DNAtrix Announces First Patient Dosed in Clinical Study of DNX-2440, an OX40 Ligand Expressing Immunotherapy, in Colorectal Cancer and Other Cancers with Liver Metastasis

HOUSTON, March 4, 2021 /PRNewswire/ -- DNAtrix, a biotech company advancing virus-driven immunotherapies for cancer, today announced the treatment of the first patient in a Phase 1 dose-escalation and dose-expansion study of DNX-2440, an OX40 ligand encoding oncolytic adenovirus, in patients with resectable liver metastasis. Expression of OX40 ligand on the surface of tumor cells is expected to enhance anti-tumor immune responses by providing costimulatory signals to T cells within the tumor microenvironment.

"We are excited to clinically explore the potential of one of our immunotherapy drug candidates, which is based on our proprietary adenovirus platform technology, in additional cancer indications," said Jeffrey Knapp, chief executive officer of DNAtrix. "Our preclinical work with DNX-2440 has demonstrated that infection of human tumor cell lines with this agent leads to viral replication, high level expression of OX40 ligand on tumor cells and effective tumor cell killing. Mouse tumor models showed specific anti-tumor immune memory, abscopal effect, and improved survival. This two-part clinical study is designed to directly demonstrate the activity of DNX-2440 and potential as therapy for colorectal cancer, as well as data with other tumor types where liver metastases occur."

The Phase 1 clinical trial of DNX-2440 will be conducted in 24-30 patients with resectable multifocal (≥ 2 lesions) liver metastasis, who are scheduled to have liver resection with curative-intent. Patients will receive two sequential (2 weeks apart) intra-tumoral injections of DNX-2440 into a liver metastasis prior to surgery for liver resection to evaluate safety and biological endpoints. The first part of the Phase 1 study is a dose-escalation phase evaluating three different dose levels of DNX-2440 in 12-18 patients with liver metastasis from tumors of various origins. Following the completion of dose-escalation, the selected dose will be further evaluated in an expansion phase where DNX-2440 will be administered using the same schedule to 12 patients with colorectal cancer liver metastasis. The primary endpoint of the study is to establish safety and identify a maximum tolerated dose. Secondary endpoints include evaluating tumor cell killing of injected and uninjected tumors, determining viral replication in the injected tumor and measuring local and systemic anti-tumor immune responses.

Daniel A. Anaya, M.D., FACS, head of the Hepatobiliary Group and chief of the Division of GI Surgery in the Department of Gastrointestinal Oncology at the Moffitt Cancer Center, and principal investigator of the study, added, "DNX-2440 is an innovative therapy that has shown promising preclinical results, including durable tumor responses. As a leading cancer center, we are committed to providing cutting-edge treatment approaches in our fight against cancer and are pleased to launch this collaborative clinical study."

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 will 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 in Phase 1 clinical testing 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.

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