



DNAtrix Announces Successful Intratumoral Delivery of DNX-2401 via Alcyone's MEMS Cannula for the Targeted Treatment of Recurrent Glioblastoma

HOUSTON and LOWELL, Mass., July 21, 2016 /PRNewswire/ -- DNAtrix, a clinical stage, biotechnology company developing virus-driven immunotherapies for cancer, announced the successful intratumoral administration of DNX-2401 with the Alcyone MEMS Cannula (AMC) to patients with recurrent glioblastoma. A substudy is being performed as part of a larger multicenter study to evaluate DNX-2401 as treatment for recurrent glioblastoma, a disease for which there is neither a cure nor adequate treatment.

DNX-2401 is a potent oncolytic adenovirus that targets and kills cancer cells, while leaving normal cells intact. Multiple clinical studies in patients with recurrent glioblastoma and gynecologic cancer have shown that DNX-2401 has a favorable safety profile, strong tumor-killing potential and can trigger an antitumor immune response. The AMC is a dual-lumen MRI-safe neuro-ventricular cannula with the smallest-in-class micro-tip and patented design features that ensure optimal and consistent drug distribution while eliminating backflow.

Analysis of intraoperative MRI from the pilot study demonstrates that the AMC delivers DNX-2401 precisely and accurately into the tumor. Neurosurgeons participating in the study have also praised the cannula's ease of use.

"The Alcyone MEMS Cannula is a compelling technology that ensures a complete dose of DNX-2401 is delivered directly to the brain tumor and provides a standard, reliable and consistent method of virus administration. We are excited to incorporate this technical advantage into our development program to combat this devastating disease," said Frank Tufaro, Ph.D., Chief Executive Officer of DNAtrix.

"Best-in-class rational delivery is fundamental to development of best-in-class therapy. The talented DNAtrix scientists recognize the value of our platform technologies for both intraparenchymal and intrathecal delivery for oncolytic virus therapy. We are excited about working with DNAtrix as we roll-out the Phase 2 study for GBM as well as studies for other indications," said PJ Anand, Founder and Chief Executive Officer of Alcyone Lifesciences.

DNAtrix is utilizing the AMC for the intratumoral administration of DNX-2401 in a Phase 2 study with DNX-2401 followed by the checkpoint inhibitor pembrolizumab.

For more information about these studies, please visit the website ClinicalTrials.gov and search for the identifiers NCT02197169 (pilot study) and NCT02798406 (Phase 2 study).

About DNX-2401 in Glioblastoma

DNX-2401 is an investigational oncolytic immunotherapy designed to treat cancer, with glioblastoma as the initial indication. Glioblastoma is the most aggressive form of brain cancer, which has a median survival of 15 months following a patient's initial diagnosis. DNX-2401 sets off a chain reaction of tumor cell killing by selectively replicating within glioblastoma cells (but not normal cells), causing tumor destruction and further spread of the oncolytic virus to adjacent tumor cells. This process can also trigger an anti-tumor immune response. DNX-2401 is currently being investigated in several clinical studies and has been well tolerated in all settings. Compelling results from Phase I clinical studies in recurrent glioblastoma indicate that DNX-2401 can (1) replicate in human brain tumors for a period of weeks to months (2) trigger immune cell infiltration into the tumor (3) cause ongoing tumor destruction detectable by MRI and (4) induce durable responses to therapy. In these studies, patient survival has been prolonged in a subset of patients, including in those achieving a complete response.

About Alcyone's MEMS Cannula (AMC) Targeted Delivery System

The Alcyone MEMS Cannula Targeted Delivery System was developed using the company's proprietary microelectromechanical system (MEMS) technology platform. Without burdening the neurosurgery community with unnecessary additional capital equipment, the AMC can be utilized with any existing commercial imaging and stereotactic system in conjunction with the work-flow friendly clinical use guideline designed by the company's scientist and neurosurgery advisors. Neurosurgeons can select a target, navigate the AMC precisely to the target, and observe in real-time the precision delivery of the therapeutic agent, all under intra-procedural MRI guidance. In addition to the MEMS tip which has dual micro-channels, the AMC features a unique patented distal end design that helps prevent reflux or back flow along the cannula shaft, which can be a significant drawback with current devices. The AMC platform device is designed for optimal targeted bio-distribution and neurosurgeon's ease of use.

About DNatrix

DNatrix is a privately held, clinical stage, biotechnology company developing virus- driven immunotherapies for cancer. DNatrix's lead product, DNX-2401, is a conditionally replicative oncolytic virus being studied in clinical trials for recurrent glioblastoma, an incurable brain cancer. The company is backed by Morningside Ventures and Mercury Fund, and has been awarded a grant from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information, please visit the company website at <http://www.DNatrix.com>.

About Alcyone Lifesciences

Alcyone Lifesciences, based in Lowell, Massachusetts, is a privately-held medical device company focused on development of novel treatment modalities for chronic neurological conditions. The Company's patented technology platform is based on a uniquely engineered amalgamation of microfabrication technologies along with advanced biomedical engineering with core product focus on targeted drug therapy and hydrocephalus. Alcyone's team of scientists, physicians and advisers includes recognized leaders in the field of neurology and neurosurgery. For more information, please visit www.alcyonels.com.

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Source: <http://www.prnewswire.com/news-releases/dnatrix-announces-successful-intratatumoral-delivery-of-dnx-2401-via-alcyones-mems-cannula-for-the-targeted-treatment-of-recurrent-glioblastoma-300301887.html>

July 21st 2016