Clinical trials completed

PHASE III CLINICAL TRIAL TO TEST THE SAFETY AND EFFICACY OF AUTOLOGOUS TUMOR LYSATE-LOADED DENDRITIC CELLS IN PATIENTS WITH NEWLY DIAGNOSED Glioblastoma

Marnix Bosch*, Linda Liau, Keyoumars Ashkan. 1Northwest Biotherapeutics, Inc., Bethesda, MD, USA; 2UCLA, Los Angeles, CA, USA; 3King’s College Hospital, London, UK

Background Glioblastoma (GBM) is an incurable form of brain cancer with a high mortality rate in which multiple treatment attempts over the past decade have proven unsuccessful at extending survival. Early stage data have suggested that immunization against tumor cell antigens may be effective in GBM. In this Phase 3 study we aimed to assess whether autologous dendritic cells (DCs) loaded with autologous tumor cell lysate, is able to improve survival in these patients.

Methods We conducted a randomized, double-blind, placebo-controlled international Phase 3 clinical trial with autologous tumor lysate-loaded DCs (DCVax-L) in 331 patients with histologically confirmed newly diagnosed GBM. Following surgery and chemoradiation, patients were randomized 2:1 to receive temozolomide plus DCVax-L or temozolomide plus placebo (i.e., autologous PBMC). Eligibility criteria included an intent for significant tumor resection (not biopsy only), sufficient doses of DCVax-L manufactured for 5 or more immunizations, and no radiographic evidence of apparent disease progression at the end of chemoradiation. A crossover option allowed all patients to receive the autologous vaccine at the time of disease progression. As a result, 90% of the randomized patients received DCVax-L at some point during their participation in the trial. Study subjects received immunizations with 2.5 million DCs or placebo at days 0, 10 and 20, followed by immunizations at months 2, 4, 8, 12, 18, 24 and 30. All subjects were assessed for progression-free survival (PFS) and overall survival (OS). This trial is registered with clinicaltrials.gov, number NCT00045968.

Trial Registration The study was registered as NCT00045968

Ethics Approval The study was approved by all applicable Institutional Review Boards or Ethics Committees

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