AMPLIFY-NEOVAC is a randomized 3-arm, window-of-opportunity, multicenter national phase 1 trial to assess the safety, tolerability, and immunogenicity of IDH1-vac combined with avelumab (AVE), an immune checkpoint inhibitor (ICI) targeting programmed death-ligand 1 (PD-L1). The target population includes patients with resectable IDH1R132H-mutant recurrent astrocytoma or oligodendroglioma after SOC. Neoadjuvant and adjuvant immunotherapy will be administered to 48 evaluable patients. In arm 1, 12 patients will receive IDH1-vac; in arm 2, 12 patients will receive the combination of IDH1-vac and AVE, and in arm 3, 24 patients will receive AVE only. Until disease progression according to immunotherapy response assessment for neuro-oncology (iRANO) criteria, treatment will be administered over a period of maximum 43 weeks (primary treatment phase) followed by facultative maintenance treatment.

Perspective: IDH1R132H 20-mer peptide is a shared clonal driver mutation-derived neoepitope in diffuse gliomas. IDH1-vac safely targets IDH1R132H in newly diagnosed astrocytomas. AMPLIFY-NEOVAC aims at (1) demonstrating safety of enhanced peripheral IDH1-vac-induced T cell responses by combined therapy with AVE compared to IDH1-vac only and (2) investigating intra-glioma abundance and phenotypes of IDH1-vac induced T cells in exploratory post-treatment tissue analyses. In an exploratory analysis, both will be correlated with clinical outcome¹⁾.

1)

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1/1