**TPS2100** **Poster Session**

# Update on GBM AGILE: A global, phase 2/3 adaptive platform trial to evaluate multiple regimens in newly diagnosed and recurrent glioblastoma.

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**Background:** GBM AGILE (Glioblastoma Adaptive, Global, Innovative Learning Environment) is a biomarker based, multi-arm, international, seamless Phase 2/3 response adaptive randomization platform trial designed to efficiently identify investigational therapies that improve overall survival and confirm efficacious therapies and associated biomarker signatures to support drug approvals and registration. GBM AGILE is a collaboration between academic investigators, patient organizations, and industry to support new drug applications for newly diagnosed and recurrent glioblastoma. **Methods:** The primary objective of GBM AGILE is to identify therapies that improve overall survival in patients with newly diagnosed or recurrent glioblastoma. Operating under a Master Protocol, GBM AGILE allows multiple drugs from different pharmaceutical/biotech companies to be evaluated simultaneously and/or over time against a common control. New investigational therapies are added as new information about promising drugs is identified, while other therapies are removed as they complete evaluation. Bayesian response adaptive randomization is used within subtypes of the disease to assign participants to investigational arms based on their performance. GBM AGILE has screened over 2300 patients and enrollment continues to be robust. An estimated 25% of all US glioblastoma patients enrolled in clinical trials participate in GBM AGILE. The trial is open at select sites in the United States, Canada, Switzerland, France, Germany, and Australia. In addition to the efficient evaluation of investigational arms, a primary goal of GBM AGILE is to expand knowledge of glioblastoma to support advancements in treatment using the data collected within the trial (learning environment). Over 7 million data points are currently available for inclusion in the development of a longitudinal model. Such a model may be able to inform randomization by providing earlier and continuous information regarding patient and arm performance. In addition, serial magnetic resonance imaging scans and biospecimens from baseline through patient progression are being collected for further analysis. An initial 500 baseline tissue samples are being characterized using whole genome sequencing and whole transcriptome analysis. Clinical trial information: NCT03970447. Research Sponsor: None.