DNAtrix Receives European Medicines Agency PRIME Designation

HOUSTON, July 27, 2016 /PRNewswire/ -- DNAtrix, a clinical stage biotechnology company developing virus-driven immunotherapies for cancer, announced that the European Medicines Agency (EMA) has granted PRIority MEdicines (PRIME) designation for DNX-2401 as a promising new treatment for recurrent glioblastoma.

The PRIME initiative was launched by the EMA in March of 2016 to accelerate the regulatory approval of breakthrough therapies that target an unmet medical need. By offering prompt interaction with Sponsors developing innovative therapies, the objective is to provide patients who have few treatment options with early access to priority medicines that could provide significant benefit.

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.

"We are pleased and honored that the European Medicines Agency has recognized the potential of our oncolytic immunotherapy DNX-2401 to make a positive impact on glioblastoma," said Joanna Peterkin, M.D., M.S., Chief Medical Officer of DNAtrix. "We look forward to working with the EMA on this important development program for DNX-2401, with the goal of improving the quality of life of patients with brain tumors."

DNAtrix has multiple ongoing studies, including a multicenter Phase 2 clinical study evaluating DNX-2401 with the checkpoint inhibitor pembrolizumab in patients with recurrent glioblastoma. For more information about this study, refer to Clinicaltrials.gov (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 Phase 1 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 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.

Contact
DNAtrix
Imran Alibhai, Ph.D.
SVP Business Development
ialibhai@dnatrix.com

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