in aligned critical success factors



Critical Success Factor 1

Establish stakeholder belief in CAN-2409 as a transformative new treatment option that advances SoC



Critical Success Factor 2

Optimize distribution, purchase, and reimbursement of CAN-2409



Critical Success Factor 3

Maximize pricing by communicating strong value proposition to payers and providers

Driving commercial success for CAN-2409 includes thoughtful medical communications, an optimized channel/distribution Go-to-Market approach, and a compelling pricing/market access strategy.

Anticipated CAN-2409 cross-functional launch readiness and milestone events

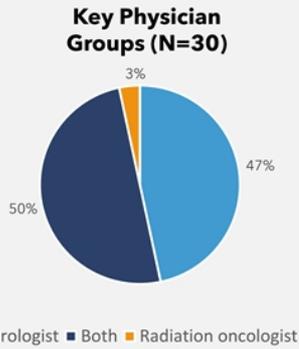
	2025			2026				2027				
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Clinical/Regulatory Milestones	★ Oral Presentation (ASCO) 2409 in Prostate	★ Oral Presentation (ASTRO) 2409 in Prostate		★ Long-Term Survivors Updated Ph 2a Data 2409 in NSCLC	★ Prostate-Specific Follow-Up Data 2409 in Prostate	★ Immunological Biomarker Data 2409 in Prostate	★ BLA Submission 2409 in Prostate				★ Expected PDUFA 2409 in Prostate	
US Launch Planning Key Activities	Precommercial Strategy & Planning			Launch Readiness							MSL/Sales Recruitment	
External Events	▼ AUA ▼ ASCO	▼ ASTRO	▼ PCF Scientific ▼ SITC	▼ ASCO ▼ GU	▼ AUA ▼ ASCO		▼ PCF Scientific	▼ LUGPA ▼ ASCO ▼ GU	▼ AUA ▼ ASCO			▼ PCF Scientific

AUA=American Urological Association, ASCO=American Society of Clinical Oncology, ASCO GU=ASCO Genitourinary Cancers Symposium, ASTRO=American Society for Radiation Oncology, HGG=high-grade glioma, LUGPA=Large Urology Group Practice Association, MSL=medical science liaison, NSCLC=non-small cell lung cancer, PCF Scientific=Prostate Cancer Foundation Scientific, SITC=Society of Immunotherapy of Cancer



Field sales launch strategy to drive rapid penetration in both community and hospital urologic oncology practices

Physicians



Urologist

- Ensure strong education and awareness around the product concept—including around its ease of use, excellent safety, and demonstrated clinical efficacy
- Communicate ability to retain treatment of patients who elect to undergo radiotherapy
- Optimize financial incentives associated with administration of CAN-2409 by the urologist

Radiation Oncologist

- As with urologists, ensure strong education around the product concept—and optimize financial incentives for radiologists who may administer the product
- Communicate potential synergy of CAN-2409 with radiotherapy

Patients

Patient engagement would be a critical component of the commercial strategy, given the influence patients have on decision-making in localized disease

- Drive patient interest through increased likelihood of cancer cure, with minimal side effects and one-off treatment—which can help avoid the significant burden of recurrence
- Manage perceptions around administration



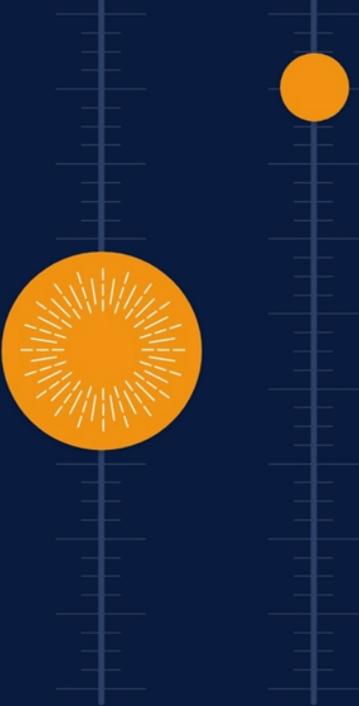
Globe Life Sciences commercial evaluation of CAN-2409 in prostate cancer, March-May 2025. Methodology included secondary analysis and primary research with 30 KOLs/physicians and 20 payers across the US/Europe.

CAN-2409 prostate cancer anticipated launch expected to create a scalable commercial platform across the pipeline



Expected outcomes:

- ✓ Reduces cost/time for future launches
- ✓ Provides repeatable BLA and supply chain frameworks
- ✓ Enables multi-indication expansion without proportional headcount growth
- ✓ Creates enterprise commercial readiness ahead of pipeline inflection points



PRE-COMMERCIALIZATION ROAD MAP

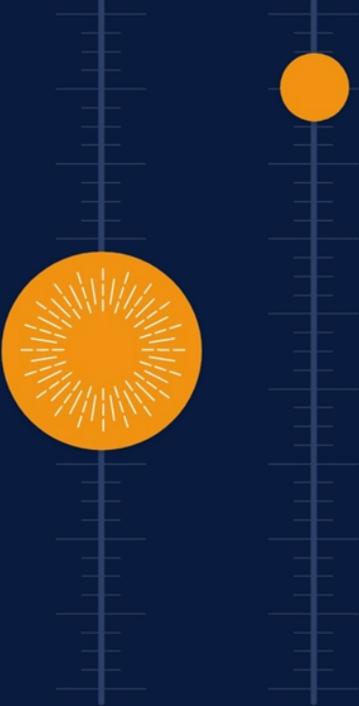
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Jonathon Mitchell, MSc, Partner, Globe Life Sciences

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Paul Peter Tak, MD, PhD, FMedSci, Candell's President and CEO

Moderator: Andres Maldonado, PhD, H.C. Wainwright & Co.



CAN-2409 FOR IMMUNE CHECKPOINT INHIBITOR REFRACTORY NON-SMALL CELL LUNG CANCER



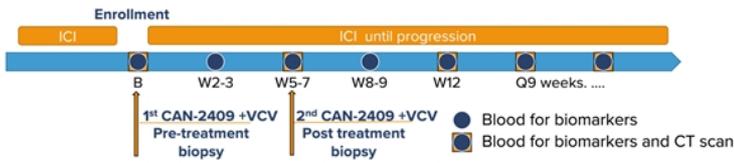
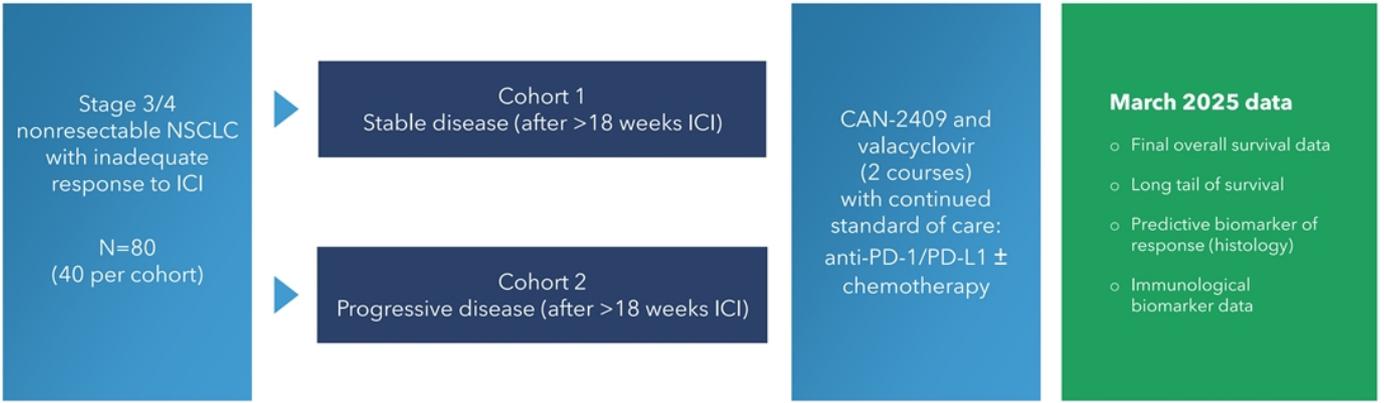
Charu Aggarwal, MD, Professor of Lung Cancer Excellence, Perelman School of Medicine,
University of Pennsylvania

Roy Herbst, MD, PhD, Ensign Professor of Medicine (Medical Oncology) and Professor of Pharmacology,
Yale Cancer Center

Dan Serman, MD, Thomas and Suzanne Murphy Professor of Medicine and Cardiothoracic Surgery,
NYU Langone Health

Moderator: John Newman, PhD, Canaccord Genuity

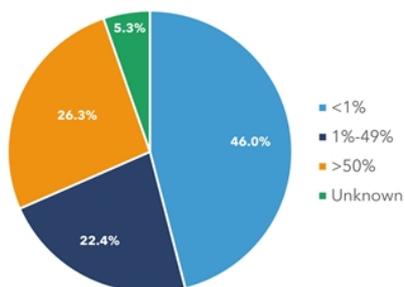
Phase 2a clinical trial of CAN-2409 + continued ICI in stage III/IV NSCLC patients with an inadequate response to ICI



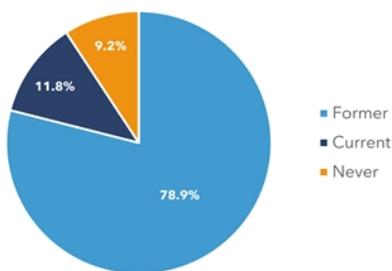
Note: ClinicalTrials.gov ID: NCT04495153.

Study population: unfavorable prognostic factors at baseline

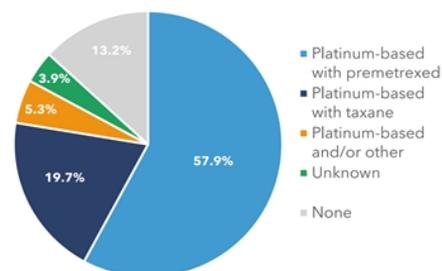
PDL-1 expression



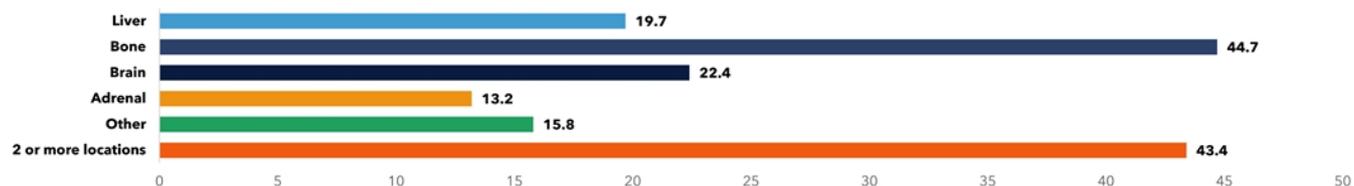
Smoking



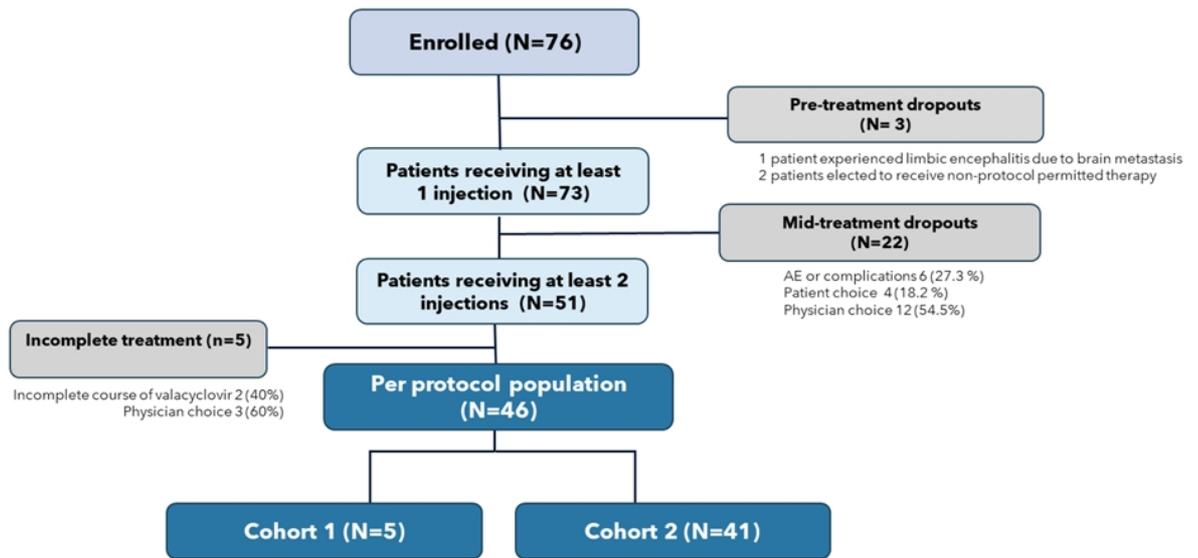
Prior lines of therapy



Distant Metastatic Involvement, % (n=76)



CONSORT diagram



Per protocol population: patients who received complete treatment consisting of 2 courses of CAN-2409 + prodrug (valacyclovir) and had a week 12 assessment.

Adverse events. Cohort 1(2inj): pneumonitis grade 3, possibly related to study drug; pulmonary embolism grade 3, unrelated to study drug. Cohort 2 (2inj): empyema grade 3, possibly related to study drug; pneumonia grade 3, pre-syncope grade 2, and bullous dermatitis grade 3, all unrelated to study drug.

Baseline demographics and characteristics: Per-protocol population is representative of overall study population

	Enrolled n=76 (%)	Per protocol n=46 (%)		Enrolled n=76 (%)	Per protocol n=46 (%)
Age			Smoking history		
Median (range), years	67 (43-88)	69 (43-84)	Never	7 (9.2%)	4 (8.7%)
Sex			Former	60 (78.9%)	38 (82.6%)
Female	34 (44.7%)	22 (47.8%)	Current	9 (11.8%)	4 (8.7%)
Male	42 (55.3%)	24 (52.2%)	Treatment regimen at enrollment		
Race			Single ICI	53 (69.7%)	30 (65.2%)
Black/African American	10 (13.2%)	7 (15.2%)	ICI plus chemotherapy	23 (30.3%)	16 (34.8%)
Asian	1 (1.3%)	1 (2.2%)	ICI regimen		
White	61 (80.3%)	37 (80.4%)	Durvalumab	3 (3.9%)	3 (6.5%)
Unknown	4 (5.3%)	1 (2.2%)	Nivolumab	5 (6.6%)	3 (6.5%)
Ethnicity			Pembrolizumab	68 (89.5%)	40 (87.0%)
Not Hispanic or Latino	67 (88.2%)	41 (89.1%)	Chemo regimen at enrollment		
Not reported	9 (11.8%)	5 (10.9%)	Pemetrexed	23 (30.3%)	16 (34.8%)
PD-L1 expression			None	53 (69.7%)	30 (65.2%)
<1%	35 (46.0%)	21 (45.7%)	Prior lines of treatment		
1%-49%	17 (22.4%)	13 (28.3%)	None	10 (13.2%)	6 (13.0%)
≥50%	20 (26.3%)	8 (17.4%)	Platinum-based with pemetrexed	44 (57.9%)	26 (56.5%)
Unknown	4 (5.3%)	4 (8.7%)	Platinum-based with taxane	15 (19.7%)	11 (23.9%)
Stage			Platinum-based and/or other	4 (5.3%)	3 (6.5%)
Stage 3	7 (9.2%)	6 (13.0%)	Unknown	3 (3.9%)	0 (0%)
Stage 4	69 (90.8%)	40 (87.0%)			

CAN-2409 demonstrated a generally favorable safety and tolerability profile

Most Common Treatment-Emergent Related Adverse Events Occurring In $\geq 5\%$ of patients (n=73)

Grade: n (%)	1	2	3	4	Total
Gastrointestinal disorders					
Diarrhea	5 (7)	0 (0)	0 (0)	0 (0)	5 (7)
Nausea	11 (15)	4 (5)	0 (0)	0 (0)	15 (21)
Vomiting	4 (5)	2 (3)	0 (0)	0 (0)	6 (8)
General disorders and administration site conditions					
Chills	8 (11)	0 (0)	0 (0)	0 (0)	8 (11)
Fatigue	16 (22)	7 (10)	0 (0)	0 (0)	23 (32)
Influenza-like illness	3 (4)	1 (1)	0 (0)	0 (0)	4 (5)
Pyrexia	12 (16)	1 (1)	1 (1)	0 (0)	14 (19)
Investigations					
Aspartate aminotransferase increased	4 (5)	0 (0)	0 (0)	0 (0)	4 (5)
Blood creatinine increased	4 (5)	3 (4)	0 (0)	0 (0)	7 (10)
Metabolism and nutrition disorders					
Decreased appetite	2 (3)	4 (5)	0 (0)	0 (0)	6 (8)
Nervous system disorders					
Headache	3 (4)	1 (1)	0 (0)	0 (0)	4 (5)
Respiratory, thoracic, and mediastinal disorders					
Dyspnea	2 (3)	4 (5)	0 (0)	0 (0)	6 (8)
Pneumonitis	0 (0)	2 (3)	2 (3)	0 (0)	4 (5)

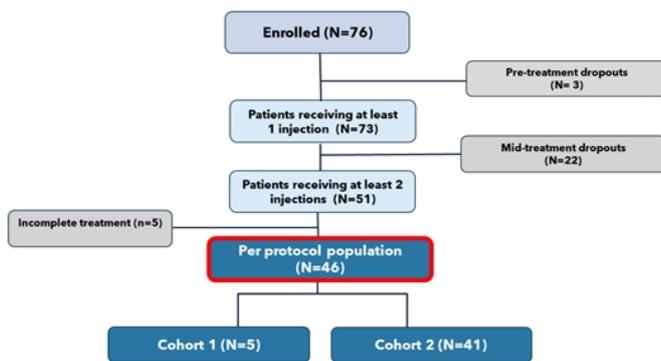
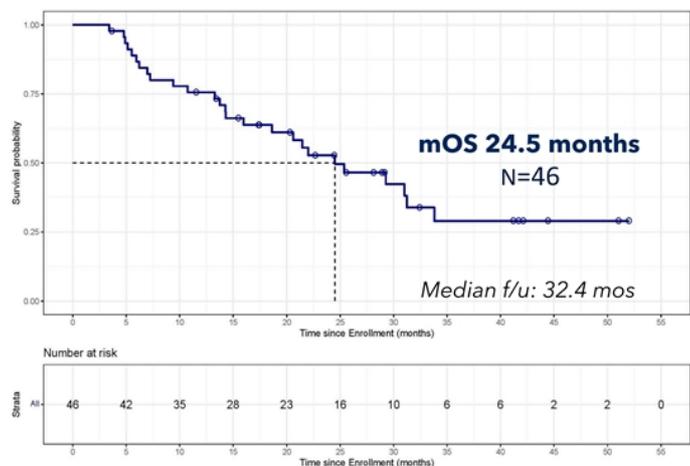
- Most treatment-related AEs (TRAEs) grade 1-2
- Grade 3 TRAEs in <5% of patients
- No DLTs or TRAEs \geq grade 4 reported
- TRAEs are consistent with the MOA (eg, chills, pyrexia)



DLT=dose limiting toxicity; MOA=mode of action; TRAE=treatment-related adverse events.

mOS of 24.5 months after CAN-2409 treatment in NSCLC patients with an inadequate response to immune checkpoint inhibitors (Cohort 1 and Cohort 2)

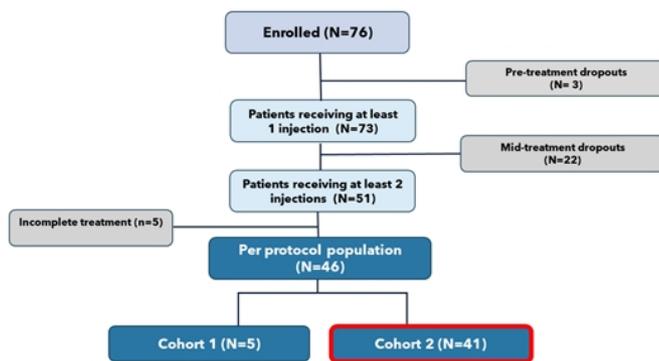
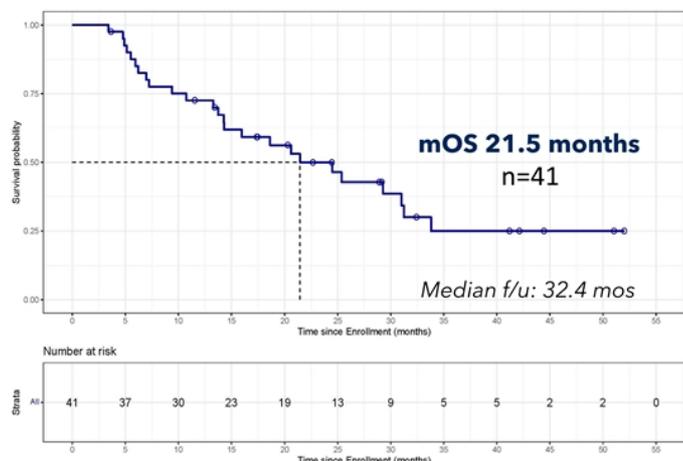
Cohort 1 + Cohort 2 (per-protocol population)



Per protocol population: patients who received complete treatment consisting of 2 courses of CAN-2409 + prodrug (valacyclovir) and had a week 12 assessment.

mOS of 21.5 months after CAN-2409 treatment in NSCLC patients with progressive disease despite immune checkpoint inhibitor (Cohort 2)

Cohort 2 (per-protocol population): Patients with the greatest unmet medical needs



Per-protocol population: patients who received complete treatment consisting of 2 courses of CAN-2409 + prodrug (valacyclovir) and had a week 12 assessment.

Historical controls: mOS in PD-1 refractory population with SoC chemo is 9.8-11.8 mos.^{1,2}



1. Paz-Ares LG et al. *J Clin Oncol.* 2024;42:2860-2872; 2. Ahn MJ et al. *J Clin Oncol.* 2024;43:260-272.

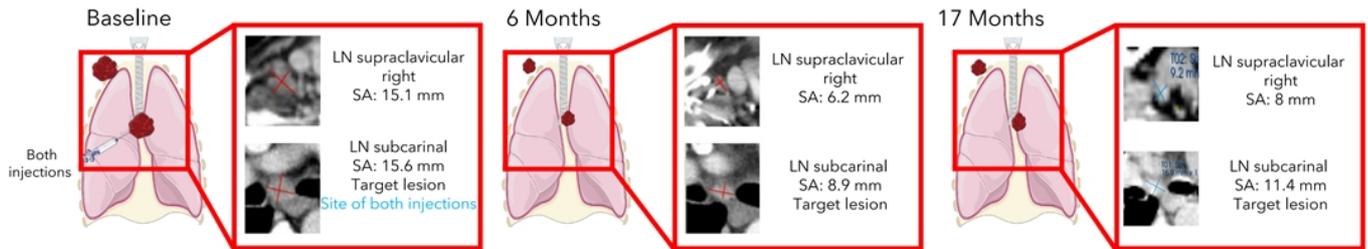
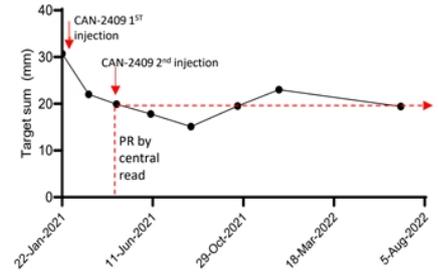
CAN-2409 induced long-term, systemic antitumor activity in progressive, metastatic NSCLC

Abscopal effect, survival >52 months (ongoing) after CAN-2409 treatment

As of 20-Oct-2025

NY-007 (Cohort 2)

74-year-old male, Stage IV nonsquamous NSCLC diagnosed February 2019, PD-L1 <1%
 Initial therapy: cisplatin/etoposide treatment February-July 2019
 Maintenance: nivolumab treatment beginning in September 2019, continued on study
OS 52.4 mo. (ongoing as of LFV June 2025)



Legend

RECIST target lesions (red)

LA=long axis; LFV=last follow up visit; LN=lymph node; SA=short axis.
 Schematics to show general lesion injection orientation; not to scale.



Local injection-induced systemic antitumor activity

Regression of uninjected lesions in ~two-thirds of patients presenting with multiple lesions

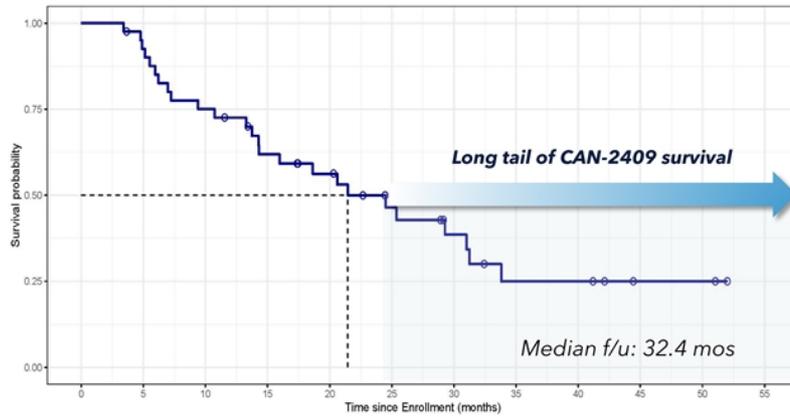


- Systemic or abscopal effect (decrease of uninjected lesions) was measured in all evaluable patients with at least 1 uninjected lesion (n=35)
- Decrease of at least 5% observed in at least 1 uninjected lesion



Long tail of survival: 37% of patients alive >2 years after CAN-2409 administration in patients with progressive NSCLC at time of enrollment

Cohort 2 (per-protocol population)



Time post treatment	No. of patients	% survivors*
>24 months	15	37%
>30 months	9	22%
>36 months	5	12%
>40 months	5	12%
>50 months	2	5%

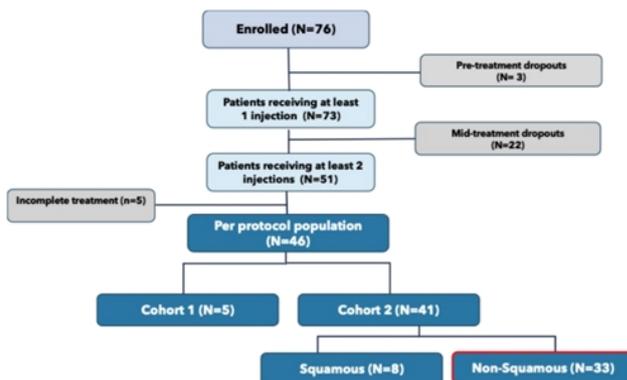
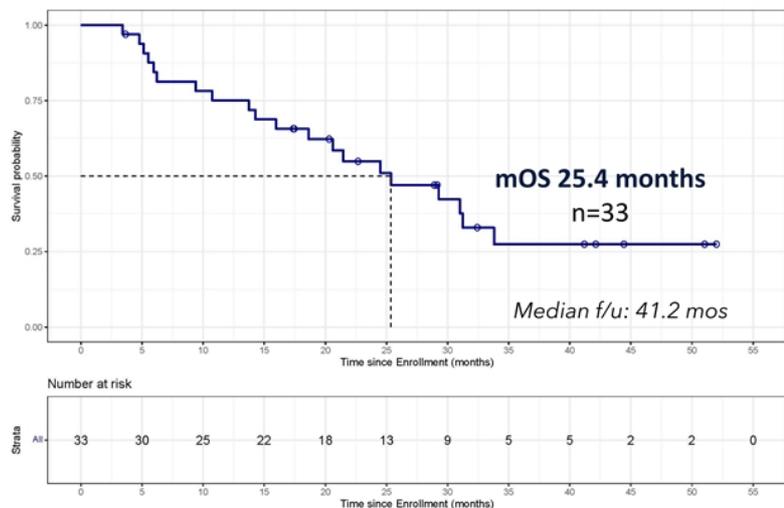
**Enrichment of nonsquamous NSCLC among long-term survivors in Cohort 2:
14/15 patients with OS >24 months and 9/9 patients with OS >30 months had nonsquamous NSCLC**



*Percentages rounded to the nearest whole number.

mOS of 25.4 months after CAN-2409 treatment in nonsquamous NSCLC patients with progressive disease despite ICI (per protocol in Cohort 2)

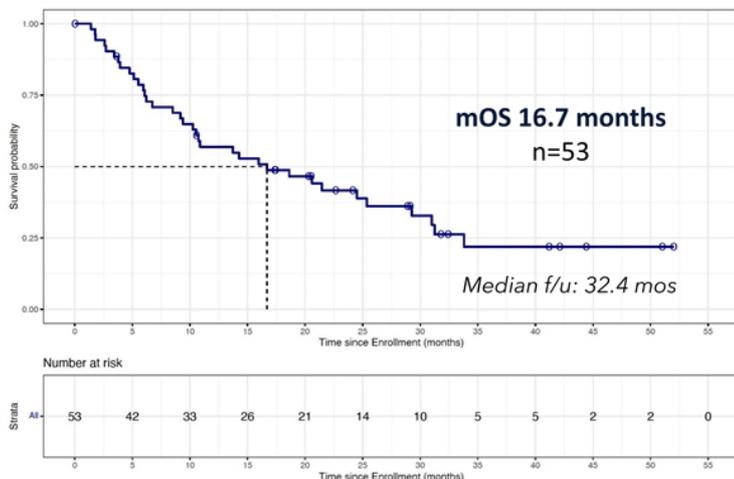
Cohort 2 (per-protocol population, nonsquamous NSCLC): Patients with the greatest unmet medical needs and histologic subset most likely to benefit from CAN-2409



Per protocol population: patients who received complete treatment consisting of 2 courses of CAN-2409 + prodrug (valacyclovir) and had a Week 12 assessment.

mOS of 16.7 months after CAN-2409 in nonsquamous NSCLC patients with progressive disease despite ICI (ITT* in Cohort 2)

Cohort 2 (ITT population,* nonsquamous NSCLC)



Historical controls: mOS in PD-1 refractory NSCLC with nonsquamous disease with SoC chemo is 9.9-12.3 mos.^{1,2}

EVOKE-01 Trial (Gilead)¹
Paz Ares L, 2024

Overall with SoC (n=304): 9.8 mos
Non-SQ with SoC (n=224): 9.9 mos
SQ with SoC (n=80): 9.2 mos

TROPION-LUNG01 Trial (AstraZeneca and Daiichi Sankyo)²
Ahn MJ, 2024

Overall with SoC (n=305): 11.8 mos
Non-SQ with SoC (n=232): 12.3 mos
SQ with SoC (n=73): 9.4 mos

***Exploratory analysis; experimental medicine Phase 2a clinical trial is designed for per-protocol analysis, not for ITT analysis.**



1. Paz-Ares LG et al. *J Clin Oncol*. 2024;42:2860-2872; 2. Ahn MJ, et al. *J Clin Oncol*. 2024;43:260-272.

Positive overall survival data in phase 2a clinical trial of CAN-2409 in NSCLC

Experimental treatment of CAN-2409 + valacyclovir in NSCLC patients with an inadequate response to ICI was well tolerated, with median overall survival (mOS) of 24.5 months after only 2 administrations

We observed mOS of 21.5 months in patients with progressive disease at baseline, markedly exceeding mOS reported in this population using SOC chemotherapy (9.8-11.8 months)

Long tail of survival with 37% of patients alive >2 years after CAN-2409 administration

Potential for precision medicine approach in patients with the greatest unmet medical needs

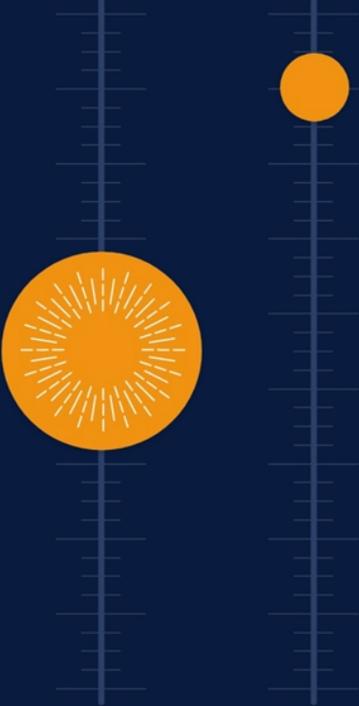
mOS of 25.4 months after CAN-2409 treatment in nonsquamous NSCLC patients (70%-75% of patients) with progressive disease despite ICI

90% of the patients had stage 4 disease; an abscopal effect was observed in ~two-thirds of the patients presenting with at least one uninjected lesion

This observation supports the hypothesis that only 1 or 2 tumors need to be injected to teach the immune cells how to recognize the patient's tumor and induce systemic and durable antitumor immunity associated with improved survival



*The comparisons in mOS for NSCLC are not head-to-head.



CAN-2409 FOR IMMUNE CHECKPOINT INHIBITOR REFRACTORY NON-SMALL CELL LUNG CANCER

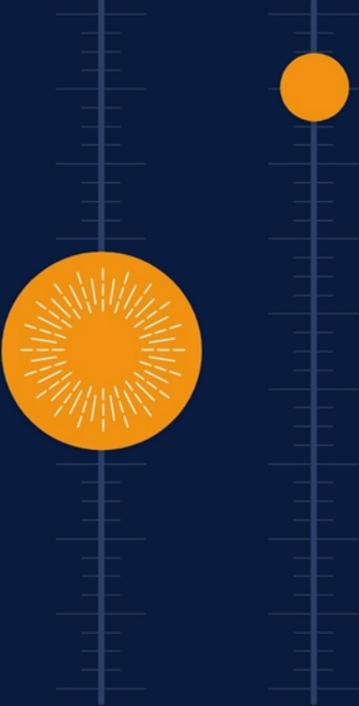


Charu Aggarwal, MD, Professor of Lung Cancer Excellence, Perelman School of Medicine,
University of Pennsylvania

Roy Herbst, MD, PhD, Ensign Professor of Medicine (Medical Oncology) and Professor of Pharmacology,
Yale Cancer Center

Dan Serman, MD, Thomas and Suzanne Murphy Professor of Medicine and Cardiothoracic Surgery,
NYU Langone Health

Moderator: John Newman, PhD, Canaccord Genuity



CAN-3110 FOR RECURRENT GLIOBLASTOMA



Francesca Barone, MD, PhD, Candel's Chief Scientific Officer

Henry Brem, MD, Professor of Neurosurgery, Johns Hopkins University

Moderator: Kemp Dolliver, Brookline Capital Markets

CAN-3110: High-grade glioma opportunity

Prevalence of glioblastoma in the US¹



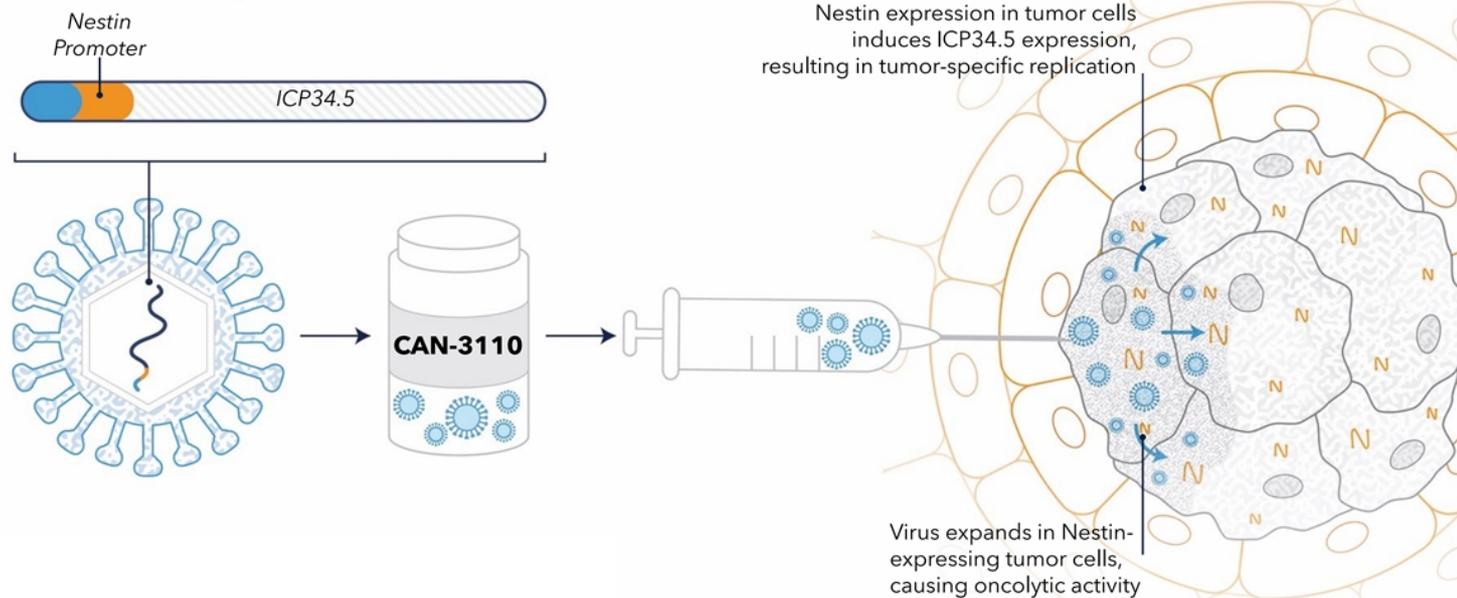
- Glioblastoma, the most common form of high-grade glioma, is a rare and often deadly cancer¹
- Fewer than 10% of patients survive >5 years past initial diagnosis²
- Median overall survival <6-9 months in recurrent high-grade glioma³
- Current standard of care includes surgical resection with few available therapeutic options
- Significant opportunity to improve survival by teaching the immune system how to recognize the cancer cells and turn "cold tumors" into "hot tumors"



1. Miller KD et al. *CA Cancer J Clin.* 2021;71:381-406. 2. Stupp R et al. *Lancet Oncol.* 2009;10:459-466. 3. vanLinde MC et al. *J Neuro Onc.* 2017;135:183-192

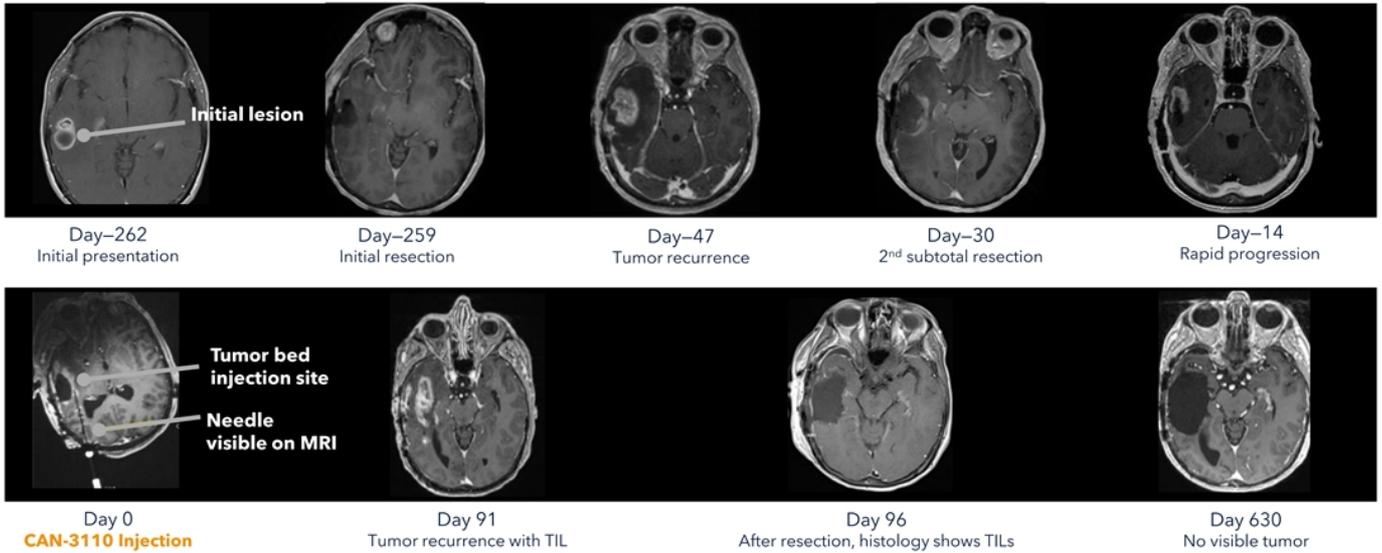
Candel's second investigational medicine, CAN-3110: Mechanism of action

Please visit <https://vimeo.com/822133681>



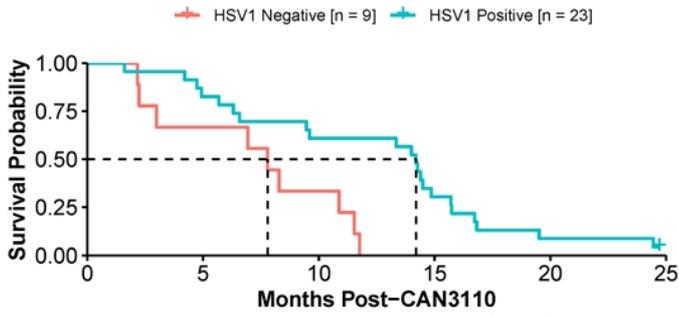
CAN-3110 is an investigational product and its mechanism of action in humans has not been definitively established. This depiction of the CAN-3110 mechanism of action and the MoA video linked above are based on preclinical data and observations in clinical studies to date.

Durable response for 2 years after single injection of CAN-3110 in recurrent glioblastoma (patient died in an accident)



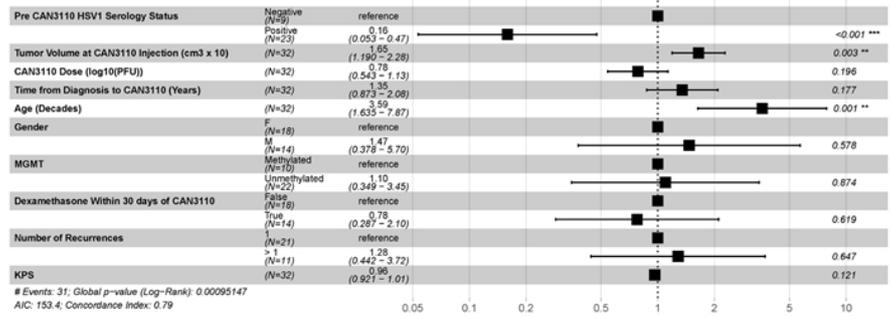
61 YOF, IDH wild-type, MGMT methylated glioblastoma, right temporal lesion initially treated with surgery, chemoradiation, and temozolomide
CAN-3110 dose: 10^8 PFUs. Patient died as passenger in a motor vehicle accident on Day 717.

Prolonged survival after CAN-3110 treatment was associated with HSV1 seropositivity



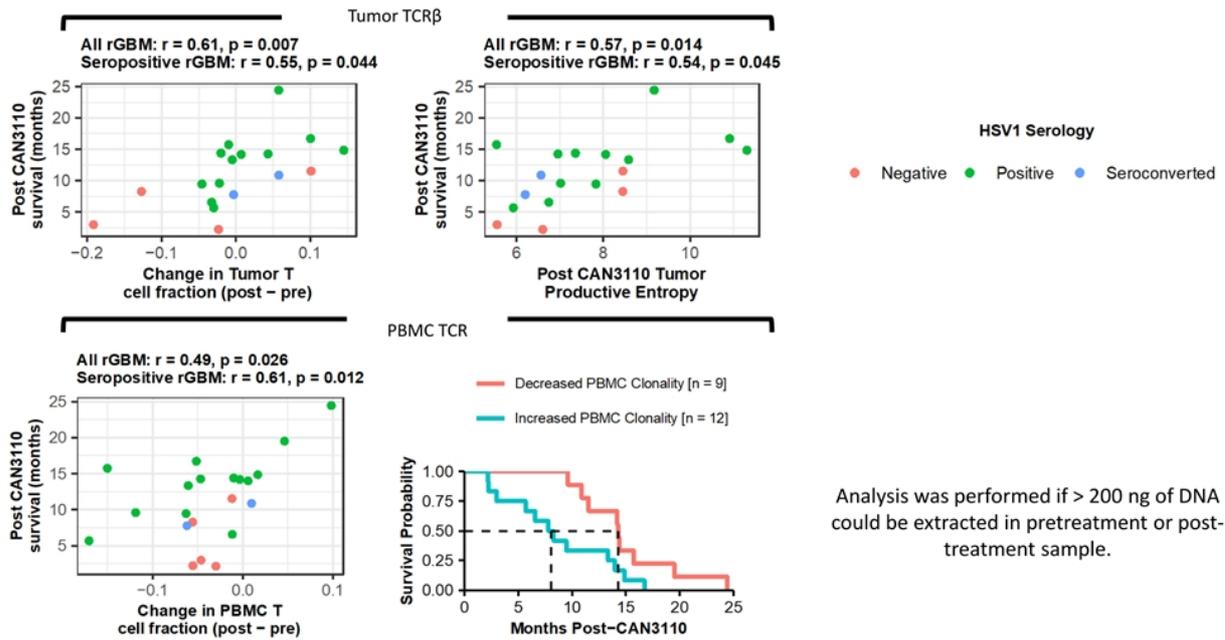
HSV2 serology status is not associated with survival.

COXPH Hazard Ratios



Ling AL et al. *Nature*. 2023;623:157-166.

Changes in T-cell fractions and TCR β diversity correlate with survival after CAN-3110 treatment



Survival data after repeated administration of CAN-3110 in recurrent glioblastoma (ongoing), suggesting a long tail of survival

At the time of data cutoff (8/15/2025), **2 patients were still alive after single CAN-3110 injection after prolonged follow-up (59.2 and 42.4 months, respectively)**

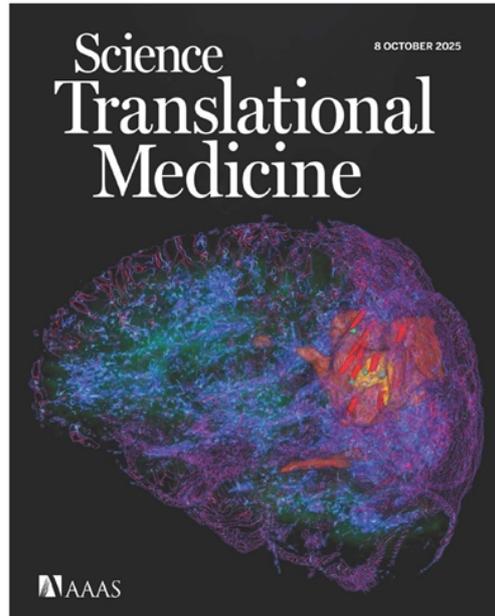
Encouraging data after repeated injections of CAN-3110

Patient	Age	Sex	# of injections	OS (months)	Status
1	54	M	4	12.42	D
2	66	F	6	28.16	A
3	75	F	6	8.94	D
4	64	M	5	13.60	D
5	61	F	4	21.75	D
6	69	F	4	5.49	D
7	53	F	4	6.11	A
8	46	F	5	5.09	A
9	59	M	5	3.09	A

Patients 1-6 received 1×10^8 pfu of CAN-3110/injection.
Patients 7-9 received 1×10^7 pfu of CAN-3110/injection.



CAN-3110 induced dynamic spatial and temporal remodeling of the tumor microenvironment, where tumor cells are replaced by immune cells



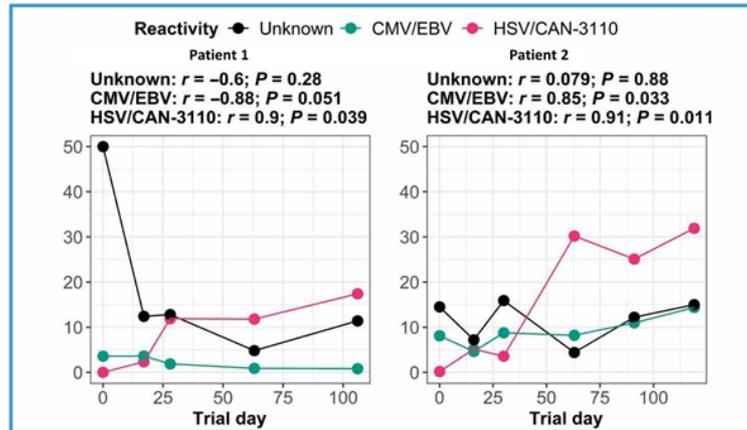
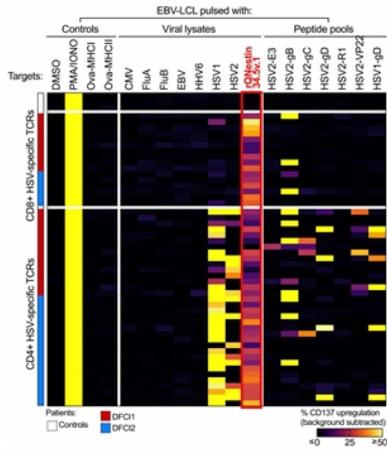
Ling AL et al. *Sci Transl Med.* 2025;17:eadv2881.

CAN-3110 induced HSV-reactive T-cell clones in rGBM

192 TCR α/β pairs from 169 clonotypes, were reconstructed and screened for antigen specificity

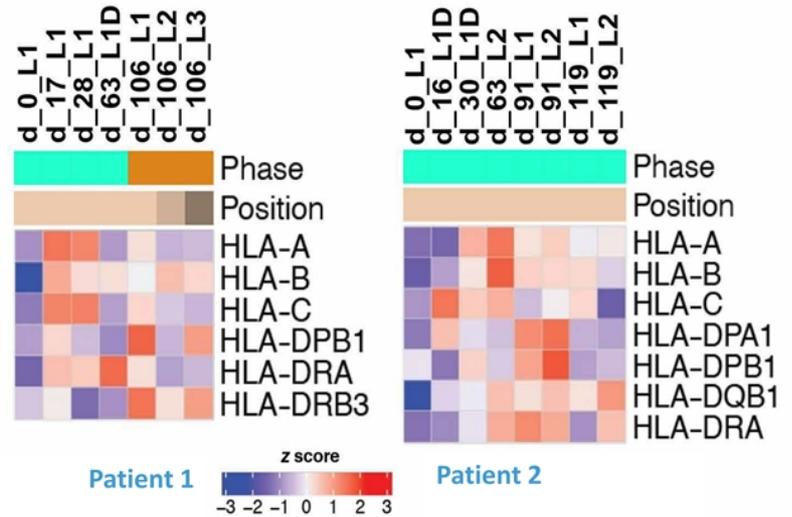
Up to 30% of identified TCRs were reactive to CAN-3110.

- CD8+ HSV/CAN-3110-reactive TILs enriched in IFNG+LAG3+ T effector cells (FDR <0.2) and displayed tissue-resident, activated program (Hobit+, TOX-)
- CD4+ HSV/CAN-3110-reactive TILs enriched in PDCD1+CTLA4+ T effector cells



CAN-3110 treatment enhanced HLA-immunopeptidome expression, including glioma-associated CTAs and tumor-associated antigens

- HLA-A, HLA-B, HLA-C, and HLA-DR levels were increased in nearly all post-treatment biopsies
- HLA-I-bound immunopeptides were elevated post-treatment
- Several upregulated immunopeptides matched pan-cancer cancer/testis antigens (CTAs) and glioma-associated testis-specific antigens (GFAP, myelin basic protein, and antigens associated with GBM progression/invasion, eg, VIM, S100A9)



Encouraging safety data, clinical activity, and immunological changes after CAN-3110 in recurrent high-grade glioma (glioblastoma)



Monotherapy treatment with CAN-3110 in rHGG is well tolerated and associated with doubling of expected median overall survival



Immunological changes in the tumor microenvironment are associated with improved survival and HSV1 seropositivity



First 9 patients have been dosed in Cohort C (fully funded by the Break Through Cancer foundation)



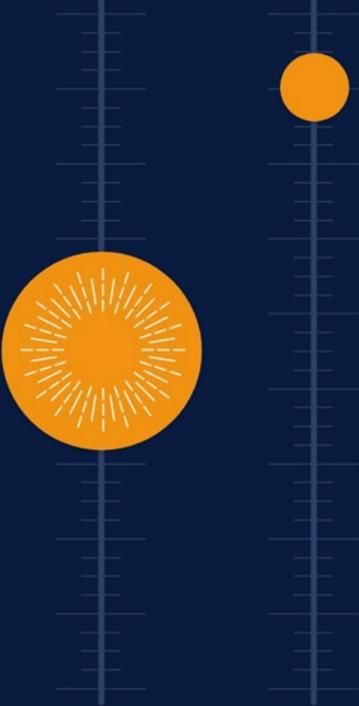
Repeated injections of CAN-3110 (up to 6) feasible, well tolerated, and associated with encouraging survival data



Near absence of tumor cells alongside dense lymphocyte infiltrates in biopsies obtained after repeated CAN-3110 administration



Despite MRI-diagnosed tumor progression, multiomic analyses revealed therapeutic effects, including expansion of CAN-3110-reactive and other T-cell clonotypes, and induced expression of human leukocyte antigen (HLA)-presented immunopeptides



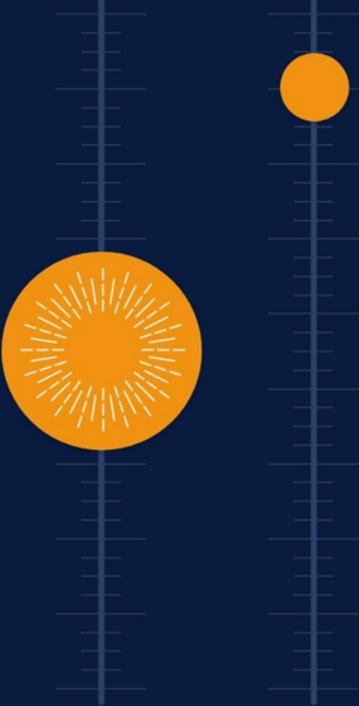
CAN-3110 FOR RECURRENT GLIOBLASTOMA



Francesca Barone, MD, PhD, Candel's Chief Scientific Officer

Henry Brem, MD, Professor of Neurosurgery, Johns Hopkins University

Moderator: Kemp Dolliver, Brookline Capital Markets



CANDEL THERAPEUTICS RESEARCH & DEVELOPMENT DAY 2025: Q&A



Kemp Dolliver, Brookline Capital Markets

Sudan Loganathan, PhD, Stephens

Andres Maldonado, PhD, H.C. Wainwright & Co.

Imogen Mansfield, MA, MBA, Cantor Fitzgerald

Oliver McCammon, LifeSci Capital

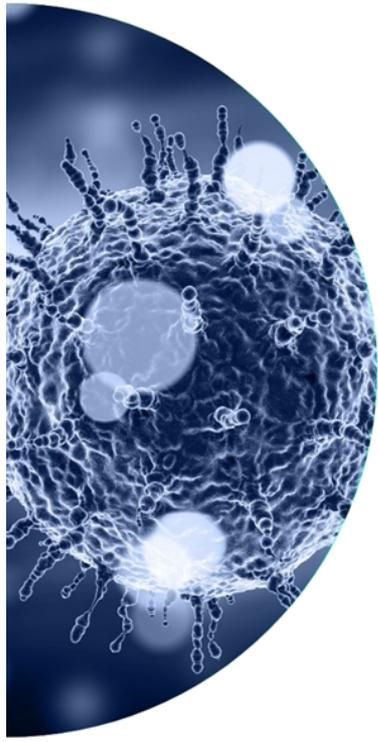
John Newman, PhD, Canaccord Genuity

Yigal Nochomovitz, PhD, Citi Group

Alec Stranahan, PhD, Bank of America

Moderator: Paul Peter Tak, MD, PhD, FMedSci, Candel's CEO





THANK YOU



Candel Research & Development Day
December 5, 2025
NASDAQ: CADL