

NOVACEA INITIATES PHASE 1/2 TRIAL OF AQ4N IN GLIOBLASTOMA MULTIFORME

Novacea

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Novacea, Inc. (NASDAQ: NOVC) announced that it has initiated a multicenter, Phase 1b/2a open-label clinical trial of AQ4N (banoxantrone), in combination with radiotherapy and temozolomide, for safety, tolerability and activity in patients with newly diagnosed glioblastoma multiforme (GBM).

The trial consists of two parts. The primary objective of the first part will be to evaluate safety and tolerability of three dose levels (200 mg/m², 450 mg/m² and 750 mg/m²). The second part will further evaluate safety and tolerability as well as efficacy and the highest safe and tolerated dose of the AQ4N treatment determined in part one. Novacea expects to enroll approximately 60 patients in the trial. For more information on the AQ4N trial, you may visit www.ClinicalTrials.gov.

“Initiating this trial is an important milestone for Novacea and the GBM patient community. For more than 20 years researchers have grappled with the issue of hypoxic (oxygen starved) tumors limiting the effectiveness of radiation and/or chemotherapy. In vitro data indicate that the level of response to radiation and/or chemotherapy in hypoxic tumor cells is one-third that of normally oxygenated cells. By selectively targeting the hypoxic tumor regions, we are hopeful that AQ4N will increase the anti-tumor activity of this regimen compared to the current standard of care,” said Brad Goodwin, chief executive officer of Novacea.