

Abstract SNO

**Abstract Title:**

Gliotarget: a Danish nationwide phase I/II platform trial focusing on individualized targeted treatment for newly diagnosed glioblastoma patients based on genomic profiling.

**Abstract Body:**

**INTRODUCTION:**

The survival in glioblastoma has been unchanged since 2005. The introduction of targeted treatments, which have improved survival in several cancers has yet to influence the treatment of glioblastoma. In Gliotarget, we will individualize the targeted treatment, and give it in the primary setting alongside standard therapy with the intention to improve the likelihood of effect.

**METHODS:**

Gliotarget is a biomarker enriched phase I/II platform trial with initially 4 predefined biomarker selected arms, one miscellaneous biomarker arm and one control arm. All patients receive standard therapy with concomitant radiochemotherapy and adjuvant Temozolomide. The experimental treatment is given alongside the adjuvant Temozolomide. Molecular analysis, including Whole Genome Sequencing, is performed on all patients, to identify actionable biomarkers. The miscellaneous arm gathers patients with not previously defined biomarkers upon which the weekly molecular tumor board decides to treat. Gliotarget includes newly diagnosed IDH-wt glioblastoma patients. In addition, to exclude the patients where the inherent poor prognosis might conceal the drug efficacy, the patients must have a 50% probability of being alive 12 months after initial surgery, according to a prognostic model developed in our institution.

The sample size is calculated with Simon's two-stage design using treatment effect at 9-months progression free survival (PFS9). We anticipate 9 patients for stage one and 24 in total, for each arm. Treatment effect is defined as 65% of the patients in an experimental arm reaching PFS9. For the survival analysis, supplementing the control arm data with leveraged external controls taken from our prospectively registered database will decrease the probability of false positive results.

**CONCLUSION:**

Gliotarget complements the field of ongoing platform trials with its distinctive trial design. The chosen biomarkers and treatments will be presented at the annual meeting. Enrollment is set to open in Q4 2021.

*Submission type: Adult*

*Abstract tumor type: Glial Tumors*

*Abstract Category: Randomized trials in Development*