Bexion PHARMACEUTICALS

Developing a New Generation of Biologic Therapy to Treat Solid Tumors and Chemotherapy-Induced Peripheral Neuropathy (CIPN)

Non-Confidential Deck

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Bexion is a clinical-stage biopharmaceutical company developing a new generation of biologic therapy to treat solid tumor cancers and chemotherapy-induced peripheral neuropathy

BXQ-350 - Lead Asset Activates Sphingolipid Metabolism (S1P)

- Completed adult and pediatric Phase 1 studies
- Demonstrated **excellent safety profile** conducive to combination treatment
- Activity seen across **multiple tumor types** – significant lifecycle expansion opportunity
- **Entering Phase 2 trial** of combination therapy in newly diagnosed **metastatic colorectal cancer** (mCRC)
  - Internal data readout 4Q23

Chemotherapy-induced peripheral neuropathy (CIPN)

- Preclinical and clinical evidence suggests that **BXQ-350 prevents/ reverses CIPN**
- Ongoing Phase 1 PK/PD proof-of-concept trial
  - Internal data readout 4Q23

Strong and experienced team

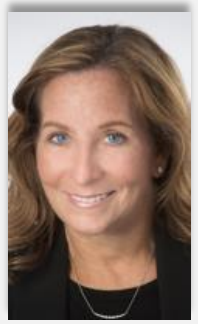
Excellent IP position

Raised over $94M in private funds with an additional $6.1M in grants, including from the National Cancer Institute NCI

Highly experienced expert leadership

Scott Shively
President & CEO

Ray Takigiku, Ph.D.
Founder and Chief Scientific Officer



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Chief Operating Officer

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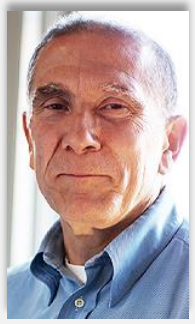
VP, Chemistry, Manufacturing & Controls



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BXQ-350
An Innovative Approach to Activating Sphingolipid (S1P) Metabolism

Sphingolipid metabolism is an underappreciated target in cancer

A Comprehensive Review: Sphingolipid Metabolism and Implications of Disruption in Sphingolipid Homeostasis

***International Journal of Molecular Sciences* 2021**

- "The biosynthesis and catabolism of these lipids play an integral role in small- and large-scale body functions, including participation in membrane domains and signalling; cell proliferation, death, migration, and invasiveness; inflammation; and central nervous system development."
- "It is now recognized that sphingolipids are involved in inflammatory processes, **neurodegeneration, cancer metastasis**, and lysosomal storage disorders."

Sphingolipids and Their Metabolism in Physiology and Disease

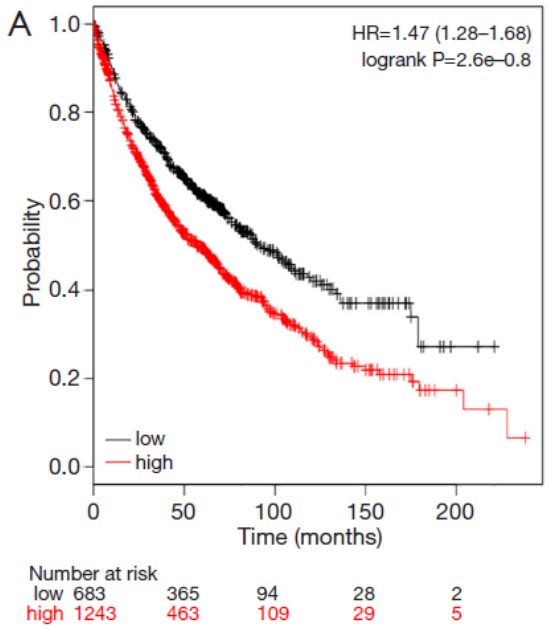
***Nature Reviews Molecular Cell Biology* 2017**

- "Bioactive sphingolipids constitute a family of lipids, including sphingosine, ceramide, sphingosine-1-phosphate (S1P) and ceramide-1-phosphate. These molecules act on distinct protein targets, including kinases, phosphatases, lipases and other enzymes and membrane receptors, and they exert distinct cellular functions."
- "A plethora of cell biological processes are critically modulated by bioactive sphingolipids, including growth regulation, cell migration, adhesion, **apoptosis, senescence** and inflammatory responses."

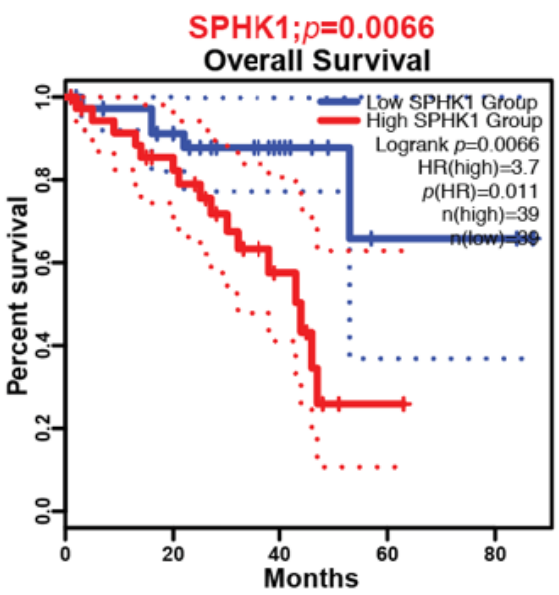
Ceramides and S1P are Associated With Survival
Multiple Solid Tumor and Hematological Cancers

- **Ceramides, S1P, and dysregulated sphingolipid metabolism have been associated with cancer cell survival** across solid tumor types and hematological cancers including CRC, GBM, TNBC, NSCLC, Melanoma, RCC, and H&N
- Investigating Sphingosine Kinase 1 (SPHK1) expression, **higher expression produces high S1P levels, associated with lower survival**

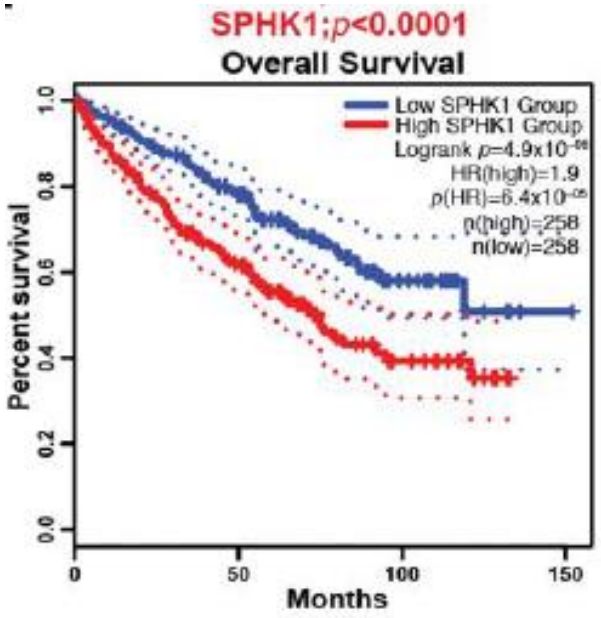
NSCLC (n=1926)



Melanoma (n=73)



RCC (n=516)



Wang, Y. et al. ***Prognostic roles of the expression od S1P metabolism enzymes in NSCLC*** in Transl Lung Cancer Res 2019, 8(5) 674.

Janneh, A., Ogretmen, B. ***Targeting Sphingolipid Metabolism as a Therapeutic Strategy in Cancer Treatment*** Cancers 2022, 14, 2183.

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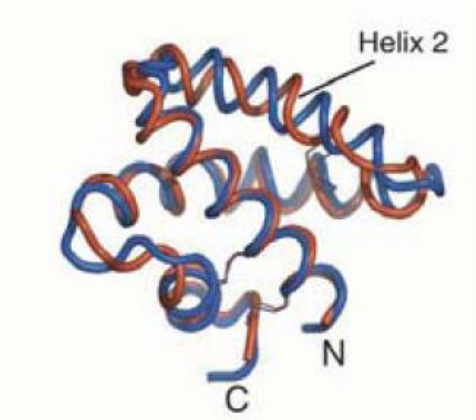
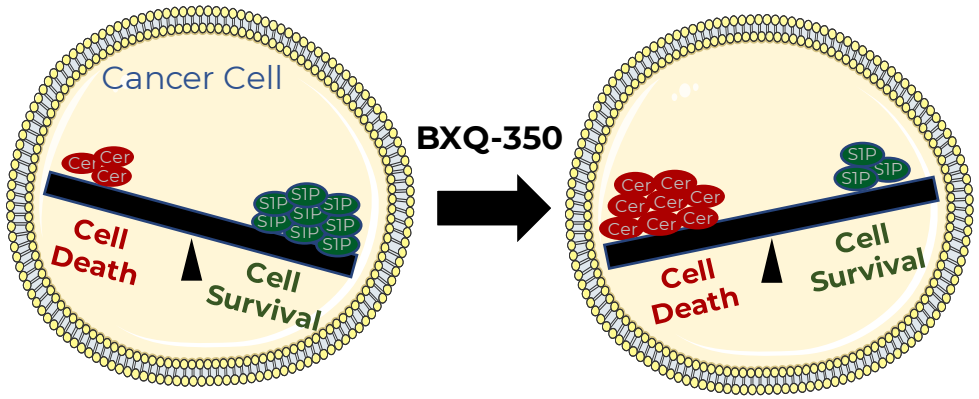
BXQ-350 Activates Sphingolipid Metabolism:

BXQ-350 is a lipid nanovesicle of Saposin C, a protein that activates sphingolipid metabolism



Saposin C allosterically activates several enzymes involved in sphingolipid metabolism



BXQ-350 Increases:
Programmed Cell Death, Blocks proliferation, Restores Homeostasis, Immune Stimulation

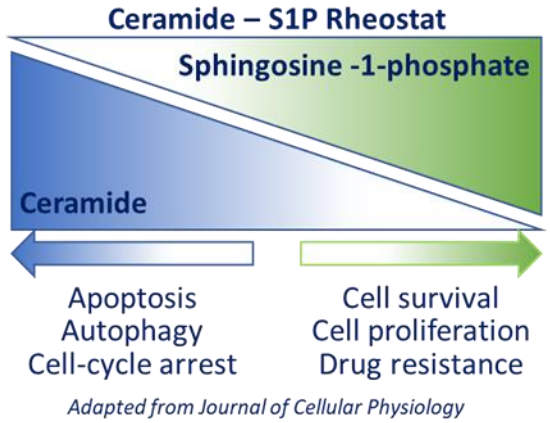
BXQ-350 Reduces:
S1P Receptor Signaling, Inflammation, Immune Suppression, CIPN

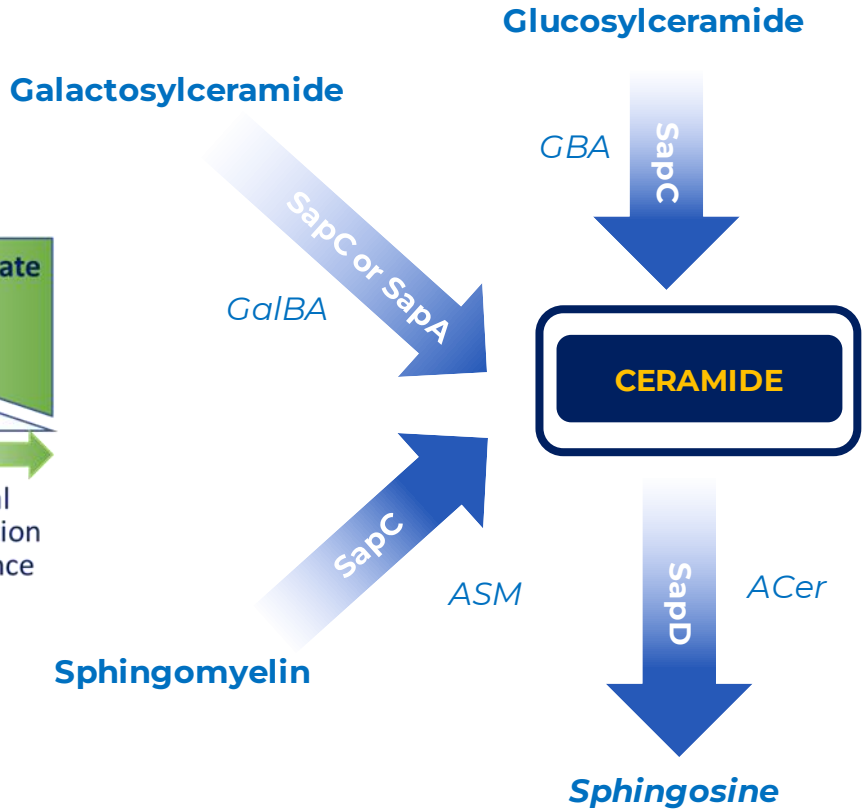
Cer **Ceramide:** pro-apoptotic, immunoeffector

S1P **S1P:** cancer proliferation, immunosuppressor

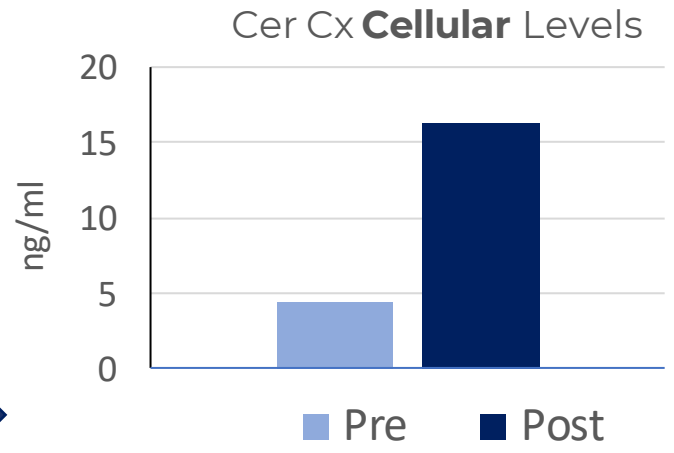
Mechanism of Action with Potential Biomarker

BXQ-350 activates sphingolipid metabolism to increase ceramides and reduce S1P
Ceramides induce neoplastic cell death & immune responses

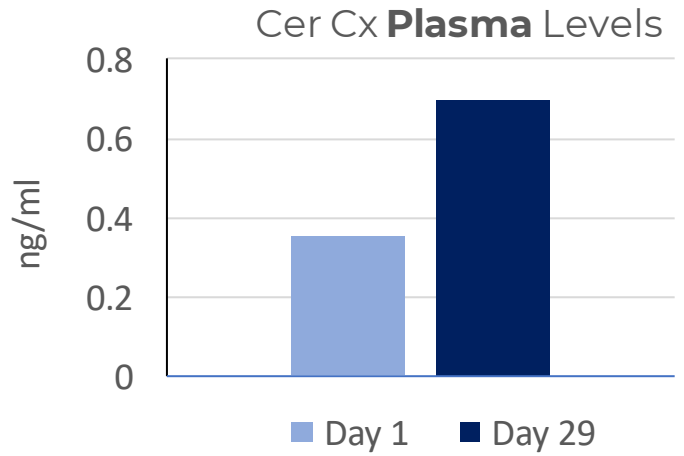




In vitro
Gli36 GBM cell line

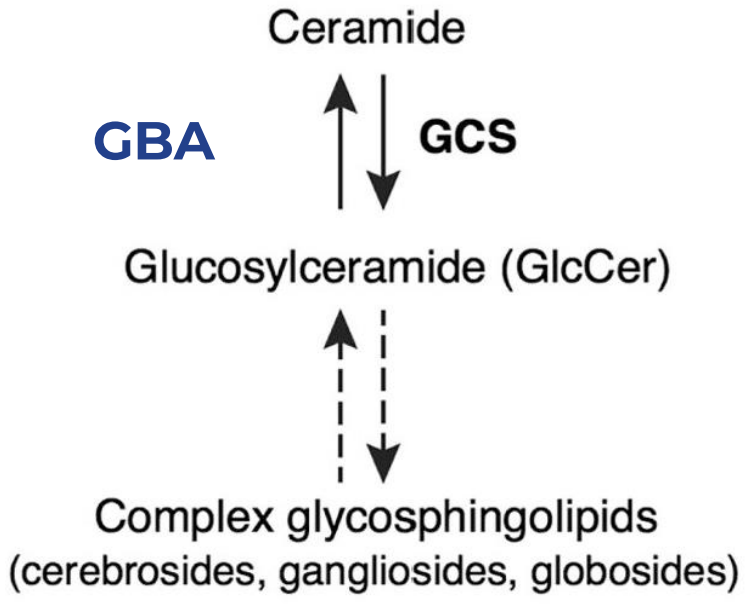


In vivo
Pt 1008-001 GBM



Ceramides and S1P:
Key Therapeutic Targets in CRC That Impact Survival

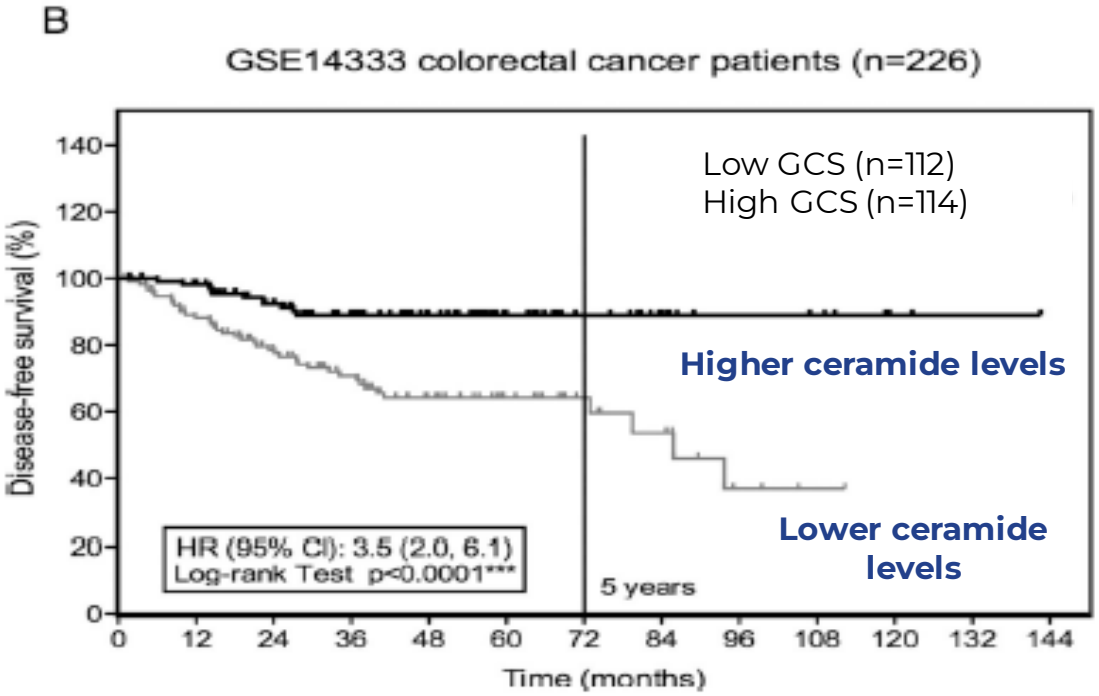
BXQ-350 activates GBA



A role for ceramide glycosylation in resistance to oxaliplatin in colorectal cancer

James P. Madigan[a,b,*], Robert W. Robey[b], Joanna E. Poprawski[b], Huakang Huang[a], Christopher J. Clarke[c], Michael M. Gottesman[b], Myles C. Cabot[d], Daniel W. Rosenberg[a,e]

Exp Cell Res. 2020 March 15; 388(2): 111860. doi:10.1016/j.yexcr.2020.111860.



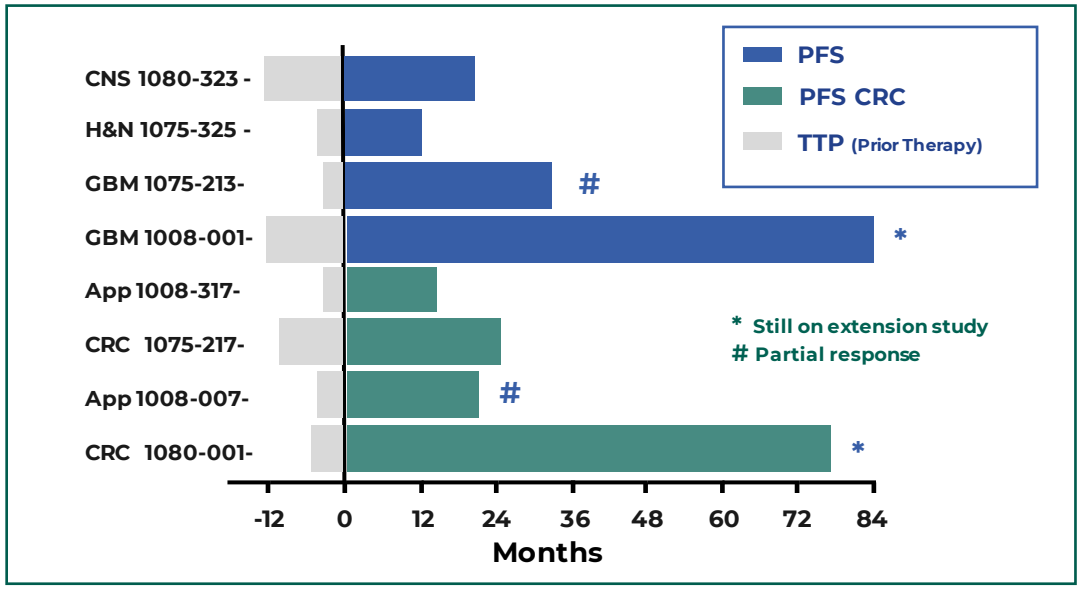
Phase 1 Monotherapy Study – Excellent Safety, Efficacy Evidence

Excellent Safety Profile

- ✓ Biologically Effective Dose identified
- ✓ **No target organ toxicity**; only 1 SAE (infusion reaction) in over 1000 doses
- ✓ No change in clinical chemistries, hematologic or coagulation parameters
- ✓ Safety profile supports **combination strategy**
- ✓ 73 patients received more than 1 cycle in all-comers Phase 1

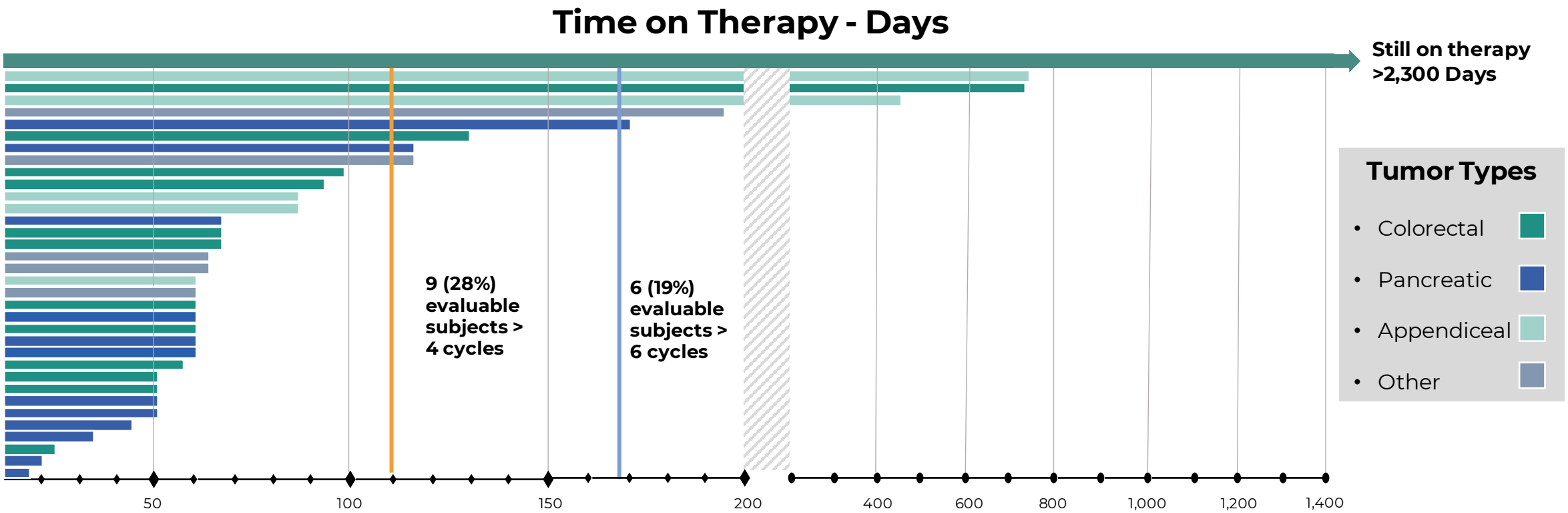
Initial Efficacy

- ✓ 13 patients SD or PR at Cycle 4 (17.8%); 8 at Cycle 8 (11.0%), despite heavily pre-treated patient population (median 7 lines prior tx)
- ✓ Patients with durable Stable Disease (PFS > 6, 12, 24, & 60+ months):



GI Cancer Subset of Phase 1 Monotherapy Study

Colorectal Cancer a Promising Focus

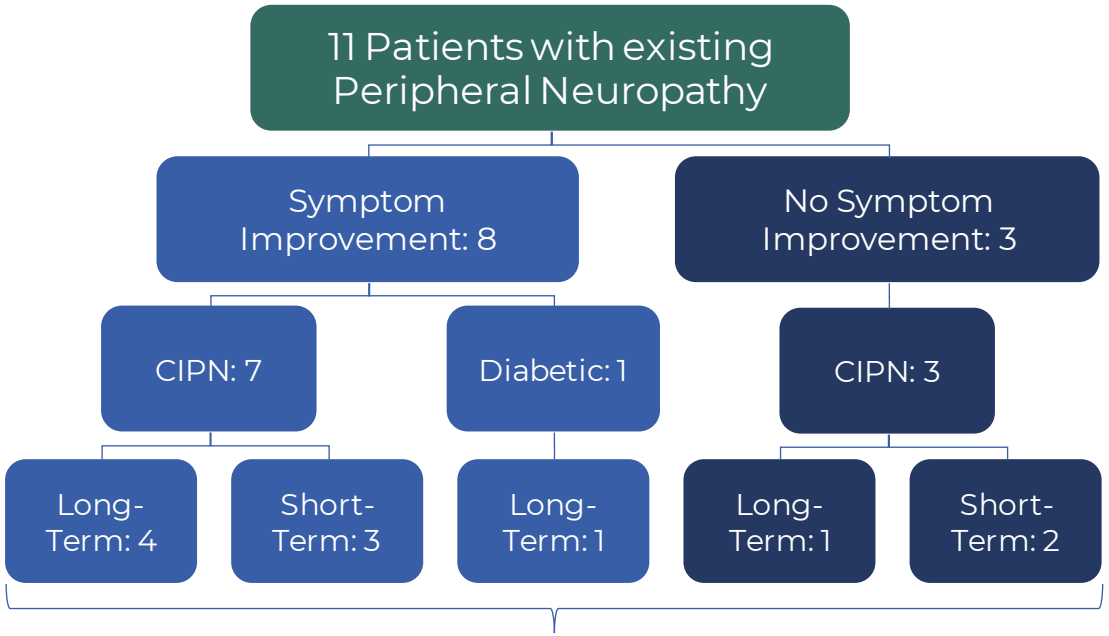


Maximum duration of response: 318+ weeks
32 GI patients in study
Heavily Pretreated (end-stage) Patients – Median of 7 prior therapies

Chemotherapy Induced Peripheral Neuropathy Opportunity

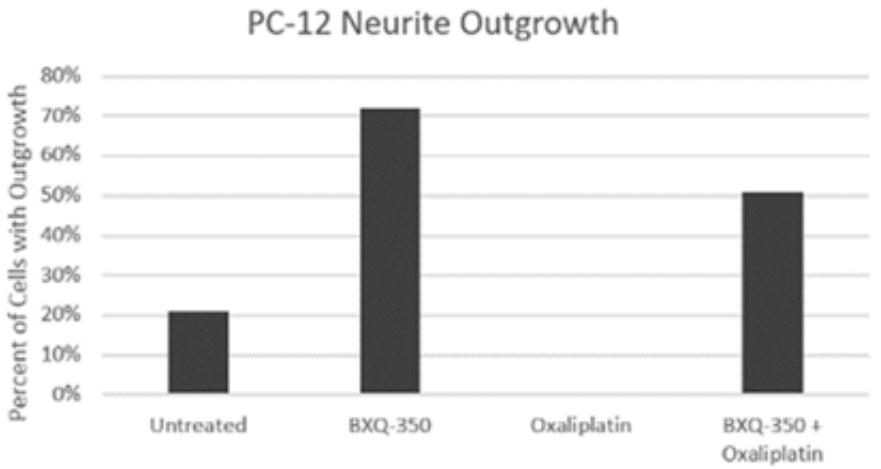
Phase 1 Findings and Preclinical Data

Patients in the Phase 1 study anecdotally reported resolution or improvement of long and short-term neuropathy. After retrospective investigation, the majority of afflicted patients improved:



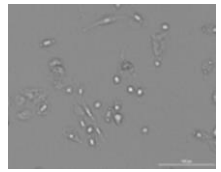
Duration of neuropathy symptoms <u>prior</u> to treatment with BXQ-350

In vitro data suggest the potential for **disease-modifying** effect

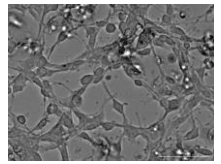


- Pre-clinical data provides potential rationale for neuropathy resolution observed during the Phase 1 clinical study of BXQ-350 (8 of 11 patients with peripheral neuropathy reported improvement)
- BXQ-350 promoted neurite outgrowth *in vitro*, even in the presence of oxaliplatin, which normally halts neurite outgrowth

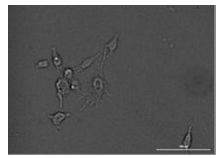
Cell Culture



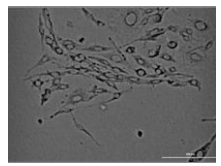
Untreated Cell Growth



Low-Dose BXQ-350 (50nM)

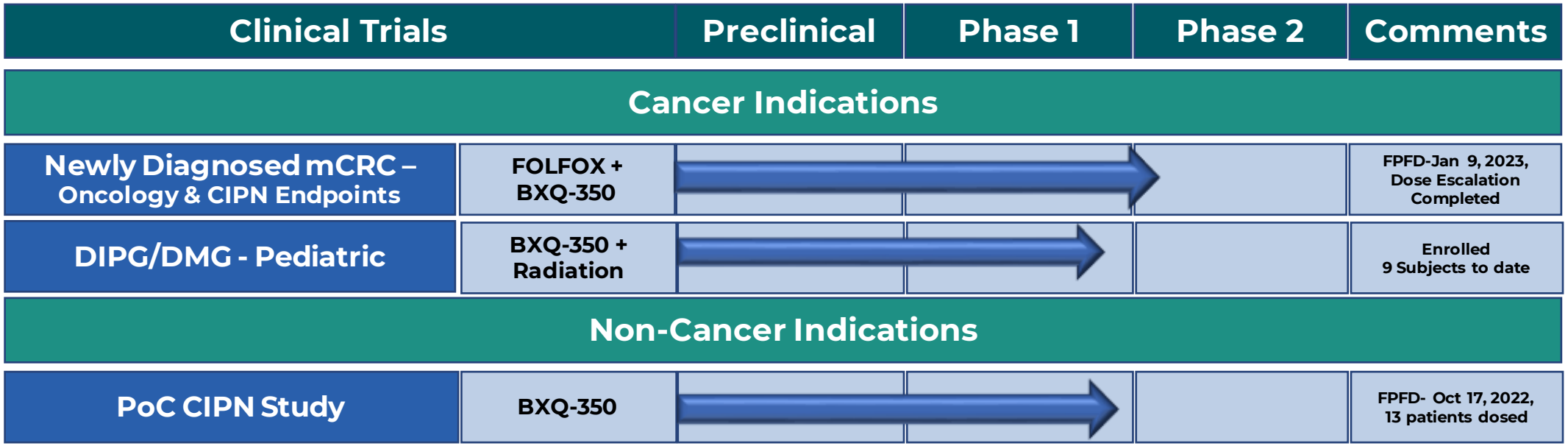


Oxaliplatin



Oxaliplatin + BXQ-350

Ongoing Clinical Trials Focused on Solid Tumors and CIPN

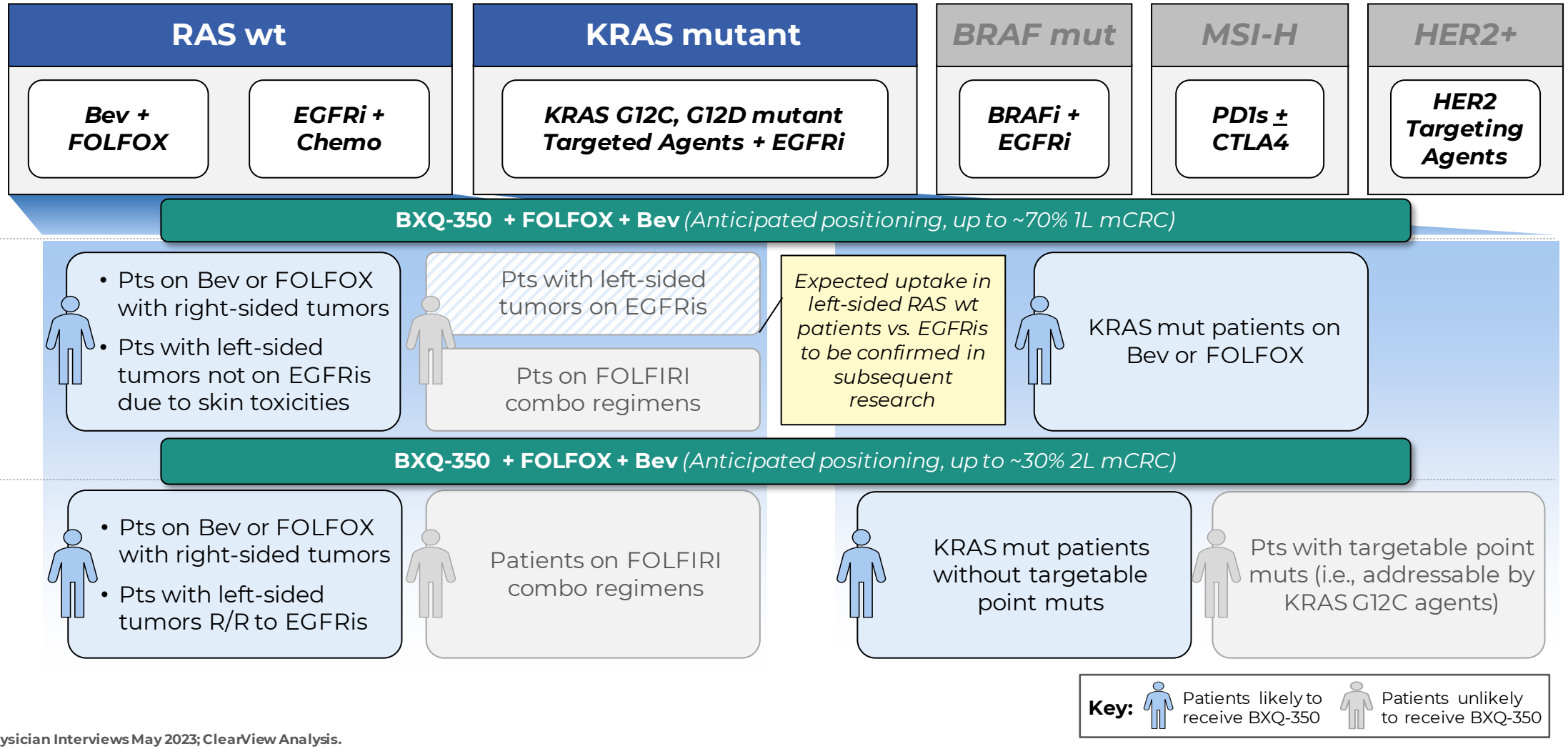


Multiple Indication Expansion Opportunities in Oncology and CNS

CRC-Colorectal Cancer
CIPN-Chemotherapy Induced Peripheral Neuropathy
DIPG-Diffuse Intrinsic Pontine Glioma **DMG**-Diffuse Midline Glioma
POC-Proof of Concept

Target Patient Archetypes for BXQ-350 in Colorectal Cancer

Broad Market Opportunity



Source: Physician Interviews May 2023; ClearView Analysis.

Qualitative Interviews with KOLs (May 2023)

Validates BXQ-350 Positioning in Colorectal Cancer

Drivers of Physician Enthusiasm

- High interest in a novel, broadly applicable mechanism of action
- Significant unmet need
- Strong safety profile with possibility of alleviating chemotherapy-related toxicities supports broad uptake
- Comfortable with drug combinations

Concerns and Remaining Hurdles

- Preference for targeted agents when available given expectation that said agents are more likely to show benefit for that segment
- Dose scheduling
- Potential need for data across subsegments to support use either with or instead of targeted agents. e.g., EGFRi in left sided WT patients

"There don't seem to be any toxicities, so I would be comfortable adding this with existing regimens."

"I haven't heard of this mechanism before, but it does not seem specific to CRC treatment."

"The cycle 1 dosing does seem quite burdensome, but this would be offset by meaningful efficacy."

Source: Physician Interviews May 2023; ClearView Analysis.

Phase 1b/2 Metastatic Colorectal Cancer Study

Study Summary

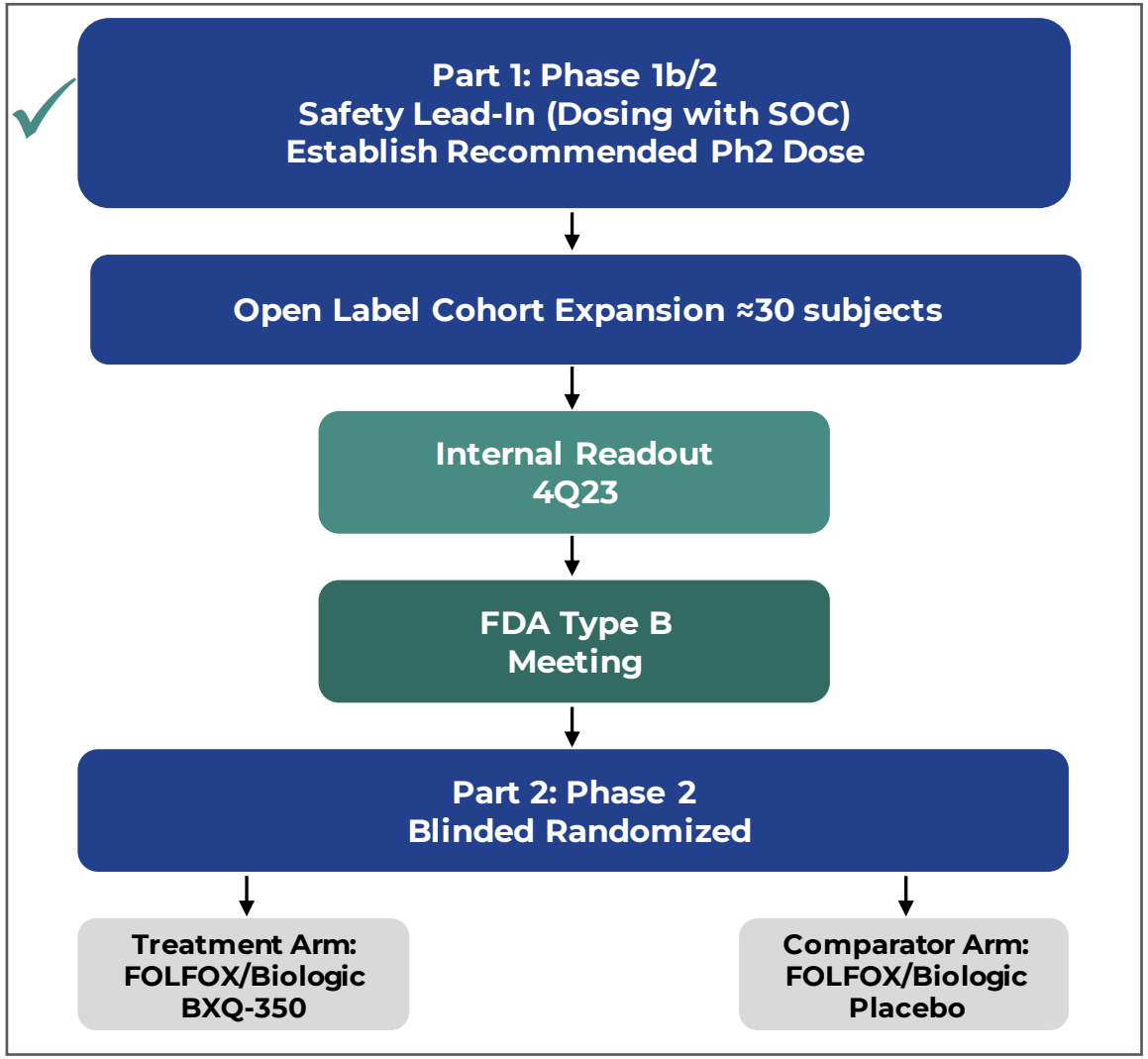
- ✓ Stage 1 site selection; launched 14 of 15 sites
- ✓ Achieved Phase 2 dose – DSMB meeting end of August
- ✓ Internal data readout projected 4Q23

Primary Endpoints:

- ORR according to RECIST 1.1 by centralized image assessment
- Total oxaliplatin administered[1]
- Safety

Secondary Endpoints:

- Overall survival and progression free survival
- Acute Oxaliplatin-induced peripheral neuropathy[2]
- Chronic Oxaliplatin-induced peripheral neuropathy[2]
- PK/PD and Biomarkers



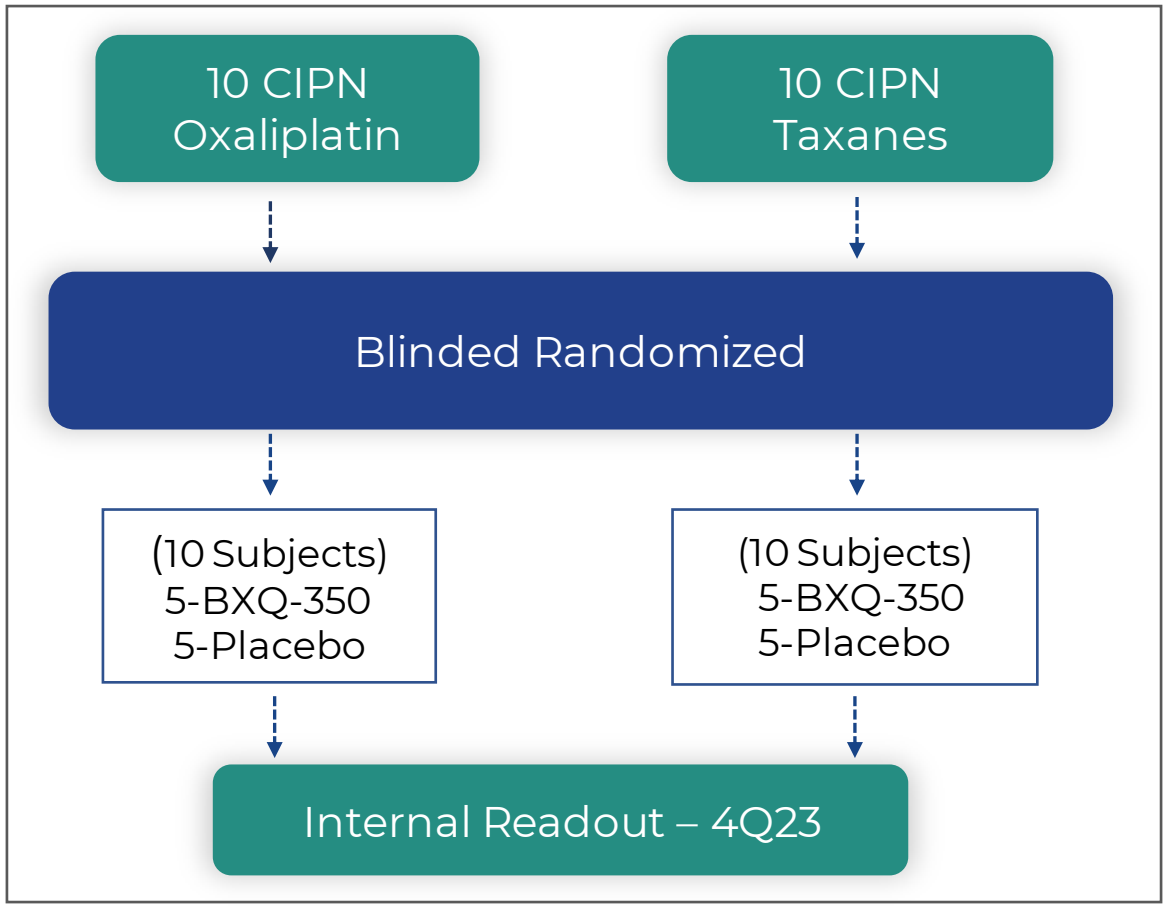
[1] Oxaliplatin dosing is typically reduced or halted in 75% of patients
[2] Patient reported outcome-validated methods

POC Study – Chemotherapy-induced Peripheral Neuropathy (CIPN)
Patients with CIPN From Prior Cancer Treatments

Internal Readout – 4Q 2023

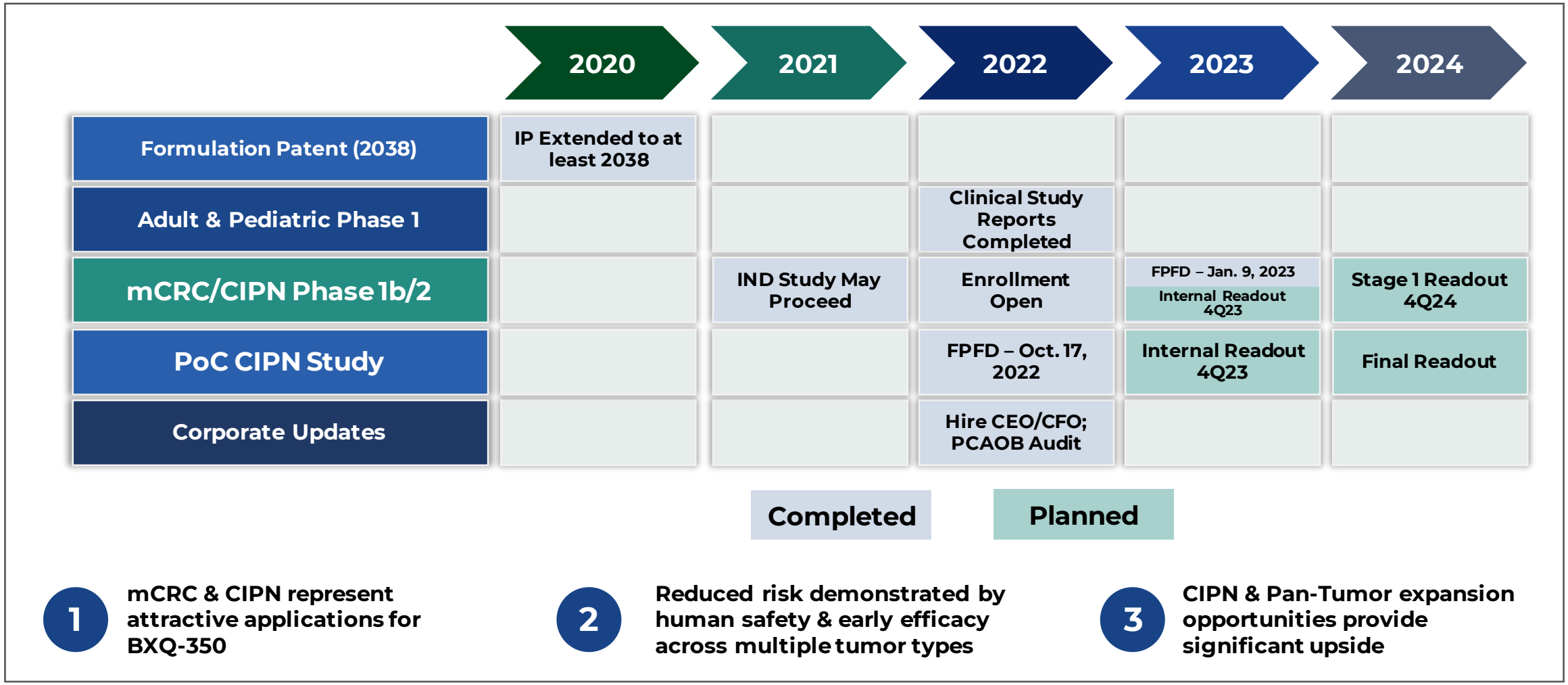
- ✓ **Study Rationale:**
  - Potentially disease-modifying:
    - *In vitro* data demonstrate BXQ-350 stimulates neurite outgrowth, even when given concurrently with Oxaliplatin
    - *In vivo* data show dose-dependent improvement in CIPN phenotype on preclinical mouse model
- ✓ **Sizeable market opportunity:**
  - ~3M Americans suffer from CIPN[1]
  - CIPN increases hospitalization, ED, falls, and outpatient visits, costing an estimated $54B per year in the US[2]
  - No approved treatments for CIPN
- ✓ **Primary Endpoints:**
  - PK/PD & Biomarkers
  - CIPN and QoL Assessment[3]

PK/PD PoC CIPN from Oxaliplatin and Taxanes



[1] Foundation for Peripheral Neuropathy
[2] Kerckhove et al., Frontiers in Pharm. 2017
[3] Patient reported outcome-validated methods

Key Catalysts and Milestones

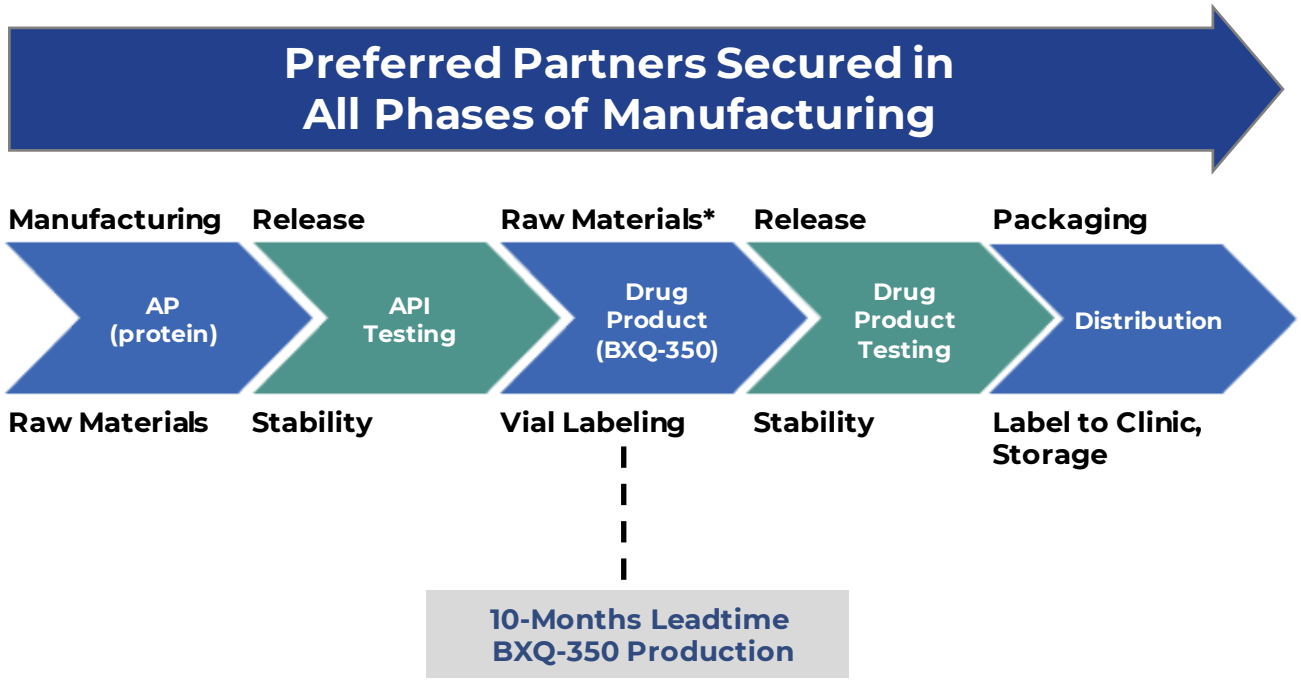


1. mCRC & CIPN represent attractive applications for BXQ-350
2. Reduced risk demonstrated by human safety & early efficacy across multiple tumor types
3. CIPN & Pan-Tumor expansion opportunities provide significant upside

Manufacturing is Complex, but Bexion Manufacturing Supply Chain is Well Established

Key Takeaways

- ✓ FDA compliant for early phase trials and **GMP supplies** on hand for Phase 2 studies
- ✓ **Multiple sites** qualified for Saposin C and for BXQ-350, increasing capacity and scale
- ✓ Shelf life: Saposin C 4 years at -70C; **BXQ-350 5 years** at refrigerated conditions
- ✓ Significant process improvement work implemented (35% reduction in COGS for Phase 2 2nd campaign)
- ✓ Patented formulation, Trade Secret manufacturing processes
- ✓ Phase 3/Pivotal Readiness plan in place (to include further COGS reduction)



Bexion has invested $32 million to date in its manufacturing process

Intellectual Property

Comprehensive, Global Intellectual Property Strategy

- New IP owned by Bexion, including clinical formulation, methods, and processes with protection through 2038
- Manufacturing processes currently protected by Trade Secret: purity and process patent applications to be filed upon scale-up/BLA filing
- Additional Potential Future IP: Ongoing Clinical Studies, Methods of Treatment, Biomarkers, Other Formulations
- Eligible for 12 years of biologic market exclusivity for first approved indication

Significant Indication and Lifecycle Expansion Opportunities

1. High Priority, Near-term Indications

Oncology Solid Tumors	Peripheral Neuropathy
Metastatic Colorectal Cancer (mCRC)	Chemotherapy-Induced Peripheral Neuropathy (CIPN)
Supportive Development: Conduct biomarker studies Develop new formulations	

2. Medium Priority Indications

Solid Tumors	Pediatric Tumors	Peripheral Neuropathies
GBM, Ependymoma, Appendiceal	DIPG/DMG	Diabetic, idiopathic
Supportive Development: Demonstrate ability to combine with multiple regimens		

3. Longer-term, Partner Indications

CNS	Hematology	Other
Parkinson's, Dementia, Gaucher's, Others	Hematological Malignancies	Anti-Viral Auto-Immune

Investment Summary

Bexion Pharmaceuticals Inc. – Lead Asset BXQ-350

- Very safe and tolerable compound **entering Phase 2**
- **Novel, first-in-class platform** opportunity by modulating the largely untapped potential of sphingolipid metabolism (S1P, Ceramide)
- Multiple **sources for profitable growth** in oncology and other indications such as neuropathy and CNS indications
- Excellent IP position, advanced manufacturing processes
- Strong and experienced **leadership team**
- **Near term** internal and interim clinical data readouts – **significant value milestones**
- Colorectal Cancer and Chemotherapy Induced Peripheral Neuropathy are each **multibillion-dollar market opportunities**

Thank You

Appendix

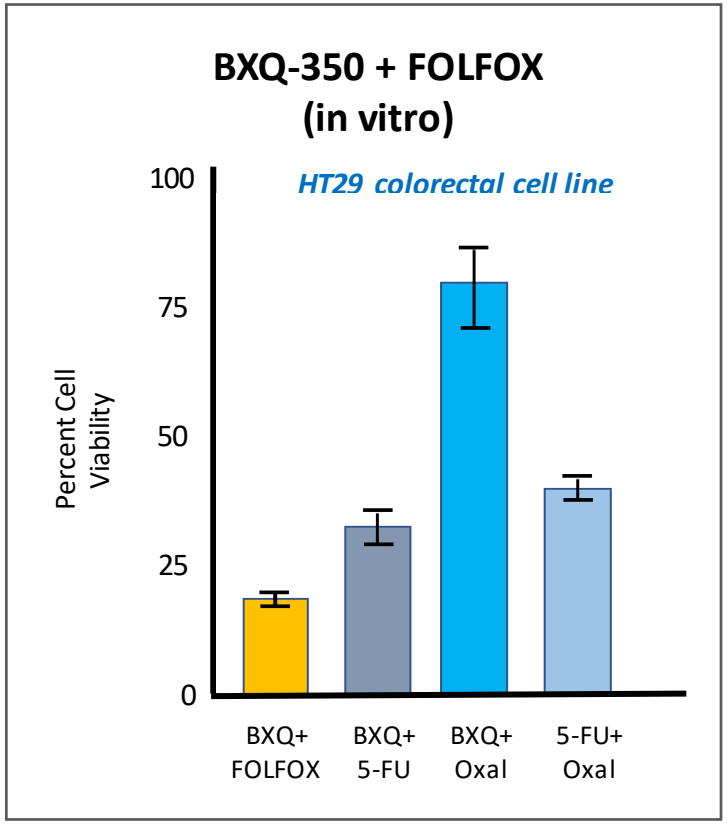
Summary of Phase 1 clinical trial results

Clinical Trial Results Summary

- BXQ-350's safety and single agent activity profiles warrant investigating combination strategies
- MOA may explain the signs of clinical activity observed in multiple cancer types and potential benefits when used in combination with Oxaliplatin + 5FU
- Biomarker(s) may be identified for patient selection or monitoring response to treatment (e.g., S1P/C18:1)

Preclinical Benefit of BXQ-350 in Combination With FOLFOX

FOLFOX & BXQ-350



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REVIEW

Check for updates

Therapeutic implications of bioactive sphingolipids: A focus on colorectal cancer

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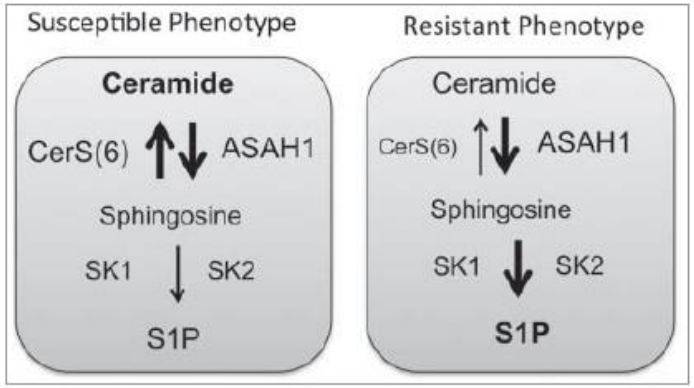
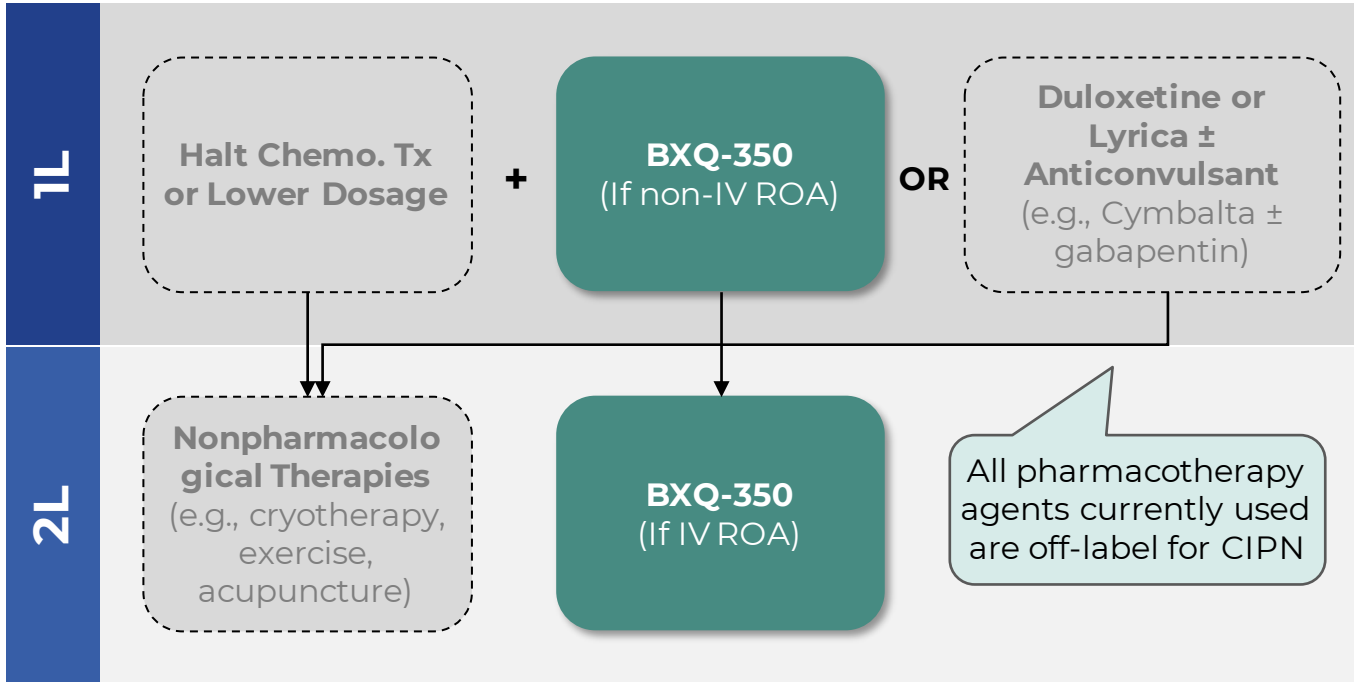


Figure 2. *Cell death susceptibility.* Cells with increased expression of acid ceramidase (ASAH1) may remain susceptible to death stimuli, if ceramide synthases activity prevails over activity of sphingosine kinases.

Bexion PHARMACEUTICALS

CIPN White Space Expected to Remain High

Given the expected continued scarcity of CIPN treatments…



While KOLs expect a novel agent with meaningful CIPN-specific data will support broad preference over SoC (assuming guideline support and favorable access), market shaping is likely required to maximize BXQ-350's opportunity as first-to-market therapeutic

…significant unmet need will persist

*"A **novel mechanism targeting CIPN** would be great compared to the broad pain medications we use right now." – Oncologist KOL*

*"All the CIPN causative agents are still being used so its prevalence hasn't changed. We need to **lower the cases altogether**." – Neurologist KOL*

*"A drug that could **repair and restore nerve function** would be an absolute game changer." – Neurologist KOL*

*"We sometimes have issues getting Cymbalta covered, so **a drug specific to CIPN** could help treatment and reimbursement." – Neurologist KOL*

Source: Physician Interviews May 2023; ClearView Analysis.