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): May 19, 2023

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** **(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 May 19, 2023, Candel Therapeutics, Inc. (the "Company") will present a corporate presentation at the American Society of Gene & Cell Therapy ("ASGCT") 26th annual meeting (the "Presentation") entitled, "*Safety and survival outcomes in recurrent high-grade glioma patients treated with CAN-3110, a first-in-class ICP34.5 expressing oncolytic HSV1*." The Presentation is posted on the "Media" section of the Company's website at www.candeltx.com, and includes updates from the Company's ongoing phase 1 clinical trial of CAN-3110.

A copy of the Presentation is attached as Exhibit 99.1 to this Item 7.01 of this Current Report on Form 8-K and incorporated herein by reference.

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 8.01 Other Events.

On May 19, 2023,the Company announced the release of new data from its ongoing phase 1 clinical trial of CAN-3110 in recurrent high-grade glioma. The new data will be presented on May 19, 2023 at the ASGCT 26th annual meeting.

A copy of the press release (the "Press Release") is filed as Exhibit 99.2 hereto and is incorporated herein by reference

Forward-looking Statements

The information in this Item 8.01 of this Current Report on Form 8-K and in the Press Release filed as Exhibit 99.2 hereto include certain disclosures that contain "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding the timing and advancement of development programs, include key data readout milestones; expectations regarding the therapeutic benefit of its programs; and expectations regarding cash runway and expenditures. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of development programs; expectations regarding the therapeutic benefit of the Company's programs; the Company's ability to efficiently discover and develop product candidates; the Company's ability to obtain and maintain regulatory approval of product candidates; the Company's ability to maintain its intellectual property; the implementation of the Company's business model, and strategic plans for the Company's business and product candidates, and other risks identified in the Company's SEC filings, including the Company's most recent Quarterly Report on Form 10-Q filed with the SEC, and subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the Company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	CAN-3110 ASGCT Corporate Presentation dated May 19, 2023
99.2	Press Release dated May 19, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

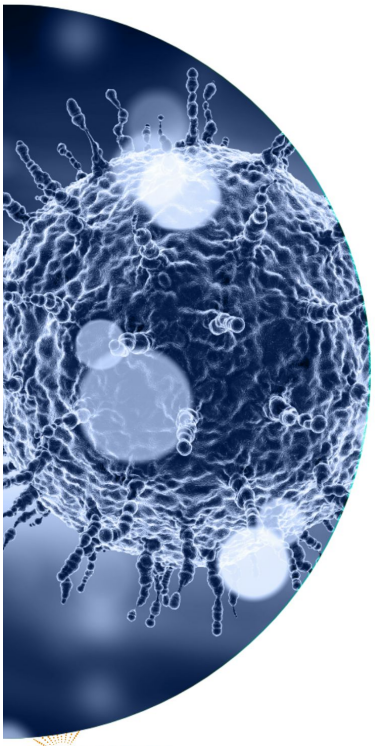
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Candel Therapeutics, Inc.

Date: May 19, 2023

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

Exhibit 99.1



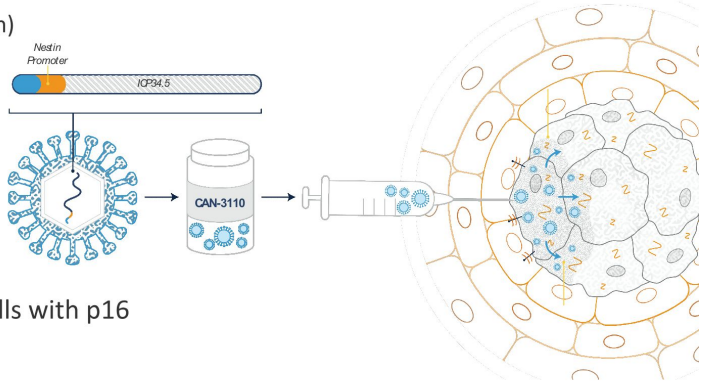
Safety and survival outcomes in recurrent high-grade glioma patients treated with CAN-3110, a first-in-class ICP34.5 expressing oncolytic HSV1

Francesca Barone, MD, PhD
Chief Scientific Officer, Candel Therapeutics, Inc.

CAN-3110 a novel oncolytic virus engineered for enhanced activity and safety

HSV-1 engineered for immunogenic potency and specificity

- ICP34.5-null viruses have shown safety, but replicate poorly
- CAN-3110: ICP34.5 expression under control of Nestin promoter
  - Nestin overexpressed in gliomas (and tumors outside of the brain)
  - Improves replication
  - Provides tumor-specific oncolytic activity

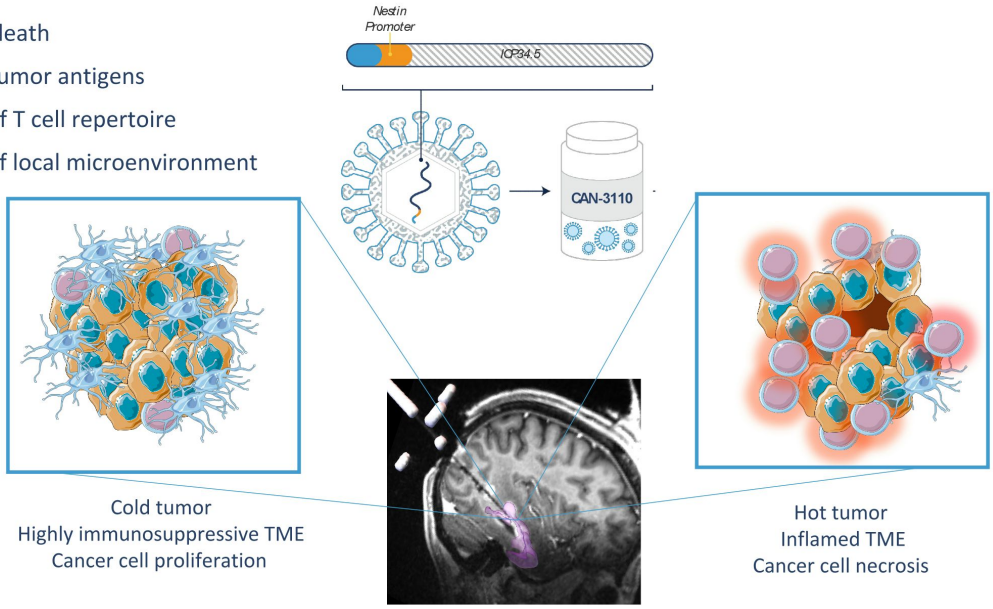


Designed for safety

- Disruption of ICP6 limits virus replication to dividing cells or cells with p16 tumor suppressor pathway defects
- Remains sensitive to anti-herpetic drugs
- Nestin provides tumor specificity

CAN-3110 induces tumor cell death and reprograms the highly immunosuppressive microenvironment of HGG

- Tumor cell death
- Release of tumor antigens
- Expansion of T cell repertoire
- Activation of local microenvironment



Cold tumor
Highly immunosuppressive TME
Cancer cell proliferation

Hot tumor
Inflamed TME
Cancer cell necrosis

Phase 1b clinical trial of CAN-3110 in recurrent high-grade glioma

PI: Dr. E. Antonio Chiocca (Brigham & Women's)

Patients with recurrent high-grade glioma

Lesions ≥ 1.0 cm

NCT03152318

Arm A

Dose escalation (Cohort I-IX)
Single stereotactic injection of CAN-3110

3+3 dose escalation
1×10^6 to 1×10^{10} PFU in half-log increments
30 patients dosed

Dose expansion (Cohort X)
1×10^9 PFU
11 patients dosed

Arm B

Pre-Administration of Cytoxan
+1 x 10^8 PFU
3 patients dosed
+1 x 10^9 PFU
6 patients dosed

Arm C

Repeat Dosing (up to 6)
+1 x 10^8 PFU x 6 doses
+1 x 10^9 PFU x 6 doses
12 patients targeted

BREAK THROUGH CANCER

Primary Endpoints
- Safety
- Determine maximum tolerated dose

Secondary Endpoints
- Immunological biomarkers
- MRI assessment of disease and progression free survival
- MRI alteration of permeability and flow at injection site

CANDEL THERAPEUTICS

Patient demographics and baseline characteristics

		Arm A (n=41*)	Arm B (n=9)	Total (n=50*)
Age, Median (range)		54 years (27 - 74)	54 years (41 - 70)	55 years (27 - 74)
Sex, n (%)				
	Female	21 (51%)	3 (33%)	24 (48%)
	Male	20 (49%)	6 (67%)	26 (52%)
Race, n (%)				
	White	38 (93%)	8 (89%)	46 (92%)
	Black or African American	1 (2%)	0 (0%)	1 (2%)
	Asian	2 (5%)	1 (11%)	3 (6%)
Ethnicity, n (%)				
	Non-Hispanic	40 (98%)	8 (89%)	48 (96%)
	Hispanic or Latino	0 (0%)	1 (11%)	1 (2%)
	Unknown	1 (2%)	0 (0%)	1 (2%)
IDH Status, n (%)				
	Wild-Type	32 (78%)	7 (78%)	39 (78%)
	Mutant	9 (18%)	2 (22%)	11 (25%)
MGMT Status, n (%)				
	Methylated	16 (39%)	2 (22%)	18 (36%)
	Unmethylated	23 (56%)	7 (78%)	30 (60%)
	Unknown	2 (5%)	0 (0%)	2 (4%)
Grade, n (%)				
	III	7 (17%)	0 (0%)	7 (14%)
	IV	34 (83%)	9 (100%)	43 (86%)
KPS Score, Median (range)		90 (70 - 100)	90 (80 - 100)	90 (70 - 100)

* See below

- 41 unique patients were dosed; one patient was treated twice, in cohort IX and X
- A total of 50 unique patients

CAN-3110 related SAEs in rHGG (arms A and B)

Cohort (arm)	Number of treated patients	Dose Level (PFU)	Number of patients with DLT	Number of patients with related SAE	Case #	Time (days)
1 (A)	3	$1x10^6$	0	0	NA	NA
2 (A)	3	$3x10^6$	0	0	NA	NA
3 (A)	3	$1x10^7$	0	0	NA	NA
4 (A)	3	$3x10^7$	0	0	NA	NA
5 (A), 1 (B)	6	$1x10^8$	0	0	NA	NA
6 (A)	3	$3x10^8$	0	0	NA	NA
7 (A), 10 (A), 2 (B)	21	$1x10^9$	0	1	046(IDHmut)	2
8 (A)	3	$3x10^9$	0	1	033(IDHmut)	16
9 (A)	6	$1x10^{10}$	0	0	NA	NA
TOTAL	50*		0	2	Time range (days)→	2 to 16

As of cutoff date 25 Apr 2023

DLT: dose limiting toxicity, SAE: serious adverse event

* Total includes one patient who received two injections, one in cohort 9 (A) and one in cohort 10 (A)

CANDEL THERAPEUTICS

Safety summary: related adverse events* (AEs) in rHGG

Arm A (n=41)	n (%)
General disorders and administration site conditions	
Fever	3 (7%)
Musculoskeletal and connective tissue disorders	
Muscle weakness	3 (7%)
Nervous system disorders	
Seizure	3 (7%)

Arm B (n=9)	n (%)
Nervous system disorders	
Edema Cerebral	1 (11%)
Hemianopia	1 (11%)
Hypoesthesia	1 (11%)

* events manifesting in ≥5% of patients

Safety summary: adverse events in rHGG

Arm A (n=41*)

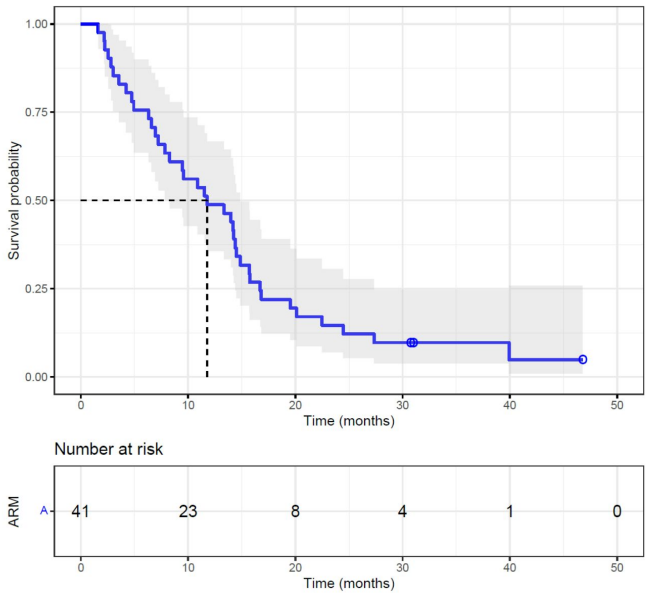
- No patients experienced a DLT in Cohorts I-X
- All patients (n=41) experienced at least 1 AE
- 27% of patients (n=11) experienced at least 1 related AE
- 59% of patients (n=24) experienced at least 1 serious AE
  - Most Serious AEs: Edema Cerebral (n=8 [20%]) and Seizure (n=5 [12%])
- 5% of patients (n=2) experienced at least 1 serious related AE
  - 001-033: Grade 3 – Seizure, Cerebral hematoma
  - 001-046: Grade 2 - Seizure, muscle weakness , facial paresis
- Most *TEAEs were Grade 1-3
  - Most common Grade 3 AEs include Edema Cerebral (n=8 [20%]), Seizure (n=5 [12%]) and Muscle weakness (n=5 [12%]).
  - One patient experienced a grade 5 cardiac arrest, non-related
  - No grade 4 AEs

Arm B (n=9)

- All patients (n=9) experienced at least 1 AE
- 11% of patients (n=1) experienced at least 1 related AE
  - 001-060: Grade 2 – Edema cerebral, left leg numbness, left visual field defect
- 22% of patients (n=2) experienced at least 1 serious AE
  - 001-061: Grade 3 – Edema cerebral, muscle weakness
  - 001-065: Grade 3 – Cerebrospinal fluid leakage, left hemiparesis, pseudo-meningocele and muscle weakness
- No patient (n=0) experienced a serious related AE
- All *TEAEs were grade 1-3
  - Most common Grade 3 AEs include Muscle Weakness (n=2 [22%])
  - No grade 4 or 5 AEs

* 41 unique patients were dosed; 00030 was treated twice, Cohort IX and X
* Treatment Emergent Adverse Events (TEAEs)

Encouraging overall survival in rHGG after single injection (arm A)

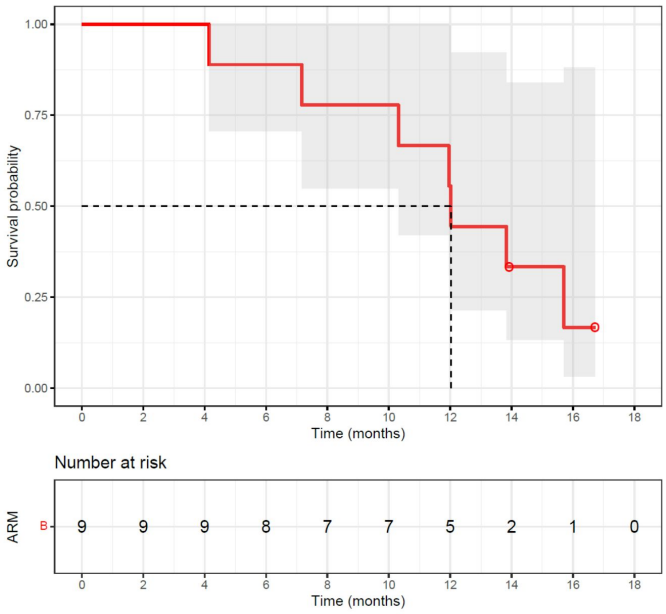


N = 30
Median overall survival: 11.8 months
Cutoff date: 20 Apr 2023

Expected median overall survival: <6-9 months

- 41 unique patients were dosed; one patient was treated twice, in cohort IX and X
- A total of 50 unique patients

Overall survival data rHGG arm B confirms data in arm A

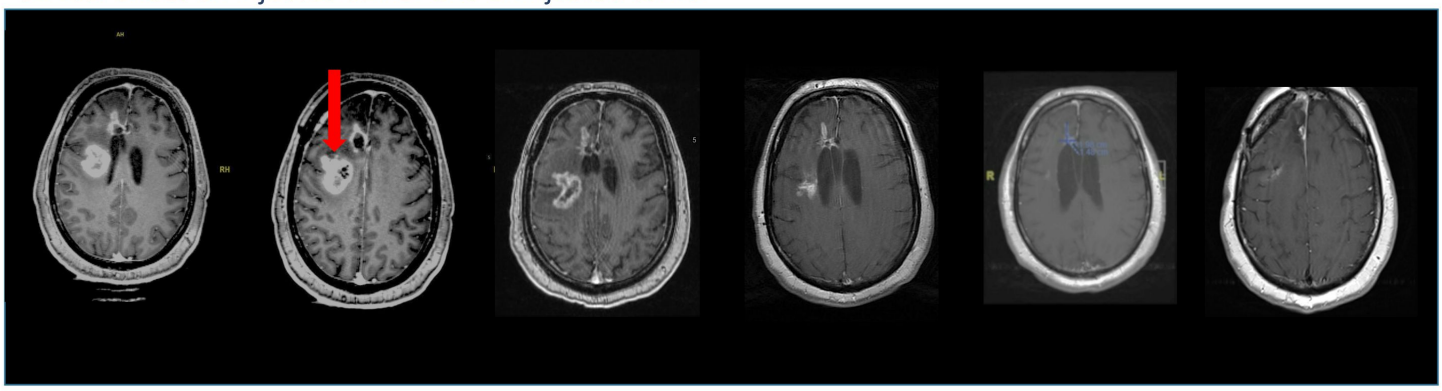


N = 9 patients pretreated with cyclophosphamide
Median overall survival: 12 months
Cutoff date 20 Apr 2023

Expected median overall survival: <6-9 months

Monotherapy activity of CAN-3110 in rHGG (arm A)

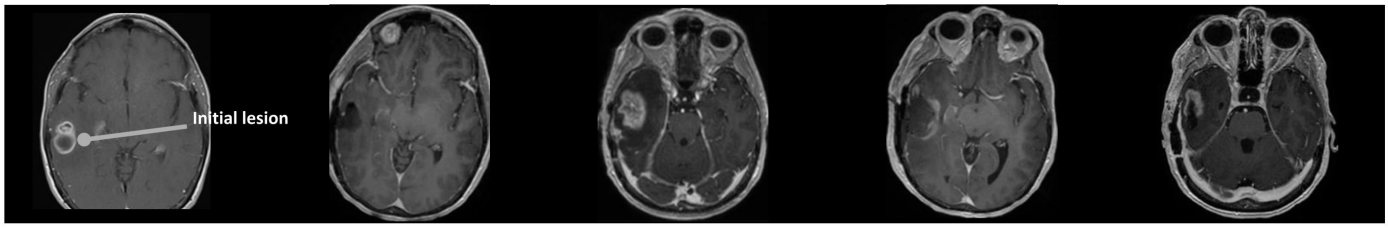
Clinical effect on injected tumor and uninjected tumor



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 GTR, chemoradiation. Recurrences at two sites.

Durable response for 2Yrs after CAN-3110 in rHGG (arm A)



Day -262
Initial presentation

Day -259
Initial resection

Day -47
Tumor recurrence

Day -30
2nd subtotal resection

Day -14
Rapid progression

Day 0
CAN-3110 Injection

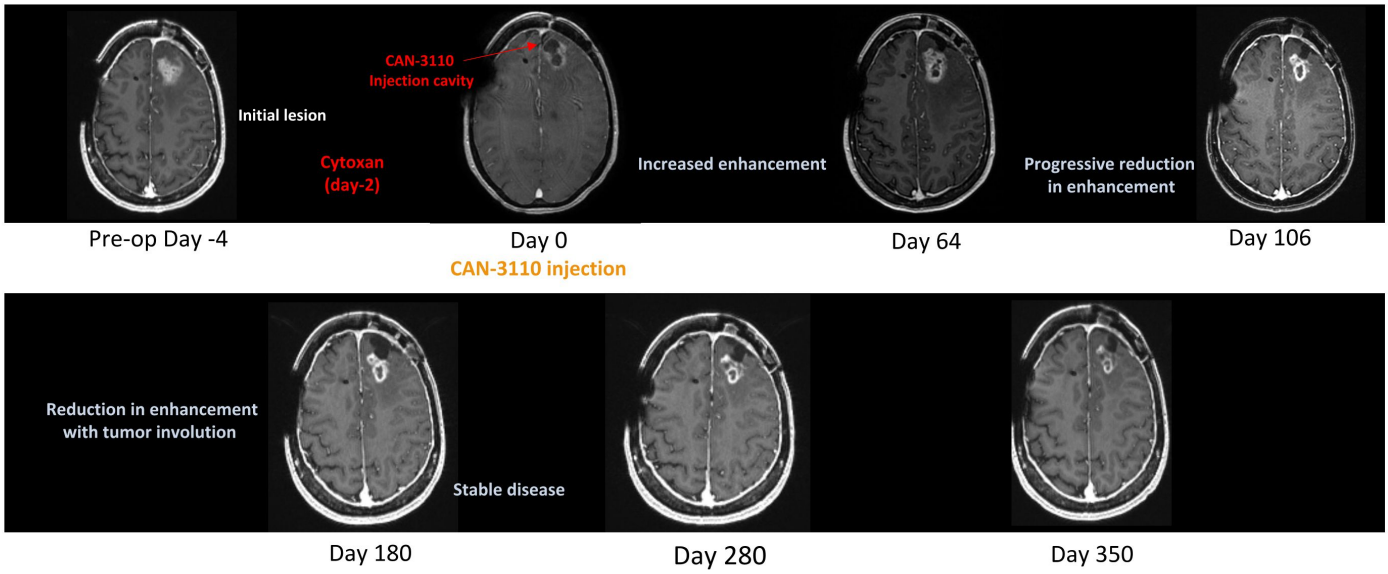
Day 91
Tumor recurrence with TIL

Day 96
After resection, histology shows TILs

Day 630
No visible tumor

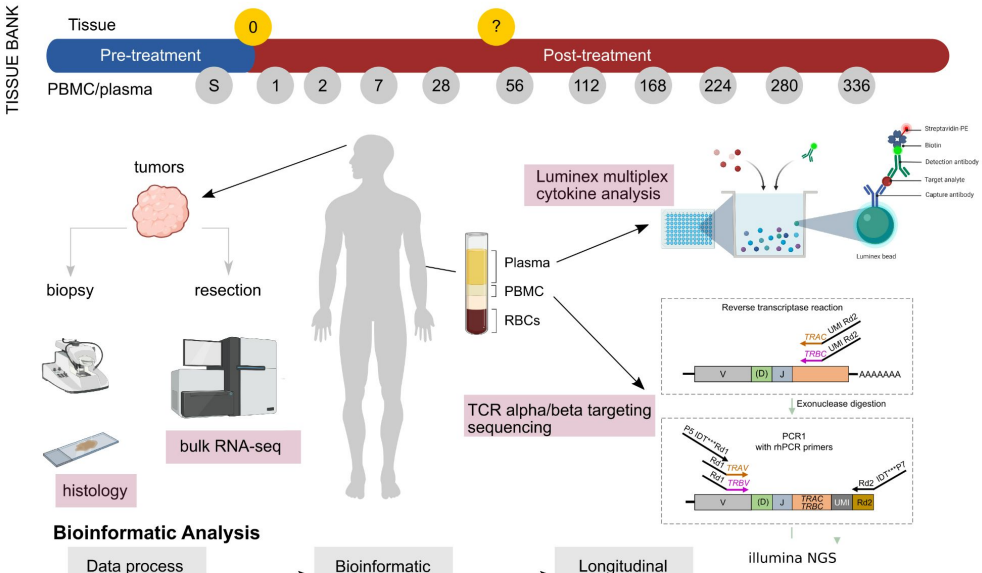
61 YOF, IDH wild-type, MGMT methylated glioblastoma, right temporal lesion initially treated with surgery, chemoradiation and temozolomide
CAN-3110 dose: 10^8 PFUs. Patient passed away as passenger in a motor vehicle accident on day 717.

Continued improvement for >12Mos after CAN-3110 monotherapy (arm B)



52 YO RH WF, IDH mutant, MGMT methylated grade IV astrocytoma (left frontal, invading corpus callosum in a butterfly fashion and lobulating into lateral and third ventricle). Recurrent disease, 1Yr after original resection. Enrolled in arm B: Cytoxan (24 mg/kg; day -2) & CAN-3110. Since injection KPS remains between 90 and 100, pt. independent at home with family, without other therapies.

Biomarker Analysis

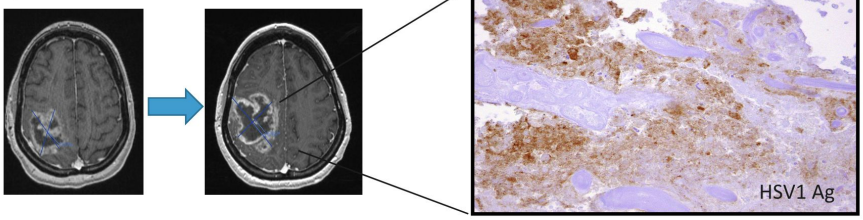


Bioinformatic Analysis

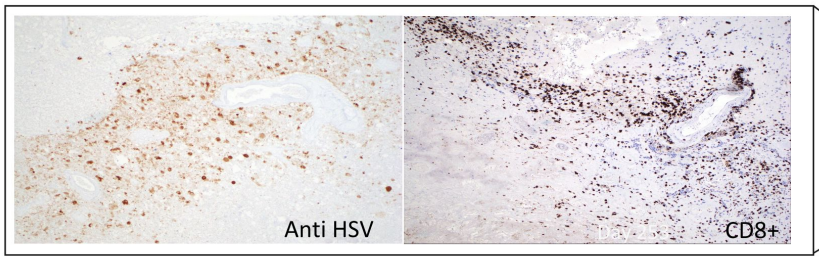
Data process (pipelines)	Bioinformatic workflow analysis	Longitudinal analysis
genomic alignment	transcriptomic anlaysis	Tracking clonotypes
annotation	pathway analysis	cytokine changes and biomakers
VDJ alignment & assemble	TCR clonotype analysis	

Persistent HSV antigen expression associated with CD8+ T cell infiltration after CAN-3110 treatment

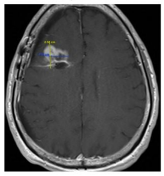
Patient A
(6 weeks post-HSV 10e6 PFUs)



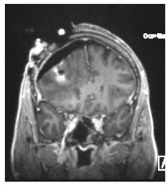
Patient B
(9 mos post-HSV 10e9 PFUs)



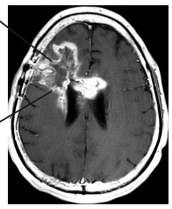
Preoperative



Intraoperative injection

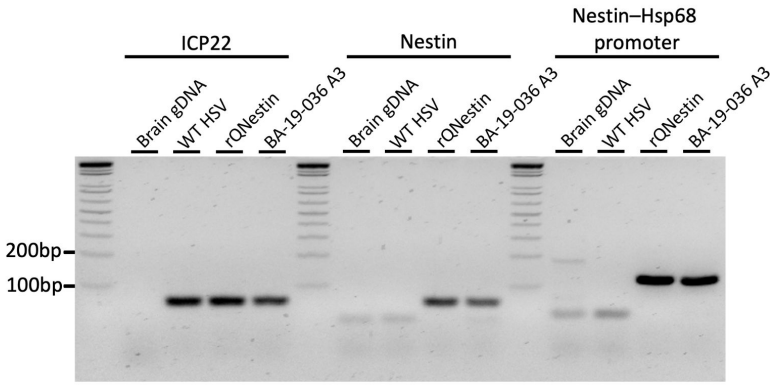


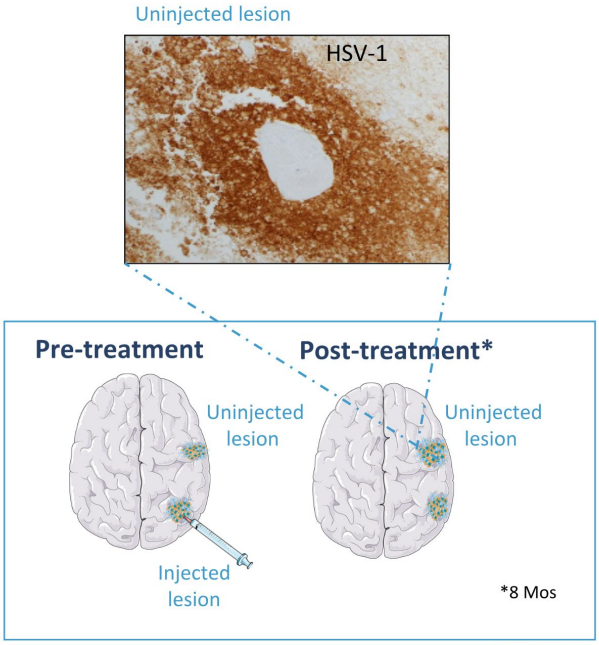
Recurrence



13/27 patients presented positive oHSV antigen in post-injection samples collected in a range of 24 to 801 days post treatment

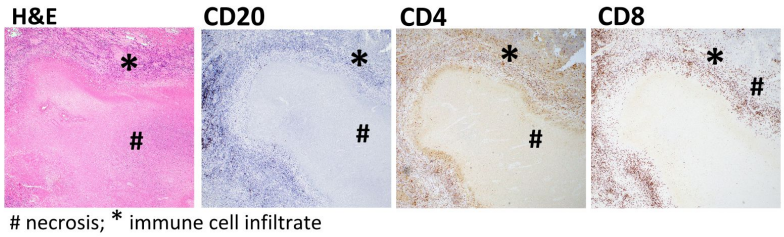
Persistent HSV antigen expression in uninjected lesion 8 Mos after CAN-3110 injection in multifocal rHGG



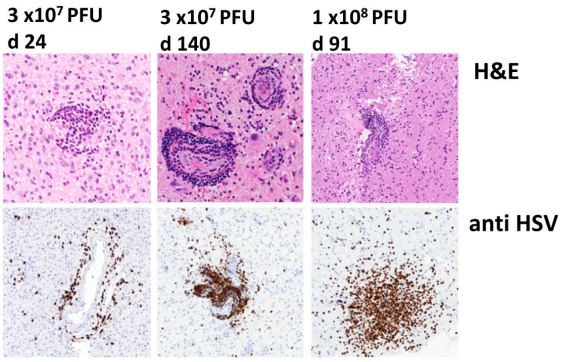


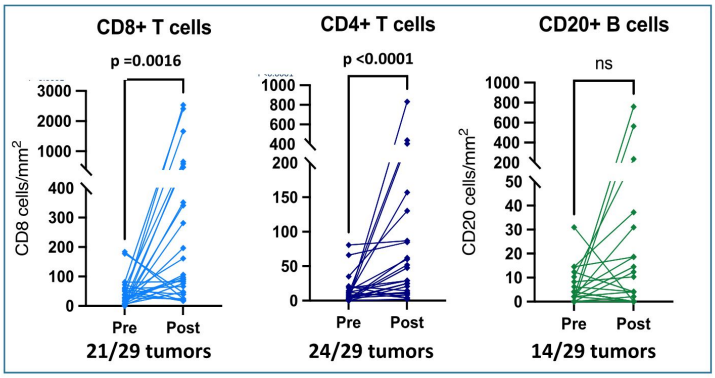
Increased infiltration by immune cells at the site of the tumor after CAN-3110 treatment in rHGG

Post-injection necrotic tumor areas surrounded by T cells

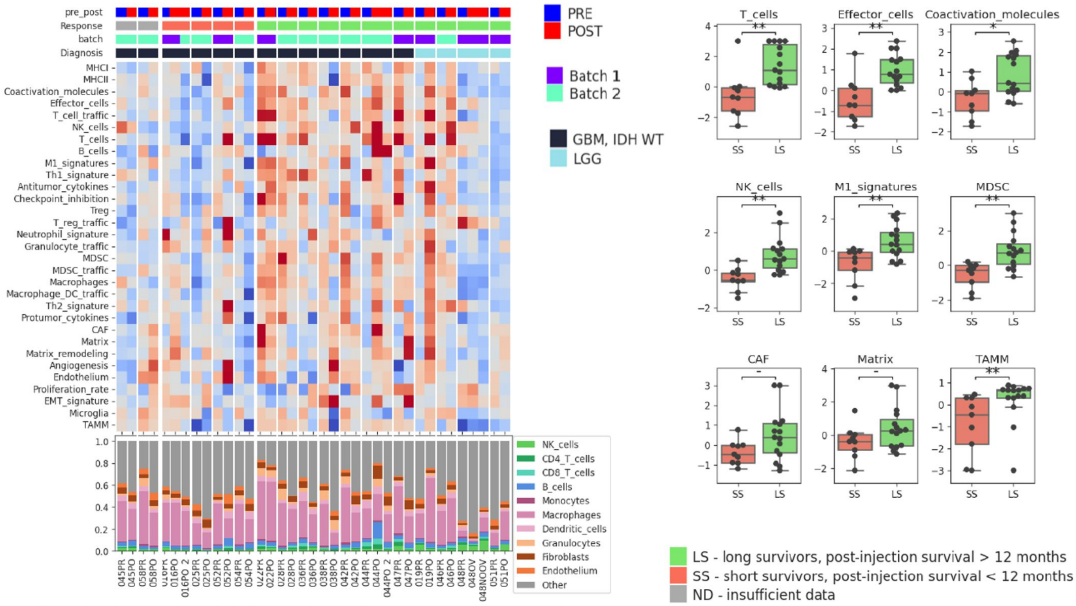


necrosis; * immune cell infiltrate





Changes in tumor microenvironment after CAN-3110 are associated with improved survival in rHGG

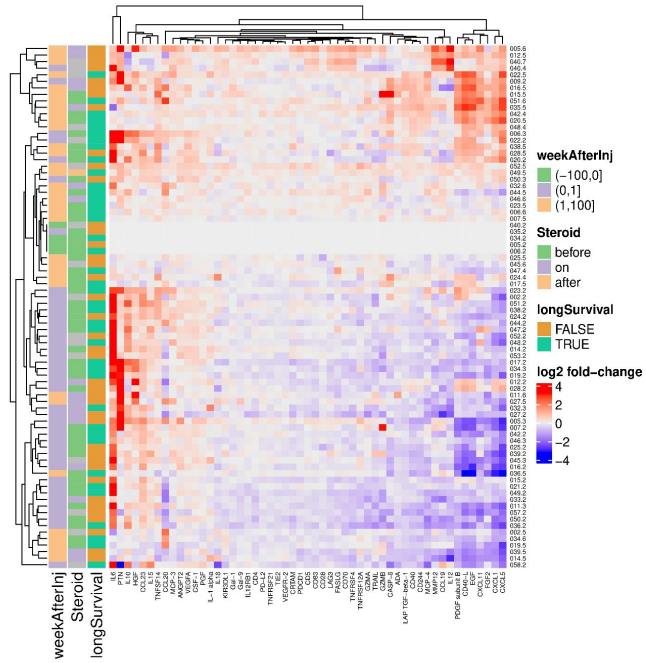


*only GBM IDH WT samples are shown on the boxplots

LS - long survivors, post-injection survival > 12 months
SS - short survivors, post-injection survival < 12 months
ND - insufficient data

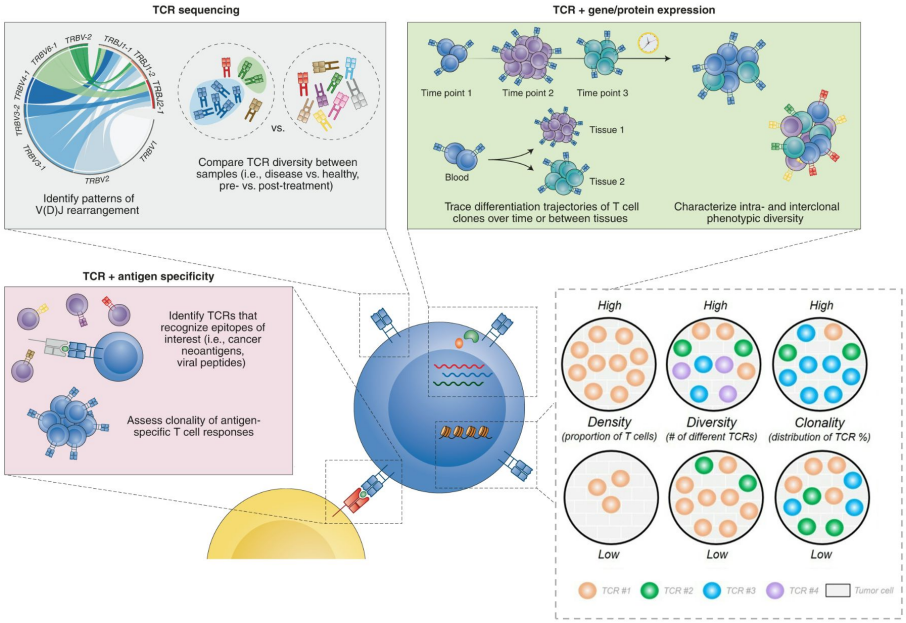
17 paired samples bioinformatic analyses by BostonGene, Inc.

Changes in protein biomarkers in peripheral blood after CAN-3110 injection in rHGG

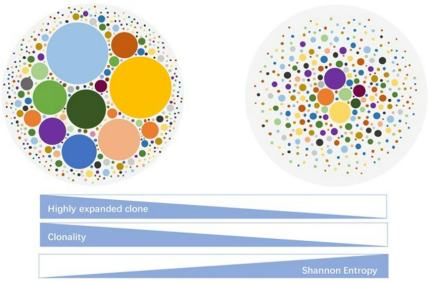


From 96 protein panel biomarkers, 53 showed statistically significant changes compared to baseline at the 1st or 2nd time points after treatment; those include IL-6, PTN, MMP12, CCL19, CD40L

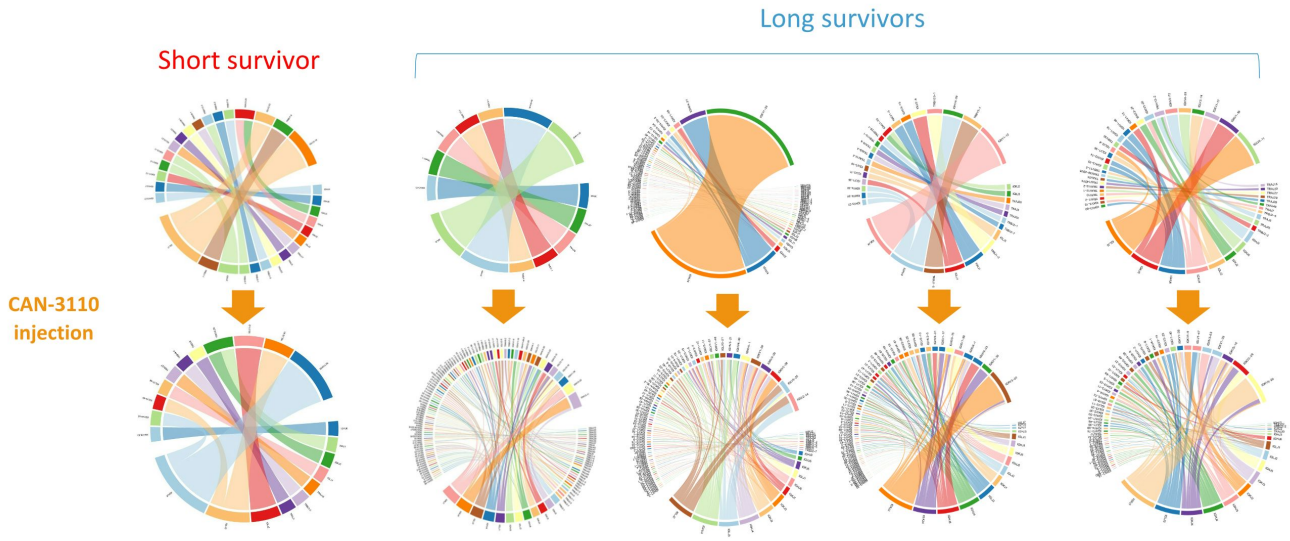
T cell receptor (TCR) analysis interpretation tool



Relationship between clonality and diversity/entropy



Increases in T cell density, entropy, and clonality are observed in long survivors after CAN-3110 injection



Conclusions

- Treatment with CAN-3110 in rHGG is well tolerated with no dose-limiting toxicity observed
- Persistence of HSV antigen expression associated with tumor necrosis and increased immune cell infiltration after CAN-3110 injection in both injected and uninjected lesions
- Evidence of abscopal effect
- Increase in pro-inflammatory mediators after CAN-3110 injection in rHGG
- Immunological changes in the tumor microenvironment after CAN-3110 injection in rHGG are associated with improved survival
- Increases in T cell density, entropy, and clonality are observed in long survivors after CAN-3110 injection
- Next, we will evaluate the effects of repeat injections with CAN-3110, supported by the Break Through Cancer foundation

Acknowledgements

Dana-Farber Cancer Institute | BWH BRIGHAM AND WOMEN'S HOSPITAL

DANA-FARBER/BRIGHAM AND WOMEN'S CANCER CENTER

CANDEL THERAPEUTICS

Alexander Ling

Isaac H. Solomon

Ana Montalvo Landivar

Hiroshi Nakashima

Andres Santos

Nafisa Masud

Patrick Wen

Keith Leigon

David Reardon

Sengupta Soma

E. A. Chiocca

Andrea Manzanera

Maria Lucia Silva Polanco

Garrett Nichols

Paul Peter Tak

BREAK THROUGH CANCER

Candel Therapeutics Announces New Data from Ongoing Phase 1 Clinical Trial of CAN-3110 in Recurrent High-Grade Glioma at the American Society of Gene & Cell Therapy (ASGCT) 26th Annual Meeting

- *Treatment with CAN-3110 in arm A showed encouraging median overall survival rate at 11.8 months after a single injection. These data are supported by independent cohort (arm B); median overall survival was 12.0 months in patients who received a single administration of CAN-3110 after cyclophosphamide pre-treatment compared to < 6 to 9 months expected with standard of care treatment options*
- *CAN-3110 was reported to be well tolerated with no dose-limiting toxicities observed*
- *The Company is currently enrolling arm C, which will evaluate a repeat dosing regimen of CAN-3110 (up to 6 injections over 4 months) in patients with recurrent high-grade glioma*

NEEDHAM, Mass., May 19, 2023 (GLOBE NEWSWIRE) — Candel Therapeutics, Inc. (Candel or the Company) (Nasdaq: CADL), a clinical stage biopharmaceutical company focused on developing viral immunotherapies to help patients fight cancer, today announced new data from an ongoing phase 1 investigator-sponsored clinical trial of its herpes simplex virus-1 (HSV-1) replication-competent viral immunotherapy candidate, CAN-3110, in patients with high-grade glioma that has recurred after standard of care (SoC) treatment. The data were presented today in an Oral Presentation Session at the 26th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) taking place in Los Angeles, CA and virtually from May 16 – 20, 2023.

“After one dose of CAN-3110, we observed encouraging responses in individual patients with recurrent high-grade glioma, including responses in both injected and uninjected lesions,” said Francesca Barone, MD, PhD, Chief Scientific Officer of Candel. “We are encouraged by the increased survival of treated patients in two independent cohorts observed to date. We believe the responses are notable, given that recurrent high-grade gliomas are fast-growing, spread quickly and are treatment-resistant.”

Dr. Barone continued, “Results demonstrated that CAN-3110 was well tolerated without dose-limiting toxicities and significantly increased the median overall survival rate to 12.0 months in nine patients from arm B. These findings support the median overall survival rate observed in 41 patients from arm A who received CAN-3110 and exceeded

the historical median overall survival rates of less than 6 to 9 months achieved by standard of care. In arm C, we look forward to investigating whether multiple doses of CAN-3110 can further increase survival rates for these patients who desperately need new treatment options."

"We believe data from the first 50 patients with recurrent high-grade glioma who received a single intratumoral injection of CAN-3110 supports the notion that this approach is generally well tolerated and may provide clinical improvement and survival benefit," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel. "Sadly these patients have extremely limited treatment options, which makes these data even more encouraging."

Dr. Tak continued, "In arm C, we and our collaborators are studying a repeat dosing regimen of CAN-3110 for up to six injections over four months in patients with recurrent high-grade glioma to evaluate whether we can further improve our current results. CAN-3110 is designed to replicate specifically in tumor cells expressing Nestin. This specificity allows us to test this asset in the future in other indications that are characterized by Nestin expression, potentially allowing for a pipeline expansion opportunity into new diseases."

Highlights from the Oral Presentation Session at ASGCT

An ongoing phase 1 clinical trial, which includes arms A, B, and C, is evaluating the safety and activity of CAN-3110 in patients with recurrent high-grade glioma who have experienced disease progression following prior treatment with SoC therapies. Based on historical clinical data, overall survival in this patient population is < 6-9 months. The Company previously announced data from arm A (n=41), which demonstrated that treatment with a single dose of CAN-3110 was generally well tolerated and resulted in median overall survival (mOS) rate of 11.6 months as of the data cutoff date on July 22, 2022. This has now been updated to 11.8 months as of the data cutoff date on April 20, 2023. New clinical data from arm B (n=9) and updated data from arm A demonstrated the following results as of the data cutoff date:

- CAN-3110 was well tolerated without dose-limiting toxicities.
- mOS in arm B is ongoing at 12.0 months and supports the encouraging clinical activity of CAN-3110 observed in in arm A.
- Responses were observed in both injected and uninjected lesions in patients with multifocal disease.
- In addition to the two patient case studies disclosed from arm A, one patient from arm B exhibited continued reduction in tumor volume approximately one year after CAN-3110 treatment. Clinical response for this patient, currently in follow-up, continues without additional treatment.
- Analysis of post treatment samples demonstrated evidence of HSV antigen expression and replication in uninjected tumor tissue associated with CD8+ T cell

infiltration, which may explain the clinical responses observed in uninjected tumors.

- Additional extensive biomarker studies including histology, transcriptomics, and single cell sequencing are ongoing.

About CAN-3110 evaluated in the phase 1 clinical trial

CAN-3110 is a first-in-class HSV-1 viral immunotherapy candidate engineered to express one copy of the ICP34.5 gene under the transcriptional control of the Nestin-specific promoter. This modification is designed to largely restrict CAN-3110 replication and oncolytic activity to Nestin+ tumor cells. The phase 1 clinical trial is evaluating the safety and activity of CAN-3110 in patients with recurrent high-grade glioma who have experienced disease progression following prior treatment with SoC therapies.

This investigator-sponsored study is led by E. Antonio Chiocca, MD, PhD, Head of the Department of Neurosurgery at Brigham & Women's Hospital and Professor at Harvard Medical School. The clinical trial comprises three arms. In arm A, 41 patients with recurrent high-grade glioma were treated by a single intratumoral injection of CAN-3110 (dose ranging from $1x10^6$ plaque forming units (pfu) to $1x10^{10}$ pfu), including nine patients with multifocal/multicentric, deep or bilateral tumors associated with poor survival. After showing tolerability of this regimen without dose-limiting toxicity, patients in arm B (n=9) were treated with a single high dose of cyclophosphamide (24 mg/kg), two days before CAN-3110 injection at doses of 1×10^8 pfu (n=3) and 1×10^9 pfu (n=6). The rationale is based on findings in mouse models, where cyclophosphamide improved viral persistence in injected tumors. In arm C, supported by the Break Through Cancer foundation, two cohorts of 12 patients with recurrent high-grade glioma will receive up to six injections of CAN-3110 over a four-month period.

Details of the oral presentation are as follows:

- **Abstract Title:** Safety and Survival Outcomes in Recurrent High-Grade Glioma Patients Treated with CAN-3110, a First-in-Class ICP34.5 Expressing Oncolytic HSV1
- **Presenter:** Francesca Barone, MD, PhD, Chief Scientific Officer, Candel Therapeutics
- **Session Title:** Late-Breaking Abstracts 1
- **Session Date and Time:** Friday, May 19, 2023, 8:00 - 9:45 am PT
- **Location:** Room 515 AB, Los Angeles Convention Center, Los Angeles, CA

About Candel Therapeutics

Candel is a clinical stage biopharmaceutical company focused on developing viral immunotherapies that elicit a systemic anti-tumor immune response to help patients fight cancer. Candel's engineered viruses are designed to induce immunogenic cell

death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens while creating a pro-inflammatory microenvironment at the site of injection. Candel has established two clinical stage viral immunotherapy platforms based on novel, genetically modified adenovirus and herpes simplex virus (HSV) gene constructs, respectively. CAN-2409 is the lead product candidate from the adenovirus platform and CAN-3110 is the lead product candidate from the HSV platform. Candel's enLIGHTEN™ Discovery Platform is a systematic, iterative HSV-based discovery platform leveraging human biology and advanced analytics to create new viral immunotherapies for solid tumors.

For more information about Candel, visit www.candeltx.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding the timing and advancement of development programs, include key data readout milestones; expectations regarding the therapeutic benefit of its programs; and expectations regarding cash runway and expenditures. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the timing and advancement of development programs; expectations regarding the therapeutic benefit of the Company's programs; the Company's ability to efficiently discover and develop product candidates; the Company's ability to obtain and maintain regulatory approval of product candidates; the Company's ability to maintain its intellectual property; the implementation of the Company's business model, and strategic plans for the Company's business and product candidates, and other risks identified in the Company's SEC filings, including the Company's most recent Quarterly Report on Form 10-Q filed with the SEC, and subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the Company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Media Contact
Aljanae Reynolds
Director
Wheelhouse Life Science Advisors
areynolds@wheelhouselsa.com

Investor Contact
Sylvia Wheeler
Principal
Wheelhouse Life Science Advisors
swheeler@wheelhouselsa.com