ASCO GI 2026
Session C
Abstract Number: 105
Poster Board Number: D17

BXQ-350 in combination with FOLFOX7 and bevacizumab: Evaluation of effect on oxaliplatin-induced CIPN—A phase 1b/2 trial to assess the efficacy and safety of BXQ-350, a first-in-class sphingolipid metabolism modulator, in newly diagnosed metastatic colorectal cancer

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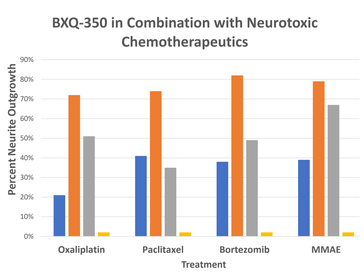
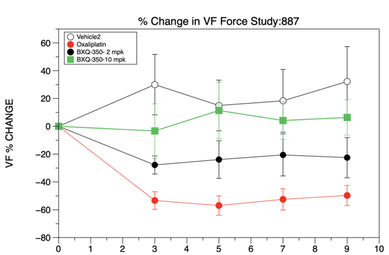
1. Background:

- **Chemotherapy-induced peripheral neuropathy (CIPN) is a significant side effect associated** with many chemotherapeutic agents.
- **CIPN is highly prevalent in CRC patients receiving therapeutic regimens including oxaliplatin;** ~15-20% of patients suffer from chronic CIPN that severely impacts quality of life (QoL) and may require dose vacation, dose reduction or treatment interruption.
- **CIPN's pathology is complex** and not completely understood; preclinical and clinical data has shown **inflammatory (IL-6, Il-8, IL-10) and immune involvement as well as increased levels of sphingolipids**, a class of bioactive signaling molecules.
- **Dysregulated sphingolipid metabolism is associated with many diseases** including cancer, autoimmune, inflammatory, Gaucher and Parkinson diseases.

2. BXQ-350 Preclinical Data:

- Protects P12 neuronal cells from chemotherapeutic agents' neurotoxicity and promotes neurite growth at nanomolar concentrations
- Protects mice from oxaliplatin-induced CIPN in a murine mechanical allodynia model in a dose-dependent manner





3. Methods:

- BXQ-350 is being investigated in a Phase 1b/2 study in combination with mFOLFOX7 and Bevacizumab (SoC) in newly diagnosed mCRC patients (NCT05322590) to assess the efficacy and safety of BXQ-350.
- Phase 1b is an open label safety dose escalation to establish the RP2D exploring 1.8 and 2.4 mg/kg BXQ-350 in combination with SoC. At 2.4 mg/kg (no DLT), 9 patients were safely dosed, then additional patients were dosed to complete a 30-patient expansion cohort.
- Primary objectives are to assess safety and preliminary efficacy of BXQ-350 in this combination, to include determining cumulative oxaliplatin dose. A secondary objective is to determine if BXQ-350 decreases intensity, frequency, and/or delays on-set of CIPN.

Summary

- **BXQ-350 is a novel biologic** and a nanovesicle formulation of Saposin C, an allosteric activator of enzymes involved in sphingolipid metabolism
- BXQ-350 modulates sphingolipid metabolism, **lowers S1P and increases ceramide levels**
- **Data in this trial and other trials show that BXQ-350 may prevent or resolve CIPN**
- BXQ-350 is **well-tolerated and showed signs of single agent activity in multiple tumor types** in patients with solid tumors refractory to standard therapies
- **Potential biomarkers based on S1P & Cer for cancer, and NfL & cytokines for CIPN**

Other Completed Trials:

- PoC and PK/PD study in cancer patients with established CIPN (NCT05291286)
- Phase 1 study in combination with radiation in pediatric DIPG/Diffuse Midline Glioma patients (NCT04771897)
- Phase 1 study of BXQ-350 in adult patients with advanced Solid Tumors (NCT02859857)

Related Posters at ASCO GI 2026:

- Trial in Progress: **Abstract Number:** TPS273 **Poster Board Number:** L7 **Session Title:** Trials in Progress Poster Session C: Cancers of the Colon, Rectum, and Anus
- Cancer Efficacy Results: **Abstract Number:** 242 **Poster Board Number:** K2 **Session Title:** Poster Session C: Cancers of the Colon, Rectum, and Anus

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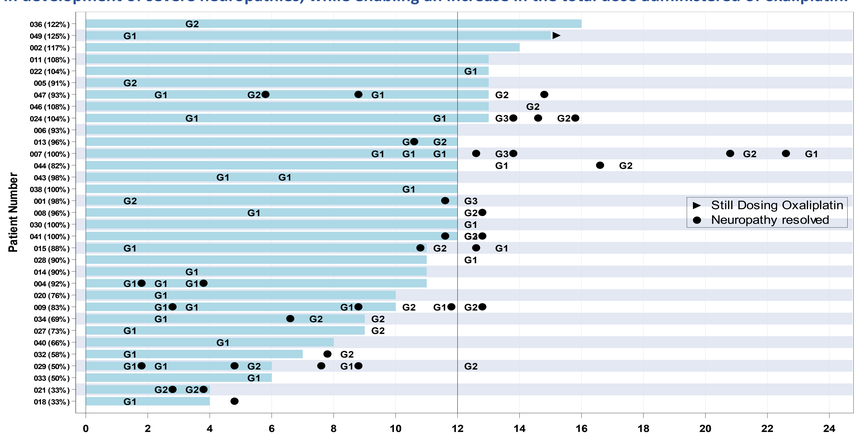
Acknowledgement: Patients who participated in the trials and their families, clinicians and staff at investigational sites, Bexion's personnel

4. Results: FOLFOX7 was co-administered with test article BXQ-350. Oxaliplatin Dosing Data with neuropathy grades and resolutions shown in the Figure, with data summary compared to Real World Evidence (RWE) in the tables below. Key findings are a reduction in incidence and delay in development of severe neuropathies, while enabling an increase in the total dose administered of oxaliplatin.



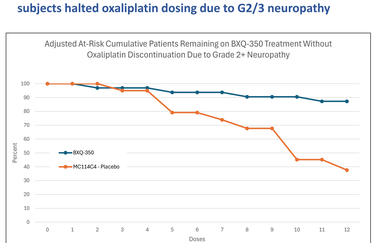
Study	% 6+ Doses Oxali	% <6 Doses Oxali
TRIBE2	68	32
Bexion .AG	94	6

Cycles Dosed	% vs RWE
C8	85% vs 50%
C10	76% vs 25%
C12	58% vs 20%
>C12	27% vs 10%

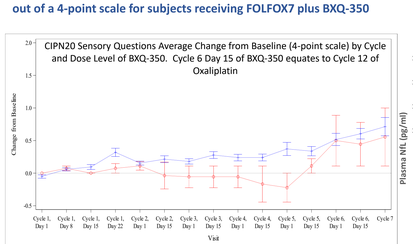
Grade CIPN	% vs RWE
G2	36% vs 50%
G3	12% vs 18%
C10 G2	28% vs 50%
C12 G3	6% vs 48%

RWE References: ELOXATIN® USPI, Giantonio 2007, Tsai 2016, Kang 2023, Weickhardt 2011, deGramont 2007, Loprinzi 2014, Cremolini 2020, 2025, Rivera, 2017 Saltz 2008

Results: Compared to an RWE trial (Loprinzi 2014), far fewer subjects halted oxaliplatin dosing due to G2/3 neuropathy



Results: CIPN20 Sensory scores increase by an average of only 0.5 out of a 4-point scale for subjects receiving FOLFOX7 plus BXQ-350



Results: Plasma NfL levels tracked with PI graded neuropathy (biomarker potential) and show fewer G3 at C12 (6%), and later on-set vs RWE (*Cersosimo 2004)