



FOR IMMEDIATE RELEASE

TVAX Biomedical Receives Fast Track Designation from the FDA

Olathe, KS, April 30, 2020 – TVAX Biomedical today announced receipt of Fast Track Designation from the US Food and Drug Administration (FDA) for the use of its vaccine-enhanced adoptive T cell therapy (VACT) for treatment of glioblastoma multiforme.

“We are very pleased to receive Fast Track Designation by the FDA for glioblastoma multiforme (GBM),” stated Dr. Wayne Carter, Chief Executive Officer. Glioblastoma is a terrible disease for which there are limited clinical options.”

FDA Fast Track Designation is designed to accelerate marketing approval of therapies aimed at treating serious and life-threatening diseases. The Designation creates an opportunity for close and regular communication between TVAX Biomedical and the FDA in order to improve the efficiency of product development. Additionally, it provides a pathway for accelerated approval and rolling review of completed Biological Licensing Application sections by the FDA.

TVAX Biomedical has completed phase 1/2a studies in multiple cancers, including GBM. Significant efficacy was demonstrated in GBM patients using TVAX’s patented vaccine-enhanced adoptive T cell therapy (VACT) in those studies. TVAX’s currently planned studies will evaluate VACT in newly diagnosed GBM patients who have healthy immune systems and minimal disease at a time when VACT would be anticipated to generate maximal efficacy.

About TVAX Biomedical

TVAX Biomedical is a clinical stage development company advancing its targeted T cell-based immunotherapy for the treatment of cancer. The company’s proprietary therapeutic approach offers the promise of improved clinical outcomes, low toxicity and the potential for fundamentally changing the way cancer is treated. Unlike other forms of immunotherapy that are effective against a limited number of cancer types, VACT is a unique personalized T cell treatment that has demonstrated the potential to effectively treat a wide range of cancers. The power of T cells is their demonstrated ability to kill cancer cells, including cancer stem cells, and cause significant numbers of objective clinical responses in treated patients.

The company’s lead candidate is focused on treating brain cancer and is supported by positive Phase 2 clinical data, as well as extensive preclinical and Phase 1 safety studies. TVAX plans to initiate a Phase 2b study in newly diagnosed GBM patients in 2020. As part of its ongoing strategy, the company is seeking to establish corporate alliances to support the development of its unique personalized form of cellular immunotherapy.

For more information visit: www.tvaxbiomedical.com

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