A Phase 2 Trial of Rindopepimut in Patients With Relapsed EGFRVIII-Positive Glioblastoma

- Rindopepimut is an investigational therapeutic vaccine. It is thought to target EGFRVIII, a constitutively activated deletion mutant that is found only in tumors. About a third of glioblastoma patients express EGFRVIII, and its presence has been linked to poor long-term survival.
- ReACT is a phase 2 study being conducted in the United States that will evaluate if rindopepimut is effective in extending progression-free survival (PFS) in patients with relapsed EGFRVIII-expressing glioblastoma, when added to standard bevacizumab.

**Key Inclusion Criteria**
- Previous treatment must include surgery [biopsy, partial resection, or full surgical resection], conventional radiation therapy, and temozolomide.
- First or second relapse of glioblastoma. Patients enrolling into group 2 must have progressed while receiving bevacizumab.
- Documented EGFRVIII-positive tumor status. A tumor sample from either the initial diagnosis or more recent relapse will be acceptable. Only patients with the EGFRVIII mutation can participate in the trial.

**Key Exclusion Criteria**
- Presence of diffuse leptomeningeal disease, gliomatosis cerebri, or infratentorial disease.
- History, presence, or suspicion of metastatic disease.
- Clinically significant increased intracranial pressure, uncontrolled seizures, or requirement for immediate palliative treatment.

**Key Trial Endpoints**
- Primary: PFS rate at 6 months (PFS-6).
- Secondary: Objective response rate, overall PFS, and overall survival.