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### Title

HOUT-17. A PRELIMINARY DATA REPORT ON A PHASE 2 STUDY OF ERC1671 IN RECURRENT GLIOBLASTOMA

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**AIM:** Time to progression (TTP) is an established response measure, and at progression patients can be included in trials. Standards for imaging interpretation of progression are lacking. We determined the differences in time to progression and in tumor volumes at progression between three methods to assess progression. **METHODS:** From a consecutive cohort of 97 patients with glioblastoma in 2012 or 2013, 63 had MRI follow-up after initial treatment to evaluate progression. TTPclinical was determined by multidisciplinary evaluation in clinical practice; TTPRANO by the RANO criteria for trial inclusion; and TTPconsensus by multidisciplinary consensus review (neuroradiologist, neurosurgeon, 2 radiation oncologists) looking back on all MRI information (on average 3.9 follow-up MRIs per patient, range 1-11) with knowledge of further progression and death, postulated as gold standard. MRIs were co-registered to facilitate the consensus review and the maximum perpendicular tumor diameters and volumes were based on enhancing tumor segmentations. **RESULTS:** No patient was without progression with consensus review, one with clinical practice evaluation and 22 with RANO criteria. The median TTPconsensus was 36 weeks, TTPclinical 40 weeks and TTPRANO 57 weeks. The median overall survival was 64 weeks. The median progression volume was 8.8 mL with consensus review, 17 mL with clinical practice evaluation, and 38 mL with RANO. **CONCLUSION:** TTP and volume at progression vary considerably depending on definition of progression. Different purposes may require different progression criteria. Early detection with small volumes may be useful to evaluate progression locations in relation to initial treatment, but can only be determined after the course of disease. RANO criteria may be useful for reproducible clinical trial inclusion, but at the price of later detection with larger volumes. Progression according to RANO criteria is considerably later than clinical practice evaluation in this cohort, potentially introducing lead time bias in trials.

#### HOUT-15. BRAIN TUMOR PATIENT AND CAREGIVER SURVEY ON CLINICAL TRIALS: IDENTIFYING ATTITUDES AND BARRIERS TO PATIENT PARTICIPATION

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The National Brain Tumor Society conducted an online survey to determine if, when, and how information about clinical trials is provided to brain tumor patients and their caregivers, as well as to understand the perceptions and barriers around clinical trial participation. Questions were tailored for either patient or caregiver respondents, each with further stratification based on whether the patient was newly diagnosed/first occurrence or diagnosed with a recurrent primary brain tumor. There was a total of 1,463 respondents, of which 54% were caregivers with 73% of patients having/had first occurrence brain tumors. Among the different brain tumor types represented in the sample, glioblastoma made up the majority (36%), followed by meningioma (18%), astrocytoma (17%), oligodendroglioma (11%) and a mix of other types (29%), with 2% of respondents unsure of their diagnosis. The survey was open to brain tumor metastases patients, but an insufficient number of respondents met the true definition of "metastatic" preventing their inclusion in the overall analysis. When asked if patients had been informed about clinical trials by their medical team, 42% reported being informed, while 36% stated they had never discussed clinical trials with their provider. When patients were informed about clinical trials, only 24% were informed at the time of their diagnosis. Of the total sample, 21% of patients had participated in a clinical trial. When asked why patients had not participated in clinical trials, the top reasons given were: 1) the patient's provider did not recommend participating in the trial, 2) the patient did not qualify for clinical trial(s), and 3) the patient and caregiver did not know where to find a clinical trial. The survey results underscore the need for better resources and decision support that will enable patients to be more fully informed about the importance of their participation in appropriately matched clinical trials.

#### HOUT-16. NON-ROUTINE DISCHARGE DISPOSITION IS ASSOCIATED WITH POST-DISCHARGE COMPLICATIONS AND 30-DAY READMISSIONS FOLLOWING CRANIOTOMY FOR BRAIN TUMOR RESECTION

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**INTRODUCTION:** Several studies have reported an association between high-volume brain tumor centers and greater rates of routine discharge disposition in the context of better outcomes. However, the relationship between in-hospital complications, discharge destination, and postoperative

adverse events (AEs) remains unexplored. The purpose of this study was thus to use a large, prospectively collected database to examine the association between discharge destination, post-discharge complications, and readmissions among patients undergoing craniotomy for brain tumor. **METHODS:** The 2011-2014 National Surgical Quality Improvement (NSQIP) database was employed to identify all adult patients who underwent a craniotomy for tumor resection and had a histologic brain tumor diagnosis via ICD-9 coding. Demographics, comorbidities, and perioperative variables were collected for each patient. Univariate statistics with subsequent binary logistic regression analyses were used to explore the relationship between these perioperative factors and postoperative events, including major post-discharge complications, minor post-discharge AEs, and 30-day readmissions. Significant variables such as demographics, comorbidities, operative time, body mass index, ASA classification and pre-discharge complications were controlled for in each model. **RESULTS:** Of the 14,854 patients identified, 11,409 (77.9%) were discharged home. After controlling for comorbidities and in-hospital AEs, non-home discharge was an independent predictor of major post-discharge complications (OR: 1.74, 95%CI: 1.36-2.22, p<0.001), minor post-discharge events (OR: 1.45, 95%CI: 1.01-2.07, p=0.045), and readmissions (OR: 2.06, 95%CI: 1.48-5.12, p<0.001). **CONCLUSIONS:** Non-routine discharge disposition is predictive of an array of complications as well as readmission following discharge. These factors may be considered in discharge planning and perioperative counseling for patients undergoing brain tumor resection.

#### HOUT-17. A PRELIMINARY DATA REPORT ON A PHASE 2 STUDY OF ERC1671 IN RECURRENT GLIOBLASTOMA

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Standard therapy for recurrent GBM is bevacizumab, a monoclonal VEGF inhibitor that targets tumor vasculature. The response to bevacizumab is transient and short-lived after which patients typically develop progressive physical and mental debilitation culminating in death. ERC1671 is an allogeneic/autologous therapeutic vaccine – composed of whole, inactivated tumor cells mixed with tumor cell lysates. The proposed action of ERC1671 is the stimulation of the patients' immune system. This ongoing phase 2 study has a goal to determine the safety and effectiveness of ERC1671 in combination with GM-CSF and cyclophosphamide as an add-on treatment to bevacizumab for recurrent GBM. ERC1671/GM-CSF is intradermally administered 2-3 times a week and for five total into maximum 18 days, while cyclophosphamide is orally administered for 4 days at the beginning. GM-CSF dose is 250 µg/m<sup>2</sup> and cyclophosphamide dose is 50 mg/day. Bevacizumab is administered as standard of care at 10 mg/kg every 2 weeks. The treatment cycle is 28 days. 9 recurrent bevacizumab-naïve GBM patients, with KPS higher than 70, were treated with ERC1671/GM-CSF/Cyclophosphamide + Bevacizumab v. Placebo + Bevacizumab. Median age was 59 (48-74), with 2 patients being female, and the average KPS 80 (70-100). These patients were unblinded at the time of further progression – 4 received vaccine, 4 received placebo, and 1 was non-evaluable due to discontinuation prior to completion of 1 cycle. Overall survival of patients treated with ERC1671 + Bevacizumab was more than 513 days, compared to patients treated with Placebo + Bevacizumab was 213 days (p=0.048). First clinical results for toxicity show an equal distribution of AEs between the Vaccine and Placebo groups, with no Gr4/Gr5 AEs. The addition of ERC1671/GM-CSF/Cyclophosphamide to bevacizumab for recurrent glioblastoma resulted in a clinically meaningful survival benefit with minimal additional toxicity. The phase 2 randomized, double-blinded study is ongoing with anticipated 2 subsites.

#### HOUT-18. SAFETY OF COMMERCIAL AIRFLIGHT IN PATIENTS WITH BRAIN TUMORS – A CASE SERIES

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**INTRODUCTION:** Patients with intracranial masses are often advised to avoid airflight due to concerns of worsening neurological symptoms. However, many patients often travel to tertiary care neuro-oncology centers and some travel internationally. This study assesses the safety of commercial airflight for brain tumor patients without severe or progressive neurological deficits. **METHODS:** Patients that had traveled to our institution for surgical evaluation via commercial airflight from 2014-2017 were identified. An electronic survey was administered (RedCap) and flight duration, aircraft