patients of group 2 experiencing at least one episode of thrombocytopenia, 36 patients in group 1 and 93 in group 2 had their treatment modified because of thrombocytopenia. Lomustine was discontinued for thrombocytopenia in 12% (17/144) of patients in group 2. Patients with O6-methylguanine DNA methyltransferase (MGMT) promoter-methylated glioblastoma treated with lomustine alone encountered more interference with study treatment than patients with tumors without MGMT promoter methylation. On adjusted analysis, major prognostic factors, treatment modification by thrombocytopenia was a positive prognostic factor for overall survival, and this effect was entirely driven by patients with tumors without MGMT promoter methylation only. Conversely, thrombocytopenia was associated with inferior progression-free survival in patients with or without MGMT promoter-methylated tumors, suggesting a link to insufficient lomustine exposure. CONCLUSION: Drug-induced thrombocytopenia is a major limitation to adequate exposure to lomustine salvage chemotherapy in patients with recurrent glioblastoma. Its association with survival suggests that mitigating thrombocytopenia to allow enhanced drug exposure in patients with MGMT promoter methylated tumors might improve outcome.

P11.64.A. LONG-TERM FOLLOW UP AND TRANSLATIONAL DATA FROM THE REOGLIO PHASE IB TRIAL OF GM-CSF AND INTRAVENOUS PELAREOREP (REOVIRUS) ALONGSIDE STANDARD OF CARE IN GBM
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BACKGROUND: We previously reported safety data from a phase Ib, open-label, trial of intravenous pelareorep (REOVIRUS) against GM-CSF, a standard-of-care strategy in glioblastoma. GM-CSF was given on days 1 and 4 of every 3 weeks from day 1 to week 4. Intravenous pelareorep was given on days 1 and 4 of every 3 weeks. A protocol amendment we also collected survival data in all patients up to 2 years after completing treatment. Data from the REOGLIO phase IB trial of GM-CSF and pelareorep were recently presented at ASCO 2022.

DATA FROM THE REOGLIO PHASE IB TRIAL OF GM-CSF AND PELAREOREP
P11.64.A. LONG-TERM FOLLOW UP AND TRANSLATIONAL
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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 rapidly identify experimental therapies that improve overall survival and confirm efficacious experimental therapies and associated biomarker signatures to support new drug approvals and registration. It is a collaboration between Adaptive Biotechnology, Global Coalition for Adaptive Research, the Global Alliance for World’s Best Cancer Therapies, Global Coalition for Adaptive Research, and the Global Coalition for Adaptive Research, to support new drug applications for newly diagnosed and recurrent GBM.

MATERIAL AND METHODS: The primary objective of GBM AGILE is to identify therapies that effectively improve overall survival in patients with newly diagnosed or recurrent GBM. Bayesian response adaptive randomization is used within subtypes of the disease to assign participants to investigational arms based on their performance. Operating under a master protocol, GBM AGILE allows multiple drugs from different pharmaceutical companies to be evaluated simultaneously and/or over time against a common control arm. Based on performance, a drug may graduate to a Stage 2 (Phase 3) within the trial, and the totality of the data can be used for a new drug application and registration. This approach allows for drug approval in post-marketing surveillance. No additional safety monitoring is required for promising new drugs identified while other therapies are removed as they complete their evaluation. The master protocol trial infrastructure includes efficiencies through an adaptive trial design, shared control arm, and as risk management process with enhanced remote therapies.

GBM AGILE has screened over 1000 patients studying multiple investigational treatments. Enrollment rates are 3 to 4 times greater than traditional GBM trials, with active sites averaging 0.73 to 1 patients/site/month.

Currently, there are 41 sites activated in the US, 4 in Canada and 2 in Switzerland and an estimated 24 sites yet to open in Germany, France, Switzerland, Italy and Austria. In addition to the continued expansion in Europe, effort is ongoing to extend the trial to China and Australia as well. Clinical trial information: NCT03970447

P11.66.A. IMMUNE CHECKPOINT INHIBITORS RELATED PERIPHERAL NERVE DISORDERS: CLINICAL AND ELECTROPHYSIOLOGICAL PRESENTATION

BACKGROUND: Immune checkpoint inhibitors (ICIs) have been used in cancer treatment allowing long-term survival in advanced cancers. However, immune related adverse events impose treatment limitations being one of the main challenges when dealing with ICI treated patients. Neurologic toxicities have unique presentations and can progress rapidly, requiring prompt recognition. Among them, ICI-related peripheral nerve disorders are