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CLINICAL TRIAL ANNOUNCEMENT

Phase III Trial to Evaluate **Marizomab** in combination of standard of care in patients with **Newly Diagnosed Glioblastoma**

Official Title: A phase III trial of marizomib in combination with standard temozolomide-based radiochemotherapy versus standard temozolomide-based radiochemotherapy alone in patients with newly diagnosed glioblastoma

The purpose of this study is to compare overall survival and assess the safety and tolerability of glioblastoma patients treated with standard TMZ-based chemoradiotherapy alone or TMZ-based chemoradiotherapy in combination with marizomib

Glioblastoma is the most common primary brain tumor in adults. It is thought to be of neuroglial origin, typically characterized by astrocytic differentiation and additional histological features such as microvascular proliferation and necrosis. The results achieved with traditional cancer therapies are poor because of defects in the apoptotic machinery of glioma cells, accounting for their resistance to irradiation and chemotherapy.

Marizomib (MRZ) is a novel, second generation proteasome inhibitor that prevents the breakdown of proteins involved in signal transduction which blocks growth and survival of cancer cells. Based on encouraging observations, MRZ exerts strong anti-glioma activity that crosses the blood brain barrier, making it a promising drug for the treatment of tumors in the central nervous system such as glioblastoma.

Two Treatment Arms will include:

- (1) Marizomab Arm: Marizomib + Standard radiotherapy + TMZ for 6 weeks; followed by maintenance TMZ + Marizomab
- (2) Standard Arm: Standard radiotherapy + TMZ for 6 weeks; followed by maintenance TMZ

Key Inclusion Criteria:

- Histologically confirmed newly diagnosed glioblastoma (WHO Grade IV)
- Tumor resection (gross total or partial), or biopsy only
- Age ≥ 18

Key Exclusion Criteria:

- Patients with known IDH mutation
- Prior treatment for glioblastoma other than surgery