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A clinical study agreement between Regeneron and Inovio

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Regeneron Pharmaceuticals, Inc. and Inovio Pharmaceuticals, Inc. announced a clinical study agreement for a Phase 1b/2a immuno-oncology trial. The study will be conducted by Inovio in patients with newly-diagnosed glioblastoma multiforme (GBM) and will evaluate Regeneron's PD-1 inhibitor, REGN2810, in combination with Inovio's INO-5401 T cell activating immunotherapy encoding multiple antigens and INO-9012, an immune activator encoding IL-12.

The open-label trial, which is expected to begin later this year, is designed to evaluate the safety and efficacy of the combination therapy in approximately 50 patients. The study will be conducted at 30 U.S. sites and the primary endpoints are safety and tolerability. The study will also evaluate immunological impact, progression-free survival and overall survival.

GBM is a devastating disease for both patients and caregivers. It is the most aggressive brain cancer and its prognosis is extremely poor, despite a limited number of new therapies approved over the last ten years.

Under the terms of the agreement, the trial will be solely conducted and funded by Inovio, based upon a mutually agreed upon study design, and Regeneron will supply REGN2810 (a PD-1 checkpoint inhibitor). Inovio and Regeneron will jointly conduct immunological analyses in support of the study. Regeneron, in collaboration with Sanofi, is developing REGN2810 both alone and in combination with other therapies for the treatment of various cancers.