



DNAtrix Awarded FDA Orphan Products Development Grant for DNX-2401

HOUSTON, Aug. 4, 2016 /PRNewswire/ -- DNAtrix, a clinical stage biotechnology company developing virus-driven immunotherapies for cancer, announced the award of a \$2 million research grant from the FDA's Office of Orphan Products Development to support its Phase 2 clinical trial evaluating DNX-2401 with the checkpoint inhibitor pembrolizumab for patients with recurrent glioblastoma.

This FDA grant program supports the development of medicines for rare diseases or conditions where no current therapy exists. Approximately 100 applications are received per year from which roughly 10 are selected for funding following rigorous scientific review.

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. DNX-2401 has already received Orphan Drug Designation and Fast Track Designation by the FDA and PRIME Designation by the EMA.

Frank Tufaro, Ph.D., Chief Executive Officer of DNAtrix said, "We are delighted by the FDA's continued recognition of DNX-2401 as a promising treatment for glioblastoma by awarding this grant to further support our product development strategy. This is an important accomplishment for the company and another significant step toward bringing DNX-2401 to patients with devastating brain tumors."

For more information about this study, please refer to [Clinicaltrials.gov \(NCT02798406\)](https://clinicaltrials.gov/ct2/show/study/NCT02798406).

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 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 and (4) induce durable responses to therapy. In these studies, patient survival has been prolonged, including in those achieving a complete response.

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, a brain cancer for which there is neither a cure nor adequate treatment. 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>.

Contact

DNatrix

Imran Alibhai, Ph.D.

SVP Business Development

ialibhai@dnatrix.com

Source: <http://www.prnewswire.com/news-releases/dnatrix-awarded-fda-orphan-products-development-grant-for-dnx-2401-300308997.html>

August 4th 2016