2028 **Poster Session**

Multi-institutional randomized phase 3 trial comparing cancer stem cell-targeted versus physician-choice treatments in patients with recurrent high-grade gliomas (NCT03632135).

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Background: Clinical outcomes in patients with recurrent high-grade glioma (HGG) remain poor. Cancer stem cells (CSCs) have been implicated in metastasis, treatment resistance and recurrence of HHGs. We have shown in several clinical studies that anti-CSC-directed therapy selected by ChemoID assay provides benefits in many cancer types; however, this is the first report of a randomized clinical trial evaluating whether CSC-targeted cytotoxic agents selected by ChemoID assay-guided therapy improves survival in patients with recurrent HGG. **Methods:** In this parallel-group, randomized, phase-3 clinical trial, patients at 13 clinical sites in the USA with grade-III/IV recurrent glioma (2016 WHO guidelines) were randomized 1:1 to either ChemoID assay-guided therapy or physician-choice therapy, and then treated and followed until unacceptable toxic effects, hospice, or death. The primary endpoint was overall survival (OS). **Results:** Combined median follow-up was 9 months. Median OS (mOS) was 12.5 months (95% CI, 10.2-14.7) in the ChemoID assay-guided group vs 9 months (95% CI, 4.2-13.8) in the physician-choice group (log-rank P =.010). Risk of death was significantly lower in the ChemoID assay group (HR = 0.44; 95% CI, 0.24-0.81; P =.008). Median progression free survival (PFS) was 10.1 vs 3.5 months (95% CI, 4.8-15.4 vs 1.9-5.1) (HR, 0.25; 95% CI, 0.14-0.44; P <.001). **Conclusions:** Primary endpoint was met in this randomized clinical trial. The mOS was 3.5 months longer in the ChemoID assay-guided group vs the physician-choice group. Clinical trial information: NCT03632135. Research Sponsor: Cordgenics, LLC.