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High-Grade Glioma outcomes in the Phase 1 BXQ-350 trial of cancer-selective SapC-DOPS nanovesicles

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Part 2

Part 3

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- No Preference

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- I agree.

Educational Objectives
1. Examine the role of novel Saposin C-dioleylphosphatidylserine (SapC-DOPS) agents in high-grade gliomas (HGG), with particular consideration to the novel information attained from the first-in-class Phase 1a BXQ-350 trial (NCT02859857)
2. Be better prepared to understand and recommend research and investigation treatment in high-grade gliomas (HGG), with particular consideration to the imaging data available.

Abstract
BACKGROUND: Saposin C-dioleylphosphatidylserine (SapC-DOPS) is a novel blood-brain barrier penetrant nanoliposomal agent that targets externalized phosphatidylserine overexpressed on tumor cell membranes. A recent Phase 1a BXQ-350 trial (NCT02859857) reported SapC-DOPS was well tolerated in both solid tumor and high-grade glioma (HGG) patients with potential for treating clinically challenging gliomas, including their diffuse infiltrative components.

METHODS: We evaluated the HGG subset of the ongoing Phase 1 study of IV BXQ-350 administered on Days 1-5, 8, 10, 12, 15, 22 (cycle 1) and each 28 day cycles thereafter. MRI neuroimaging (e.g., Axial T1-post-contrast Ax SE T1 POST-FC and medically necessary views) at Days 29, 57, 113, and 171 (or withdrawal) were completed. RANO assessment, functional neurological deficits, ECOG Performance Status, and safety were assessed.

RESULTS: The HGG patients (9/17) were dosed at 0.7 (N = 1), 1.1 (N = 1), 1.4 (N = 2), 1.8 (N = 2), or 2.4 (N = 3) mg/kg, with 8/9 completing a full cycle before withdrawal (7 due to progression, 1 voluntary withdrawal). BXQ-350 was not linked to dose limiting toxicities or severe adverse reactions. Functional neurological deficits and ECOG decline were proportional to radiological progression, with ECOG scores declining from a baseline 0-1 in 2/9 (22%) to 3. One patient completing 6 cycles (>12 months) of BXQ-350 therapy (0.7 mg/kg) exhibited stable disease, -7% lesion size, and no significant progressive functional neurological deficits. Three patients underwent surgery for progression while on treatment. Ultrastructural evaluation using scanning electron microscopy showed electron-dense accumulations resembling autophagic vacuoles in recurrent tumor tissue as well as reactive astrocytes not typical in recurrent GBM, possibly representing a yet uncharacterized treatment-specific histologic effect.

CONCLUSIONS: BXQ-350 was well tolerated by GBM patients with promising best response apparent in neuroimaging, suggesting therapeutic benefit warranting further trials. Updates from the ongoing trial will be presented.

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