



DNAtrix Announces Positive Data from Phase 2 CAPTIVE (KEYNOTE-192) Study with DNX-2401 in Patients with Recurrent Glioblastoma Highlighted in an Oral Late-Breaking Presentation During Society for Neuro-oncology (SNO) Annual Meeting

- *Median Overall Survival of 12.5 Months Observed in Patients with Recurrent Glioblastoma*
- *Four Patients Being Followed for Survival Beyond 23 Months, Including Two Durable Complete Responses*
- *Pivotal Phase 3 Study Planned*

HOUSTON, Nov. 20, 2020 /PRNewswire/ -- DNAtrix, a biotech company advancing virus-driven immunotherapies for cancer, today announced that the Phase 2 CAPTIVE study evaluating treatment with DNX-2401 (tasadenoturev) and pembrolizumab in patients with recurrent glioblastoma (GBM) demonstrated a median overall survival of 12.5 months. DNX-2401 is an adenovirus-based immunotherapy that is engineered to selectively kill tumor cells and trigger a robust anti-tumor immune response.

"We are excited by the promising activity seen in patients with recurrent GBM, which is a notoriously difficult-to-treat cancer with a high mortality rate," said Jeffrey Knapp, chief executive officer of DNAtrix. "The median overall survival of 12.5 months achieved with DNX-2401 and pembrolizumab compares very favorably against historical benchmarks for standard of care agents, lomustine and temozolomide, where our meta-analysis indicates the median overall survival achieved with either of these therapies is on the order of 7.2 months. We look forward to advancing this treatment regimen into a global, randomized Phase 3 study. Additionally, we are also evaluating DNX-2401 in a Phase 1 study for the treatment of diffuse intrinsic pontine glioma, where we have received FDA Fast Track and Rare Pediatric Disease designations. Beyond DNX-2401, we are poised to begin a Phase 1 study in patients with colorectal and other cancers with liver metastases with our second product candidate, DNX-2440, an armed oncolytic virus that induces the expression of OX40 ligand on tumor cells."

Gelareh Zadeh, M.D., Ph.D., FRCS(C), FAANS, professor and dan chair of Neurosurgery at the University of Toronto, head of the Division of Neurosurgery at Toronto Western Hospital, and president of Society-of-Neuro-Oncology added, "My clinical and research focus has been in neuro-oncology, and I have seen the devastating impact of recurrent GBM first-hand. The data we have from the Phase 2 CAPTIVE study are very promising, demonstrating prolonged survival unlike what we have seen with available therapies. I can say that having seen some of the long- responders in my own patients genuinely has me very excited about the promise this therapy holds for GBM, in particular the subset who respond well. If successful, this could represent an important treatment for patients who are in desperate need of additional therapeutic options."

The Phase 2 multicenter CAPTIVE trial studied DNX-2401 in combination with the anti-PD-1 antibody, pembrolizumab, in 49 patients with GBM at first or second disease recurrence. In the study, patients were given a single dose of DNX-2401 followed by 200 mg pembrolizumab infusions every three weeks. The median treatment duration with pembrolizumab was seven cycles. The first part of the study evaluated escalating doses of DNX-2401, and the highest dose evaluated was selected for advancement into the dose expansion phase of the study.

The median overall survival for patients treated with the full dose DNX-2401 and pembrolizumab (n=42) was 12.5 months, and the survival rate at 18 months was 20.2%. Four patients, all of whom have survived more than 23 months, continue to be followed for survival. Five patients (11.9%) had confirmed responses, including two durable ongoing complete responses and 3 partial responses. The median duration of response has not been reached. The most commonly reported adverse events were headache, fatigue, and brain edema, which were primarily mild to moderate and manageable. Detailed results were presented at a late-breaking session during SNO's 25th Annual Scientific Meeting and Education Day.

About DNX-2401 (Tasadenoturev)

DNX-2401 is an oncolytic adenovirus engineered specifically to infect, replicate in, and directly kill cancer cells, as well as elicit a broader anti-tumor immune response. DNX-2401 is currently being evaluated as a potential treatment for highly aggressive brain tumors, including recurrent glioblastoma in adults and newly-diagnosed diffuse intrinsic pontine glioma (DIPG) in children. Clinical studies have demonstrated that DNX-2401 was well tolerated and extended survival for patients with recurrent glioblastoma. DNX-2401 has been granted Fast Track and Orphan designation by the FDA and PRIME and Orphan designation by the EMA.

About DNX-2440

DNX-2440 is an oncolytic adenovirus expressing the immune modulator OX40 ligand, a powerful costimulatory molecule known to enhance T cell responses directed to tumors. DNX-2440 is in Phase 1 clinical testing following the demonstration of anti-cancer activity in preclinical studies, including tumor reductions, immune memory, and abscopal effect.

About DNAtrix

DNAtrix is a privately held biotech company developing virus-driven immunotherapies to treat cancer. Its proprietary adenovirus platform is based on an engineered version of the common cold virus that is designed to selectively infect and kill cancer cells while leaving healthy cells unharmed. The company's lead product candidate is DNX-2401, which is expected to enter into a global pivotal Phase 3 clinical study for patients with recurrent glioblastoma. DNX-2401 is also being evaluated in a Phase 1 study for diffuse intrinsic pontine glioma, for which it has received FDA Fast Track and Rare Pediatric Disease designations. A second product candidate, DNX-2440, is entering a Phase 1 clinical study in patients with colorectal and other cancers with liver metastasis. The company's investors include Morningside Ventures and Mercury Fund. For more information, please visit the company website at www.DNAtrix.com.

Source: <https://www.prnewswire.com/news-releases/dnatrix-announces-positive-data-from-phase-2-captive-keynote-192-study-with-dnx-2401-in-patients-with-recurrent-glioblastoma-highlighted-in-an-oral-late-breaking-presentation-during-society-for-neuro-oncology-sno-annual-meetin-301178137.html>

November 20th 2020