



Candel Therapeutics Announces Data from Phase 1 Trial of CAN-3110 in Recurrent High-Grade Glioma at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting

June 4, 2021

NEEDHAM, Mass. --(BUSINESS WIRE)-- Candel Therapeutics, Inc., a late clinical stage biopharmaceutical company developing novel oncolytic viral immunotherapies, today announced initial results from an ongoing Phase 1 clinical trial of its oncolytic virus, CAN-3110, in patients with high-grade glioma (HGG) that has recurred after initial treatment. The data are presented today in an Oral Abstract Session of the Clinical Science Symposium at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.

Highlights from the Oral Abstract Session of the Clinical Science Symposium at ASCO 2021

An ongoing Phase 1 study is evaluating the safety and activity of CAN-3110, an engineered replication-competent herpes simplex virus (HSV) oncolytic viral immunotherapy, in patients with HGG who have experienced disease progression following prior treatment with standard of care therapies. As of the data cutoff date of April 21, 2021:

- 30 patients were evaluable for safety.
- Nine dose levels ranging from 1×10^6 to 1×10^{10} plaque forming units (PFU) were administered.
- No dose-limiting toxicity was observed. The maximum administered dose was 1×10^{10} PFU.
- CAN-3110 was well-tolerated and all but one adverse events (AEs) were Grade 1 or 2.
- A preliminary Kaplan-Meier estimate of median overall survival was 11.7 months.
 - All patients have been treated for more than 12 months.
- One patient who responded for over a year, a 56-year-old male with multifocal glioblastoma, demonstrated a significant reduction in both an injected and an uninjected lesion, suggesting an abscopal effect of CAN-3110.
- An additional 12 patients have been enrolled into a dose expansion arm of the trial.

"CAN-3110 has demonstrated a significant number of durable responses in patients with high-grade glioma who experienced disease progression following prior standard of care therapy," said Antonio Chiocca, MD, PhD, FAANS, Neurosurgeon-in-Chief and Chairman, Department of Neurosurgery at Brigham and Women's Hospital. "The results of this first-in-human study are encouraging as they demonstrate a median overall survival that was substantially longer than the six to nine months typically observed for these patients as well as a favorable safety profile."

"This is the first clinical trial of a novel oncolytic HSV engineered to selectively express ICP34.5 in tumor cells, leading to tumor-specific cell death. This novel oncolytic viral immunotherapy has been shown to be well tolerated with primarily low grade, and manageable side effects," said Paul Peter Tak, MD, PhD, FMedSci, President and Chief Executive Officer of Candel Therapeutics. "There are few treatment options for patients with high-grade glioma whose tumors progress following initial surgery and chemoradiation. We are encouraged by the duration of the responses observed to date in this patient population given the extremely limited treatment options. Based on these data, we are excited to advance this innovative agent into further clinical trials."

Details of the presentation are as follows:

Abstract Title: First-in-human CAN-3110 (ICP034.5 expressing HSV-1 oncolytic virus) in patients with recurrent high-grade glioma

Presenter: Dr. E. Antonio Chiocca

Session Date and Time: The presentation is available to ASCO attendees beginning June 4, 2021 at 9 AM EDT/ 6 AM PDT and has been reposted to the Candel Therapeutics website at www.candeltx.com/news

Abstract Link: <https://meetinglibrary.asco.org/session/13562>

Session Title: CNS Targeting: From Delivery to Biomarker Assessment

Abstract Number: 2009

About CAN-3110

CAN-3110 is an HSV replication-competent oncolytic virus engineered to enhance selective killing of malignant cells while sparing healthy normal neighboring cells. CAN-3110 selectively expresses ICP34.5, a key gene in HSV replication, in tumor cells that overexpress nestin, a cytoskeletal protein. Nestin is highly expressed in glioma cells and other tumor tissue but is absent in the healthy adult brain.

Candel is evaluating the effects of treatment with CAN-3110 for recurrent glioblastoma. For more information on this clinical study, please visit <https://www.clinicaltrials.gov/ct2/show/NCT03152318>

About Candel Therapeutics

Candel is a late clinical stage biopharmaceutical company focused on helping patients fight cancer with oncolytic viral immunotherapies. Our engineered viruses are designed to induce immunogenic cell death through direct viral-mediated cytotoxicity in cancer cells, thus releasing tumor neo-antigens and creating a pro-inflammatory microenvironment at the site of injection. Our approach combines an in-depth knowledge

of viral immunotherapy with extensive clinical experience across a wide range of indications. Based on the broad range of data that we have generated from our preclinical models and clinical trials using our approach, we have observed what we believe to be a systemic immune response against locally injected tumors and their distant metastases. To learn more, visit www.candeltx.com.

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