



## **FDA GRANTS FAST TRACK STATUS TO DRUG DNX-2401 FOR RECURRENT GLIOBLASTOMA**

**SAN DIEGO, CA. – June 17, 2014** – DNAtrix, Inc., experts in oncolytic virus development, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track status for its lead product, DNX-2401, a replication competent adenovirus, for patients with recurrent glioblastoma.

The FDA gives Fast Track status to facilitate the development of new products for serious or life-threatening conditions which demonstrate the potential to address unmet medical needs, with the goal of getting important new products to patients earlier. Fast Track status will also allow the company to work closely with the FDA to expedite the review of aspects of the DNX-2401 program to improve the efficiency of product development. For more information about Fast Track Designation, visit

[www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccessstoimportantnewtherapies/ucm128291.htm](http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccessstoimportantnewtherapies/ucm128291.htm).

"We are very pleased to receive Fast Track status for DNX-2401 and are pleased that the FDA supports our position that there is an urgent need for additional therapies to treat glioblastoma," said Dr. Frank Tufaro, president and chief executive officer of DNAtrix. "Fast Track status reinforces our goal to quickly move forward with the development of DNX-2401. Recurrent glioblastoma is extremely challenging to treat, and clinical results from DNX-2401 to date indicate that the drug may be an important treatment option for the disease."

### **About DNX-2401 and Glioblastoma**

Glioblastoma is a devastating primary brain tumor resistant to conventional therapies and is the second most common cause of death from intracranial disease. The lack of effective therapy for brain tumors has led to intense investigations of novel therapeutic approaches that use vectors and recombinant viruses.

Oncolytic virus therapy is based on the concept of using live viruses to selectively infect and replicate in cancer cells, with minimal destruction of normal tissue. Replication amplifies the input dose of the oncolytic virus and helps spread the agent to adjacent tumor cells.

DNX-2401, a conditionally replication-competent adenovirus, is being developed for the treatment of several cancer indications including patients with recurrent glioblastoma. DNX-2401 is the culmination of more than a decade of scientific and clinical research and is the most potent and effective oncolytic virus delivered to human brain tumors to date.

In a Phase I dose-escalating monotherapy study conducted with DNX-2401 at the UT MD Anderson Cancer Center for patients with recurrent malignant glioma, efficacy results have been extremely promising, with evidence of total tumor destruction and long-term survival in several patients. A second Phase 1 trial evaluating DNX-2401 in combination with the drug Temozolomide is currently underway at the Clinica Universidad de Navarra in Pamplona, Spain for patients with recurrent glioblastoma.

## **About DNatrix, Inc.**

DNatrix is a company developing modified viruses for the treatment of the most aggressive forms of cancer. Since viruses are already efficient at killing cells, scientists have harnessed this ability by modifying a common cold virus so that it targets and selectively kills cancer cells. DNatrix is a privately held company located in Houston, Texas and San Diego, California. For more information, please visit the Company's website at [www.dnatrix.com](http://www.dnatrix.com).

Contact:

Frank Tufaro, Ph.D.  
Chief Executive Officer  
ftufaro@dnatrix.com