Researchers report encouraging Phase 1 data for glioblastoma treatment

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Preliminary clinical data for glioblastoma multiforme patients enrolled

in a Phase 1 clinical trial at the University of Alabama at Birmingham demonstrated that 92% of evaluable patients treated with INB-200 exceeded a median progression-free survival of seven months with concomitant temozolomide chemotherapy. The median follow-up was 11.7 months.

These preliminary clinical data were presented at a poster session of the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. Mina Lobbous, M.D., assistant professor of neurology at Cleveland Clinic (after completing his Neuro-Oncology fellowship at UAB) was the poster presenter.

This survival data along with radiographic improvements are indicative of positive treatment effects, which highlights the potential of IN8bio's genetically modified, chemotherapy-resistant gamma-delta T cells as a potential first-in-class therapy for patients with newly diagnosed glioblastoma. Glioblastoma multiforme is the most aggressive type of cancer originating in the brain.

The clinical trial was led by Burt Nabors, M.D., in collaboration with IN8bio. Nabors is a professor of neurology at UAB, division director of Neuro-Oncology and a senior scientist in the O'Neal Comprehensive Cancer Center at UAB. Gamma-delta T cells are a specialized population of T cells that possess unique properties, including the ability to differentiate between healthy and diseased tissue.

IN8bio is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell product candidates for solid and liquid tumors. Larry Lamb, Ph.D., former professor in the UAB Marnix E. Heersink School of Medicine Department of Medicine, and the scientific co-founder and current chief scientific officer at IN8bio Inc., helped develop the technology. INB-200 is the first genetically modified gamma-delta T cell therapy to

enter clinical trials.

The current standard of care for newly diagnosed glioma patients consists of primary resection and six weeks of daily chemoradiation therapy, followed by six cycles of monthly maintenance temozolimide therapy. This Stupp regimen achieves a median progression-free survival of seven months and an overall survival of approximately 14 to 16 months.

The Phase 1 study assessed the safety and preliminary efficacy of adding DeltEx DRI gamma-delta T cells to maintenance therapy with temozolomide. The trial assessed the administration of 10 million cells per dose across three different dosing regimens, increasing from a single dose delivered on Cycle 1, Day 1 during maintenance in Cohort 1, to three doses delivered on Day 1 of Cycles 1-3 in Cohort 2, to six doses delivered on Day 1 of Cycles 1-6 in Cohort 3.

Thirteen patients have been enrolled and treated with INB-200, including three patients in Cohort 1 (one dose), four patients in Cohort 2 (three doses) and six patients in Cohort 3 (six doses). All of the patients in the Phase 1 study who received all of their protocol-defined treatments with INB-200 exceeded the median progression-free survival of seven months, including one patient in Cohort 2 who remains alive and progression-free after nearly three years.

"For far too long, there has been little advancement for patients with glioblastoma multiforme to improve their treatment outcomes," Nabors said. "The addition of multiple intracranial injections of IN8bio's DeltEX DRI gamma-delta T cells shows the potential for extending progression-free survival in this patient population, when administered in combination with the current standard of care used to treat newly diagnosed glioblastoma patients."

No treatment-related serious adverse events have been reported in any cohort.

"The safety profile of gamma-delta T cells continues to be strong across all three dose cohorts with no cell therapy-related toxicities such as immune effector cell-associated neurotoxicity syndrome or cytokine release syndrome reported in patients receiving up to the maximum dose of six infusions of the therapy," said Trishna Goswami, M.D., chief medical officer for IN8bio. "We are now dosing newly diagnosed patients in Arm A of a Phase 2 study with INB-400, evaluating up to six infusions of our autologous gamma-delta T cells in combination with the Stupp protocol."

Radiographic evaluation pre- and post-treatment included resolution of midline shift in one patient with evidence of changes in enhancement attributed to treatment effect in multiple patients. One subject was found to have a 36% decrease in a lesion attributed to positive treatment effect.

"As these encouraging results from our ongoing INB-200 Phase 1 study continue to mature, we look forward to reporting additional results from a long-term follow-up of Cohort 3 at future medical meetings," said William Ho, CEO and co-founder of IN8bio.

Provided by University of Alabama at Birmingham