



Corporate Presentation

November 2025

Forward-Looking Statements

This presentation includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. BioXcel Therapeutics, Inc. (“BioXcel” or the “Company”) intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this presentation other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to the safety, efficacy, and regulatory and clinical design or progress, potential regulatory submissions, approvals and timing thereof for BXCL501 as a potential acute treatment for AAD and agitation related to schizophrenia and bipolar disorders; developments and plans relating to the TRANQUILITY and SERENITY programs; and the potential for the results from the Company’s completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates in both the care-facility and at-home settings. When used herein, words including “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon the Company’s current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; the impact of the reprioritization; its significant indebtedness, ability to comply with covenant obligations and potential payment obligations related to such indebtedness and other contractual obligations; the Company has identified conditions and events that raise substantial doubt about its ability to continue as a going concern; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY program; its dependence on the success and commercialization of IGALMI, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; its lack of experience in marketing and selling drug products; the risk that IGALMI or the Company’s product candidates may not be accepted by physicians or the medical community in general; the Company still faces extensive and ongoing regulatory requirements and obligations for IGALMI; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company’s product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; the significant influence of and dependence on BioXcel LLC; its exposure to patent infringement lawsuits; its reliance on third parties; its ability to comply with the extensive regulations applicable to it; impacts from data breaches or cyber-attacks, if any; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; risks associated with federal, state or foreign health care “fraud and abuse” laws; and its ability to commercialize its product candidates, as well as the important factors discussed under the caption “Risk Factors” in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC’s website at www.sec.gov and the Investors section of the Company’s website at www.bioxceltherapeutics.com. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management’s estimates as of the date of this presentation. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause the Company’s views to change. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this presentation.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this presentation concerning our industry and the markets in which BioXcel Therapeutics operates, including its general expectations, market position and market opportunity, is based on its management’s estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. While BioXcel Therapeutics believes the information from these third-party publications, research, surveys and studies is reliable, it does not guarantee the accuracy or completeness of such information, and BioXcel Therapeutics has not independently verified this information. Management’s estimates are derived from publicly available information, their knowledge of the company’s industry and their assumptions based on such information and knowledge, which they believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in BioXcel Therapeutics’ periodic reports filed with the SEC under the captions “Forward Looking Statements,” “Risk Factor Summary” and “Risk Factors.” These and other factors could cause BioXcel Therapeutics’ future performance and market expectations to differ materially from its assumptions and estimates.



Our Mission

Develop transformative
medicines in neuroscience
utilizing artificial intelligence

IGALMI® and BXCL501 Market Expansion Potential

Land and expand strategy with novel agitation treatment option for multiple conditions & settings

CURRENT

Agitation Associated with Bipolar Disorders or Schizophrenia



(healthcare provider supervision)



Igalmi®
(dexmedetomidine)
sublingual film · 120 mcg, 180 mcg

~16M

BPD/SCZ Institutional Episodes¹⁻³

SHORT-TERM POTENTIAL

Agitation Associated with Bipolar Disorders or Schizophrenia



(at-home setting)

SERENITY Program

BXCL501

~57-77M

BPD/SCZ At-Home Agitation Episodes¹⁻⁴

LONGER-TERM POTENTIAL

Agitation Associated with Alzheimer's Dementia



(in care & at-home settings)

TRANQUILITY Program

BXCL501

~100M

AAD Episodes¹

1. Data on file. BioXcel Therapeutics, Inc. New Haven, CT December 2020.

2. Kwong, M et al., Presented at the Academy of Managed Care Pharmacy Nexus 2021, October 18-21, 2021; Symphony claims data.

3. Source: InVibe Feb 2023 Q4: In the past month, about how many agitation episodes [IF PATIENT SHOW "have you" IF CG SHOW "has your loved one"] experienced?

4. Roberts et al. BMC Psychiatry (2018) 18:104.

BXCL501 Has Broad Potential in Neuropsychiatric Disorders

Numerous opportunities to address significant unmet acute and chronic conditions

~\$12.5M in Grants Awarded

Acute

(Company Sponsored)

~60-93 million
annual BPD/SCZ
medical institution &
at-home agitation
episodes¹⁻⁴

Agitation Associated
with Bipolar Disorders
or Schizophrenia

SERENITY At-Home Pivotal
Phase 3 Trial

~100 million
annual AAD episodes¹

Agitation Associated
with Alzheimer's
Dementia (AAD)

TRANQUILITY In-Care Pivotal
Phase 3 Trial

Locus
Coeruleus
Activation

Chronic

(Externally Sponsored)

NIH National Institute
on Drug Abuse

CDMRP
CONGRESSIONALLY DIRECTED
MEDICAL RESEARCH PROGRAMS

Opioid Use Disorder

COLUMBIA UNIVERSITY

Post-Traumatic Stress
Disorder

Yale SCHOOL OF MEDICINE

Acute Stress Disorder



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

MDD with Anxious
Distress

9 million patients
diagnosed with OUD, with
over 5 million patients
receiving OUD treatment⁵

~13 million
patients with PTSD
in any given year⁶

40 million patients
enter ED after a trauma⁷

11 – 16 million
patients with MDD may also
have anxious distress⁸

1. Data on file. BioXcel Therapeutics, Inc. New Haven, CT December 2020. 2. Kwong, M et al., Presented at the Academy of Managed Care Pharmacy Nexus 2021, October 18-21, 2021; Symphony claims data. 3. Source: InVibe Feb 2023 Q4: In the past month, about how many agitation episodes [IF PATIENT SHOW "have you" IF CG SHOW "has your loved one"] experienced? 4. Roberts et al. BMC Psychiatry (2018) 18:104. 5. [https://www.cdc.gov/mmwr/volumes/73/wr/mm7325a1.htm#:~:text=In%202022%2C%20an%20estimated%203.6,medications%20for%20OUD%20\(Figure\)](https://www.cdc.gov/mmwr/volumes/73/wr/mm7325a1.htm#:~:text=In%202022%2C%20an%20estimated%203.6,medications%20for%20OUD%20(Figure).). 6. Blanco, Xu, 2013, <https://doi.org/10.1016/j.drugalcdep.2013.04.016>. 7. Kessler, R.C., Ressler, K.J., House, S.L. et al. Socio-demographic and trauma-related predictors of PTSD within 8 weeks of a motor vehicle collision in the AURORA study. *Mol Psychiatry* 26, 3108–3121 (2021). <https://doi.org/10.1038/s41380-020-00911-3>. 8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10141876/>

Key Company Milestones

Positive Business Momentum



Serenity At-Home safety and exploratory efficacy data announced

- Analyses ongoing for clinical study reports



sNDA preparation in progress

- Content and format of sNDA aligned with FDA in August
- sNDA non-clinical section completed, clinical and CMC sections in-progress



Developing commercialization and partnering strategy for at-home setting



Feedback received from FDA on TRANQUILITY In-Care trial design and evaluating CROs for trial initiation



Strengthened balance sheet

IGALMI® (dexmedetomidine) Sublingual Film

Approved for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults under healthcare provider supervision

120mcg


Igalmi®
 (dexmedetomidine)
 sublingual film • 120 mcg, 180 mcg



IGALMI® Indication and Important Safety Information

INDICATION

IGALMI® (dexmedetomidine) sublingual film is a prescription medicine, administered under the supervision of a health care provider, that is placed under the tongue or behind the lower lip and is used for the acute treatment of agitation associated with schizophrenia and bipolar disorder I or II in adults. The safety and effectiveness of IGALMI has not been studied beyond 24 hours from the first dose. It is not known if IGALMI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart rate) and alertness after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell their healthcare provider if they feel dizzy, lightheaded, or faint.
- **Heart rhythm changes (QT interval prolongation)**. IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.
- **Sleepiness/drowsiness**. Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.
- **Withdrawal reactions, tolerance, and decreased response/efficacy**. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full [Prescribing Information](#).

IGALMI[®] (dexmedetomidine) Sublingual Film

Approved for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults under healthcare provider supervision



- **Patient administered** under the supervision of a healthcare provider who should monitor vital signs and alertness to prevent falls and syncope
- **Absorption** of dexmedetomidine into the bloodstream and quantifiable in plasma after 5 to 20 minutes with a T-max of 2 hours and half life of 2.8 hours
- IGALMI[®] **significantly reduced agitation** as early as 20-30 minutes following administration
- Mucoadhesive, so it **cannot be spit out or swallowed**
- **Sublingual** or **buccal** placement
- **First & only** FDA-approved orally dissolving sublingual film
- IGALMI[®] is **non-scheduled**
- Manufactured and supplied by ARx in Glen Rock, PA



TWO DOSAGE STRENGTHS

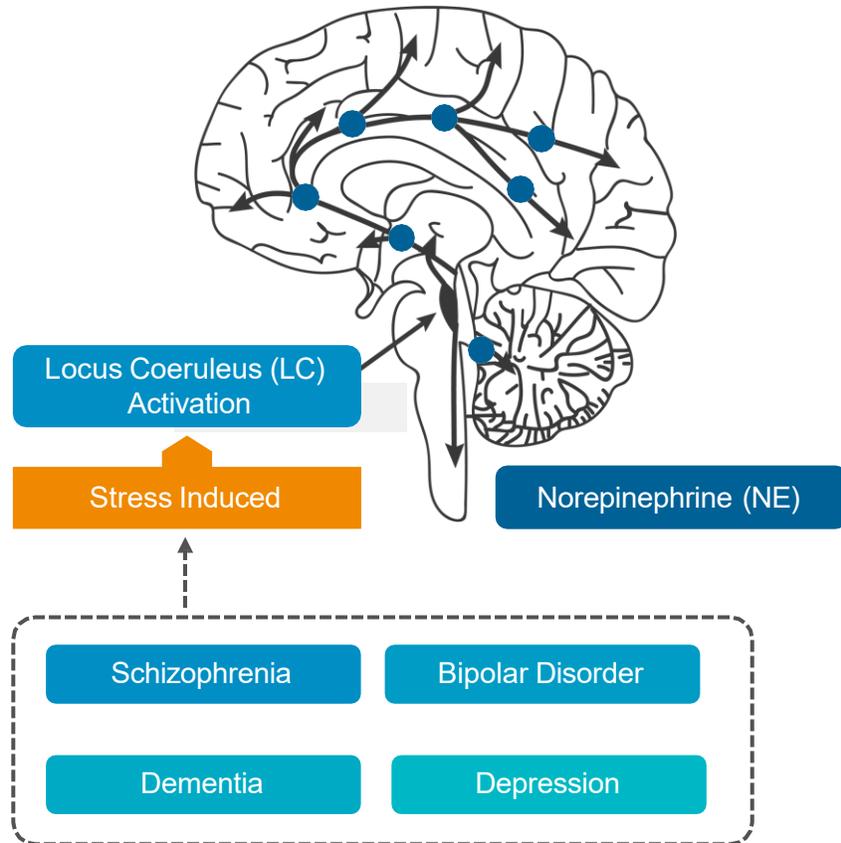
SELF-ADMINISTRATION

**FOR MILD, MODERATE,
AND SEVERE AGITATION**

Agitation Mechanism and BXCL501 (Dexmedetomidine) MOA

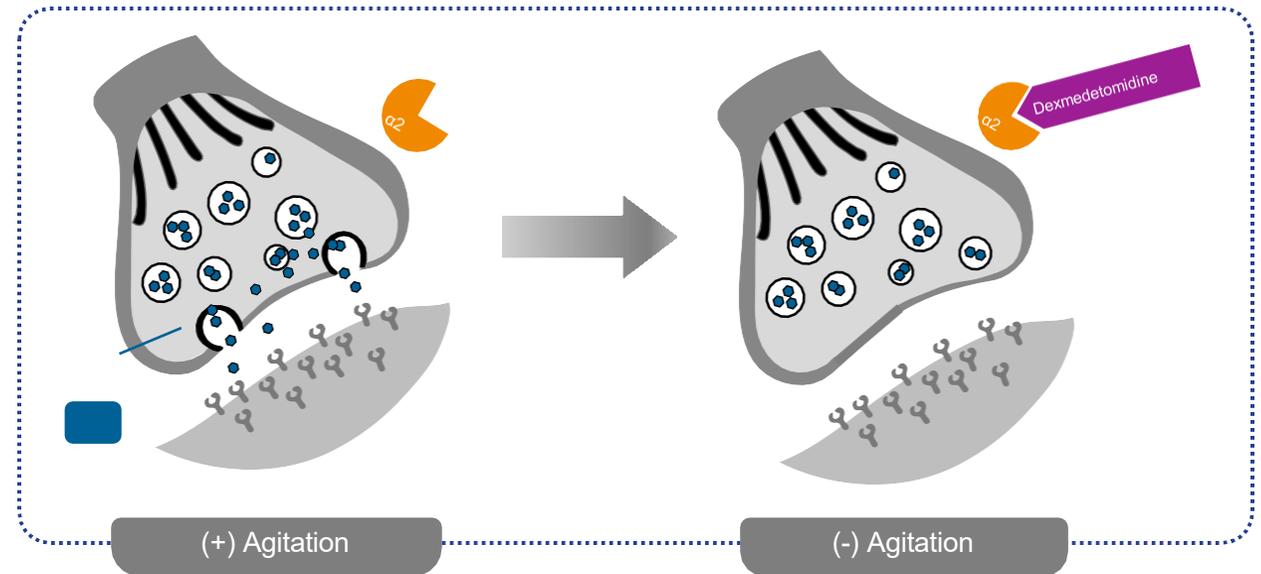
Disorders like schizophrenia, bipolar, and dementia can affect the hyperarousal pathway, causing LC neurons to fire in a tonic mode causing fight-or-flight response

Hyper-Arousal Physiology



Dexmedetomidine is one of the most potent, selective, full agonists at Alpha-2A receptors
Dexmedetomidine has been shown to reduce hyper-arousal through selective agonist action at presynaptic Alpha-2A Adrenergic Autoreceptors.

Dexmedetomidine MoA



Our Neuroscience Development Portfolio

Compound	Indication/Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Marketed
IGALMI® (dexmedetomidine) sublingual film	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults under healthcare provider supervision						
BXCL501 Company-sponsored trials*	SERENITY PROGRAM Acute treatment of agitation associated with bipolar disorders or schizophrenia (at home)						
	TRANQUILITY PROGRAM** Acute treatment of agitation associated with Alzheimer's dementia						
BXCL501 Investigator-sponsored trials*	Opioid use disorder ¹						
	Alcohol use disorder with comorbid post-traumatic stress disorder ²						
	Acute stress disorder ³						
BXCL502 (latrepirdine)	Chronic agitation in dementia***						
Candidate BXCL503	Apathy in dementia***						
Candidate BXCL504	Aggression in dementia***						

**IGALMI® label expansion:
Q3 2025 data readout**

*The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

**Program paused subject to funding.

***Development paused due to Strategic Reprioritization announced on Aug. 14, 2023.

Substantial Intellectual Property and Patent Protection*

- **30+** granted or allowed patents and **140** additional patent applications in prosecution
- **13** currently listed U.S. patents for IGALMI® in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) with patent protection through 2043



Acute Treatment of Agitation Associated with Bipolar Disorders or Schizophrenia *(at-home setting)*

SERENITY Program



Agitation is Relatively Common and Difficult-to-Manage¹

Debilitating for patients and threatening for healthcare providers



Characterized by recurring episodes¹



Symptoms differ by patient, vary between episodes, and range from mild to severe²⁻⁷



Multi-billion-dollar healthcare burden⁸



Best-practice guidelines recommend agitation be treated by:

- Behavioral calming techniques
- Verbal de-escalation
- Medications voluntarily accepted by patients without coercion; pharmacologic goal of calming without unarousable sedation⁹



Current treatment approaches:

- May involve physically restraining patients¹⁰
- Over-sedating therapies such as antipsychotics and benzodiazepines¹⁰



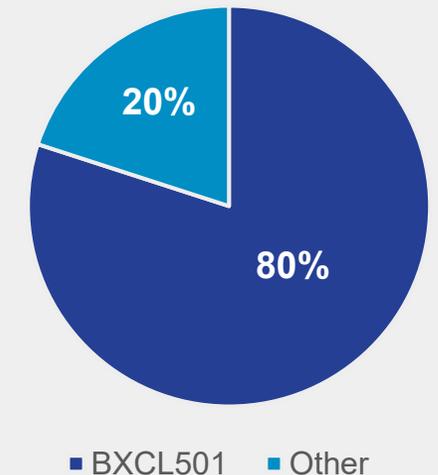
1. Sacchetti E, Amore M, Di Sciascio G, et al. Psychomotor agitation in psychiatry: an Italian expert consensus. *Evidence-based Psychiatric Care*. 2017;1:1-24. 2. Dunder Y, Greenhalgh J, Richardson M, et al. Pharmacological treatment of acute agitation associated with psychotic and bipolar disorder: a systematic review and meta-analysis. *Hum. Psychopharmacol*. 2016;31(4):268-285. 3. Garriga M, Pacchiarotti I, Kasper S, et al. Assessment and management of agitation in psychiatry: expert consensus. *World J Biol Psychiatry*. 2016;17(2):86-128. 4. Nordstrom K, Zun LS, Wilson MP, et al. Medical evaluation and triage of the agitated patient: consensus statement of the American association for emergency psychiatry project Beta medical evaluation workgroup. *West J Emerg Med*. 2012;13(1):3-10. 5. Martinez-Raga J, Amore M, Di Sciascio G, et al. 1st international experts' meeting on agitation: conclusions regarding the current and ideal management paradigm of agitation. *Front. Psychiatry*. 2018;9(54):1-9. 6. Depression and Bipolar Support Alliance (DBSA). *Understanding agitation: recognizing the signs of agitation and knowing what to do when they appear*. 2014. 7. Montoya A, Valladares A, Lizán L, et al. Validation of the excited component of the positive and negative syndrome scale (PANSS-EC) in a naturalistic sample of 278 patients with acute psychosis and agitation in a psychiatric emergency room. *Health Qual Life Outcomes*. 2011;9:18. 8. Cloutier M, Gauthier-Loiselle M, Gagnon-Sanschagrin P, Guerin A, Hartry A, Baker RA, Duffy R, Gwin K, Sanon Aigbogun M. Institutionalization risk and costs associated with agitation in Alzheimer's disease. *Alzheimers Dement (N Y)*. 2019 Nov 23;5:851-861. 9. Wilson MP, Pepper D, Currier GW, et al. The psychopharmacology of agitation: consensus statement of the American Association for Emergency Psychiatry Project Beta Psychopharmacology Workgroup. *West J Emerg Med*. 2012;13(1):26-34. 10. Zeeller SL, Citrome L. Managing agitation associated with schizophrenia and bipolar disorder in the emergency setting. *West J Emerg Med*. 2016;17(2):165-172 doi: 10.1016/j.trci.2019.10.004. PMID: 31799369; PMCID: PMC6881649.9.

The At-Home Market for BXCL501 in Bipolar Disorders and Schizophrenia: Summary

The potential for BXCL501 in the at-home setting reflects significant unmet need and attractiveness to patients

- **Our market research indicates approximately 3 episodes of agitation per month in the home setting**
 - Previous estimate of 23M annual episodes was based on historic claims data (~1.2 episodes per month)
 - Due to the lack of approved treatment options, the claims data likely underestimate the true episode frequency
 - Consequently, the total addressable market (TAM) is significantly higher than previously reported
- **Based on the target product profile, HCPs indicated that they would treat ~16% of their patients with BXCL501**
- **HCPs believe that the most significant unmet need is the lack of effective and fast-acting treatments for the at-home setting**
- **Patients are the primary stakeholder for the treatment of their agitation episodes**
 - Patients feel that they lack control over their thoughts and actions during agitation episodes, which occur approximately three times per month on average
 - Patients want to treat the episode as soon as it begins and before it escalates in severity
- **Patient research suggests that they would use BXCL501 in 80% of the episodes experienced at-home**
- **Pricing flexibility in the market may allow up to \$1,400+ per prescription**
- **Attractive market access factors**

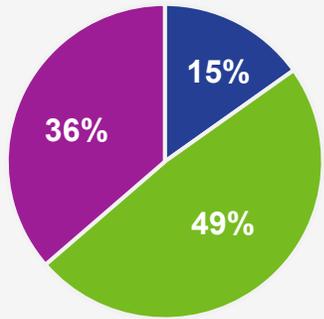
**Anticipated Episodic Patient Choice
(Future Market)**
(% of Episodes, Market research, n=240)



Episode Frequency in Patients Experiencing Agitation

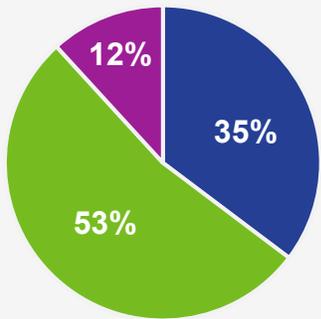
Agitation episodes expected to occur 3-4 times per month based on multiple data sources

Primary Market Research (N=80)¹



Schizophrenia (n=20)
35 Episodes per year (~3/month)

■ Mild ■ Moderate ■ Severe



Bipolar Disorder (n=60)
38 Episodes per year (~3/month)

■ Mild ■ Moderate ■ Severe

Published Survey (N=583)²

Severity	Number of episodes/year
Mild	22.4
Moderate	15.4
Moderate-intense	6.8
Severe	2.9
Total	47.5 (~4/month)

BXCL501 Serenity at Home Pivotal Phase 3 Trial

Data from more than 2,200 episodes collected, with an average of 4 episodes per patient per month

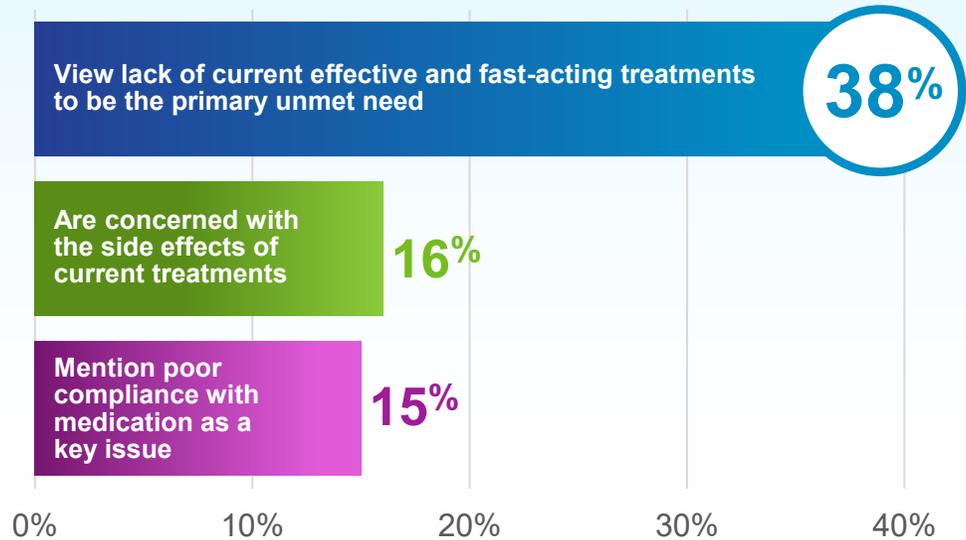
¹Source: InVibe Feb 2023 Q4: In the past month, about how many agitation episodes [IF PATIENT SHOW “have you” IF CG SHOW “has your loved one”] experienced?

Q5. Of the [XX] agitation episodes you experienced in the past month, how many would you categorize as mild, moderate, or severe?

²Roberts et al. BMC Psychiatry (2018) 18:104.

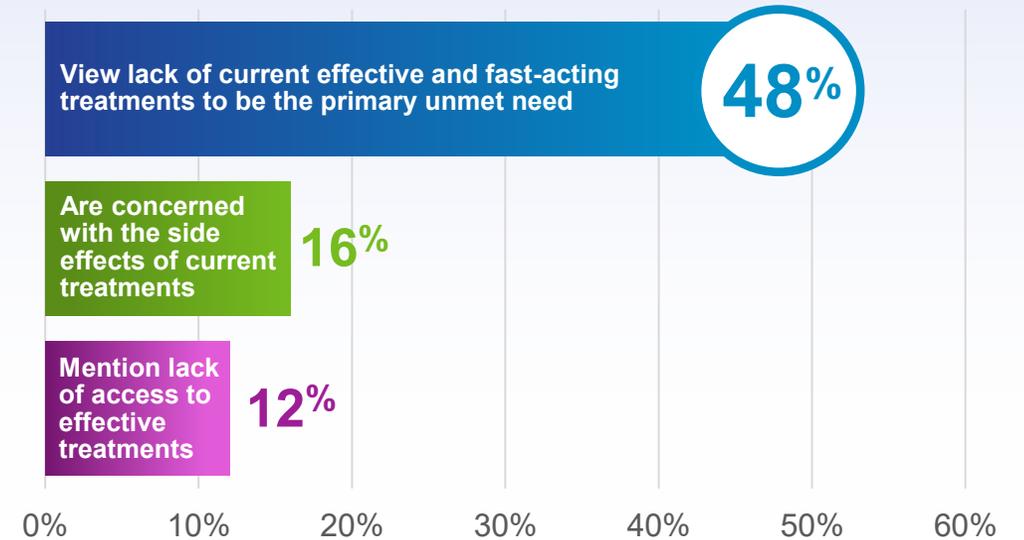
Physician Market Research Cites Need for Effective, Fast-acting, More Tolerable Treatment Options

Key unmet needs in bipolar disorders



“ The available drugs either work too slowly or have unacceptable side effects.”
– Psychiatrist

Key unmet needs in schizophrenia

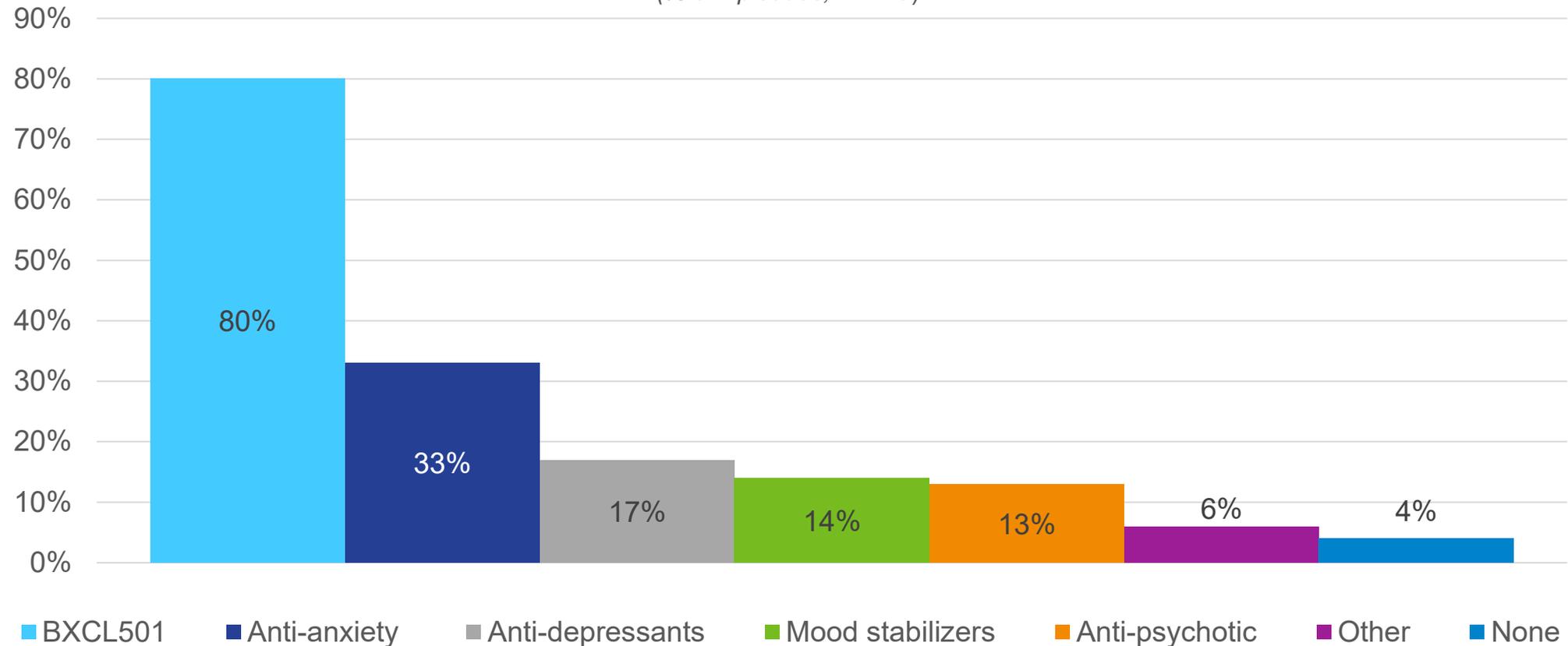


“ Other than the sedative effects of antipsychotics, there really aren't any good options for managing agitation without just making the patient drowsy.”
– Psychiatrist

Potential Patient Use of BXCL501 At Home

When shown product profile stimulus, patients stated they would use a product with the BXCL501 target profile for 80% of their bipolar/schizophrenia agitation episodes

Potential Uptake for BXCL501 (if approved for at-home use)
(% of Episodes, N=240)

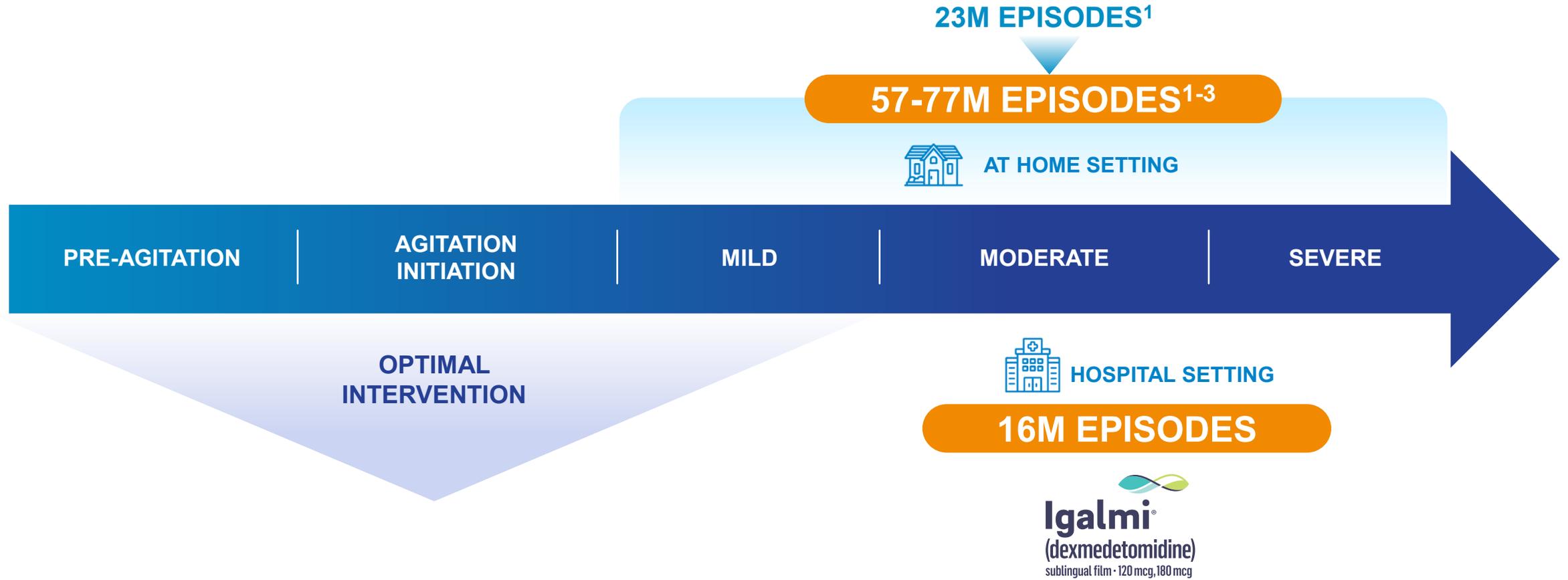


Q22. You previously indicated that you used the following medications to manage your last 3 agitation episodes. Now please imagine that Igalmi was also available for you to use. Please indicate what treatment you would have chosen to treat the last 3 episodes if Igalmi were also available to you. We have provided your previous response below for reference.

Source: InVibe Feb 2023.

At-Home Intervention: Early Intervention May Prevent Severity Escalation

Potentially reduce ER visits, hospitalizations, or first-responder interventions

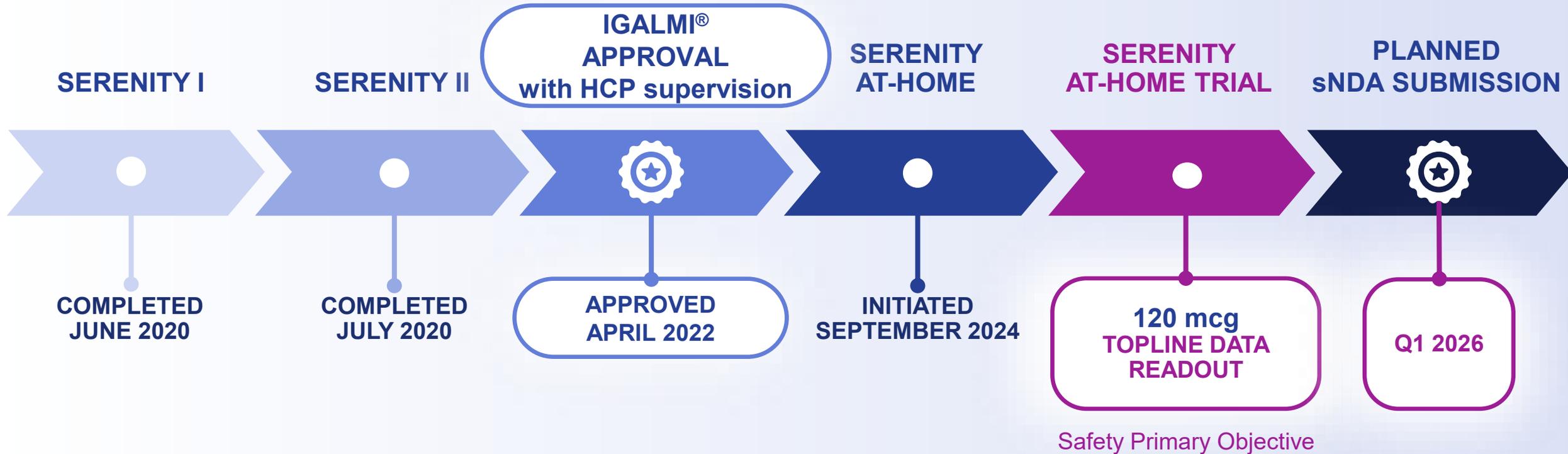


1. Kwong, M et al., Presented at the Academy of Managed Care Pharmacy Nexus 2021, October 18-21, 2021; Symphony claims data.
 2. Source: InVibe Feb 2023 Q4: In the past month, about how many agitation episodes [IF PATIENT SHOW “have you” IF CG SHOW “has your loved one”] experienced?
 3. Roberts et al. BMC Psychiatry (2018) 18:104.

SERENITY Program Seeks IGALMI® Label Expansion

No FDA-approved therapies for agitation associated with bipolar disorders or schizophrenia in the at-home setting

SERENITY Program Journey



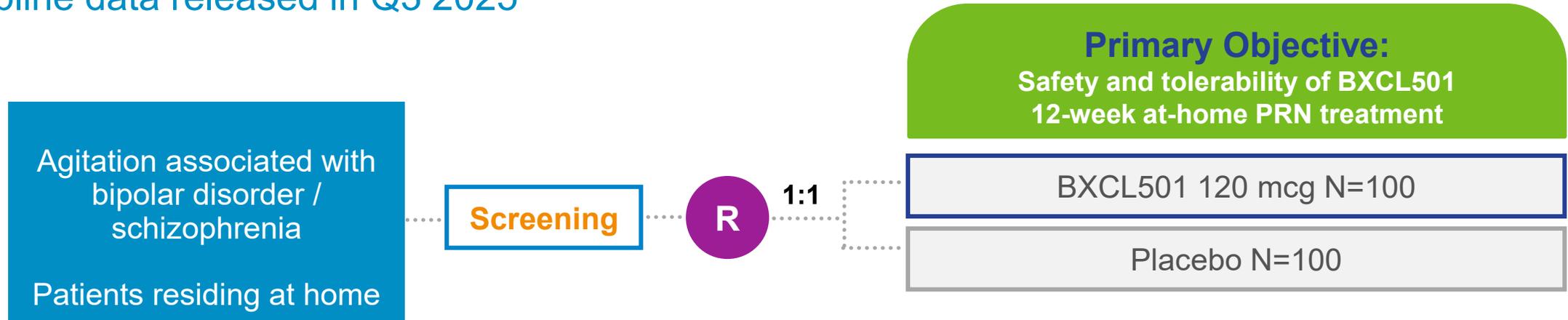
SERENITY At-Home

Topline Results



SERENITY At-Home Trial Design

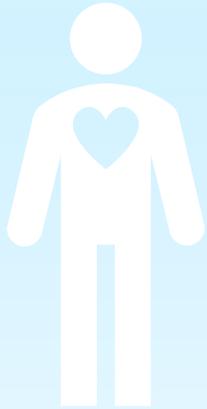
Topline data released in Q3 2025



- **Design:** double-blind, placebo-controlled trial to evaluate the safety of a 120 mcg dose of BXCL501 in the home setting
- **Recruitment Criteria**
 - Patients with or without co-resident family members/informants
 - Patients with episodes of agitation in the month prior to enrollment
- **Treatment**
 - Single dose to treat agitation at levels that typically require intervention
 - Maximum of 1 dose of study medication within 12 hours
- **Primary Objective:** Safety
- **Exploratory Endpoint:** Patients or caregivers/informants will complete a modified clinical global impression of change (mCGI-C) two hours after dosing to evaluate their impression of use in outpatient setting

Defining The At-Home Study Population

INCLUDED PATIENTS



- Male and female patients ages 18–75 years with bipolar I or II disorder, schizophrenia, schizoaffective, or schizophreniform disorder
- On a stable psychotropic regimen for ≥ 30 days prior to screening
- History of ≥ 3 agitation episodes in past 3 months

EXCLUDED PATIENTS



- Unstable or serious medical illness (e.g., CHF, recent MI, hepatic disease)
- Diagnosis of antisocial, borderline, or narcissistic personality disorder that predated schizophrenia or bipolar disorder
- Moderate to severe substance use disorder in past 6 months
- Agitation due primarily to acute intoxication or substance use

Baseline Demographics and Disease Characteristics

PARAMETER	IGALMI 120 MCG (N=102)	PLACEBO (N=106)	OVERALL* (N=246)
Age, years, Mean (SD)	47.5 (12.4)	47.2 (13.0)	47.0 (12.9)
Female, n (%)	48 (47.1%)	60 (56.6%)	120 (48.8%)
Race, n (%)			
White	52 (51.0%)	59 (55.7%)	131 (53.3%)
Black or African American	44 (43.1%)	40 (37.7%)	100 (40.7%)
Asian	2 (2.0%)	3 (2.8%)	5 (2.0%)
Other	3 (3.0%)	4 (3.8%)	9 (3.6%)
Ethnicity, Hispanic, n (%)	29 (28.4%)	36 (34.0%)	76 (30.9%)
Primary Diagnosis, n (%)			
Schizophrenia	54 (52.9%)	57 (53.8%)	134 (54.5%)
Bipolar Disorder	48 (47.1%)	49 (46.2%)	112 (45.5%)
Patients with Informant, n (%)	21 (20.6%)	26 (24.5%)	60 (24.4%)
Time Since Diagnosis, years, Mean (SD)	17.7 (12.4)	17.0 (11.1)	17.4 (11.8)

*7 patients did not take study treatment for their episodes, and 31 patients did not record any agitation episodes.

Agitation Episodes and Dosing Frequency

Large safety database generated to support sNDA submission

- **2,437 agitation episodes were treated in 208 patients**
 - 168 (81%) treated patients completed the full 12-week study
 - Average of 11.7 agitation episodes were recorded per treated patient
- **Data collected for 2,628 agitation episodes in 215 patients***
- **A total of 246 patients randomized****
- **All patients were able to successfully self-administer the film**

*7 patients did not take study treatment for their episodes.

**31 patients did not record any agitation episodes.

BXCL501 was Well Tolerated

Primary objective of the pivotal safety trial was met

- **No patients discontinued due to TEAEs in the BXCL501 arm**
- **Adverse event profile consistent with approved IGALMI[®] Label and other clinical trials in institutional setting**
 - No drug-related serious adverse events (SAEs), falls, or syncopes were reported
 - No new or unexpected treatment emergent adverse events (TEAEs) occurred with BXCL501 treatment in the home setting
 - No severe TEAEs associated with BXCL501 treatment; most TEAEs were mild
- **Tolerability remained consistent with repeated dosing throughout the trial**

BXCL501 Tolerability Profile Consistent With IGALMI[®] Label

Most common treatment-emergent adverse events (TEAEs) in Serenity At-Home trial and comparison with same TEAEs in the existing label

Treatment-Emergent Adverse Event	SERENITY I & II (IGALMI [®] Label ¹)		SERENITY AT-HOME Adverse Event by Dose (Episode) ¹			
	SINGLE DOSE		FIRST DOSE		ALL DOSES	
	IGALMI [™] 120 MCG (N=255) n (%)	PLACEBO (N=252) n (%)	BXCL501 120 MCG (N=102) ¹ n (%) ²	PLACEBO (N=106) ¹ n (%) ²	BXCL501 120 MCG (N=1160) ¹ n (%) ²	PLACEBO (N=1277) ¹ n (%) ²
Somnolence ³	56 (22%)	16 (6%)	23 (22.5%)	18 (17.0%)	161 (13.9%)	103 (8.1%)
Oral Paresthesia/Hypoesthesia	14 (6%)	2 (1%)	2 (2%)	1 (0.9%)	6 (0.5%)	1 (0.1%)
Dizziness	10 (4%)	2 (1%)	5 (4.9%)	1 (0.9%)	19 (1.6%)	2 (0.2%)
Dry Mouth	19 (7%)	3 (1%)	7 (6.9%)	1 (0.9%)	56 (4.8%)	24 (1.9%)
Nausea	6 (2%)	4 (2%)	1 (1.0%)	0 (0%)	6 (0.5%)	1 (0.1%)
Headache	12 (5%)	12 (5%)	0 (0%)	2 (1.9%)	4 (0.3%)	4 (0.3%)

¹SERENITY I and II evaluated a single agitation episode in each patient. SERENITY AT-Home evaluated a total of 2437 episodes in 208 patients. Adverse events are presented on an episode basis. N denotes number of episodes. Only AEs observed in Serenity At-Home Pivotal Phase 3 trial are listed.

²Percent of TEAE events per dosing episode.

³Includes fatigue.

BXCL501 Tolerability Profile Consistent With Repeat Dosing

Incidence of TEAEs did not increase with additional dosing

TEAEs: Events per dosed episode by dose numbers

Treatment-Emergent Adverse Event	After Doses 1-3		After doses 4 to 12		After doses 13 and beyond	
	BXCL501 (N=266) ¹ n (%) ²	PLACEBO (N=274) ¹ n (%) ²	BXCL501 (N=398) ¹ n (%) ²	PLACEBO (N=485) ¹ n (%) ²	BXCL501 (N=496) ¹ n (%) ²	PLACEBO (N=518) ¹ n (%) ²
Somnolence ³	58 (22.0%)	43 (16.0%)	61 (15.3%)	52 (10.8%)	42 (8.5%)	8 (1.5%)
Oral Paresthesia/Hypoesthesia	4 (1.5%)	1 (0.4%)	2 (0.5%)	0 (0%)	0 (0%)	0 (0%)
Dizziness	10 (3.8%)	1 (0.4%)	7 (1.8%)	1 (0.2%)	2 (0.4%)	0 (0%)
Dry mouth	14 (5.3%)	2 (0.7%)	29 (7.3%)	2 (0.4%)	13 (2.6%)	20 (3.9%)
Nausea	1 (0.4%)	1 (0.4%)	3 (0.8%)	0 (0%)	2 (0.4%)	0 (0%)
Headache	3 (1.1%)	2 (0.7%)	0 (0%)	2 (0.4%)	1 (0.2%)	0 (0%)

¹Number of Dosed Episodes.

²Percentage of Dosed Episodes.

³Includes Fatigue.

BXCL501 Tolerability Profile Consistent Over the Trial Duration

Incidence of TEAEs did not increase over time

TEAEs: Events per dosed episode by week in trial

Treatment-Emergent Adverse Event	Weeks 1 to 4		Weeks 5 to 8		Weeks 9 to 12	
	BXCL501 (N=454) ¹ n (%) ²	PLACEBO (N=474) ¹ n (%) ²	BXCL501 (N=369) ¹ n (%) ²	PLACEBO (N=433) ¹ n (%) ²	BXCL501 (N=337) ¹ n (%) ²	PLACEBO (N=370) ¹ n (%) ²
Somnolence ³	74 (16.4%)	53 (11.2%)	47 (12.7%)	29 (6.7%)	36 (10.7%)	19 (5.2%)
Oral Paresthesia/Hypoesthesia	6 (1.3%)	1 (0.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Dizziness	13 (2.9)	2 (0.4%)	3 (0.8%)	0 (0%)	3 (0.9%)	0 (0%)
Dry mouth	25 (5.5%)	2 (0.4%)	20 (5.4%)	10 (2.3%)	11 (3.3%)	12 (3.3%)
Nausea	3 (0.7%)	1 (0.2%)	2 (0.5%)	0 (0%)	1 (0.3%)	0 (0%)
Abdominal Discomfort	0 (0%)	0 (0%)	1 (0.3%)	1 (0.2%)	0 (0%)	0 (0%)

¹Number of dosed episodes.

²Percentage of dosed episodes with an AE.

³Includes Fatigue.

Exploratory Assessments of Treatment Benefit

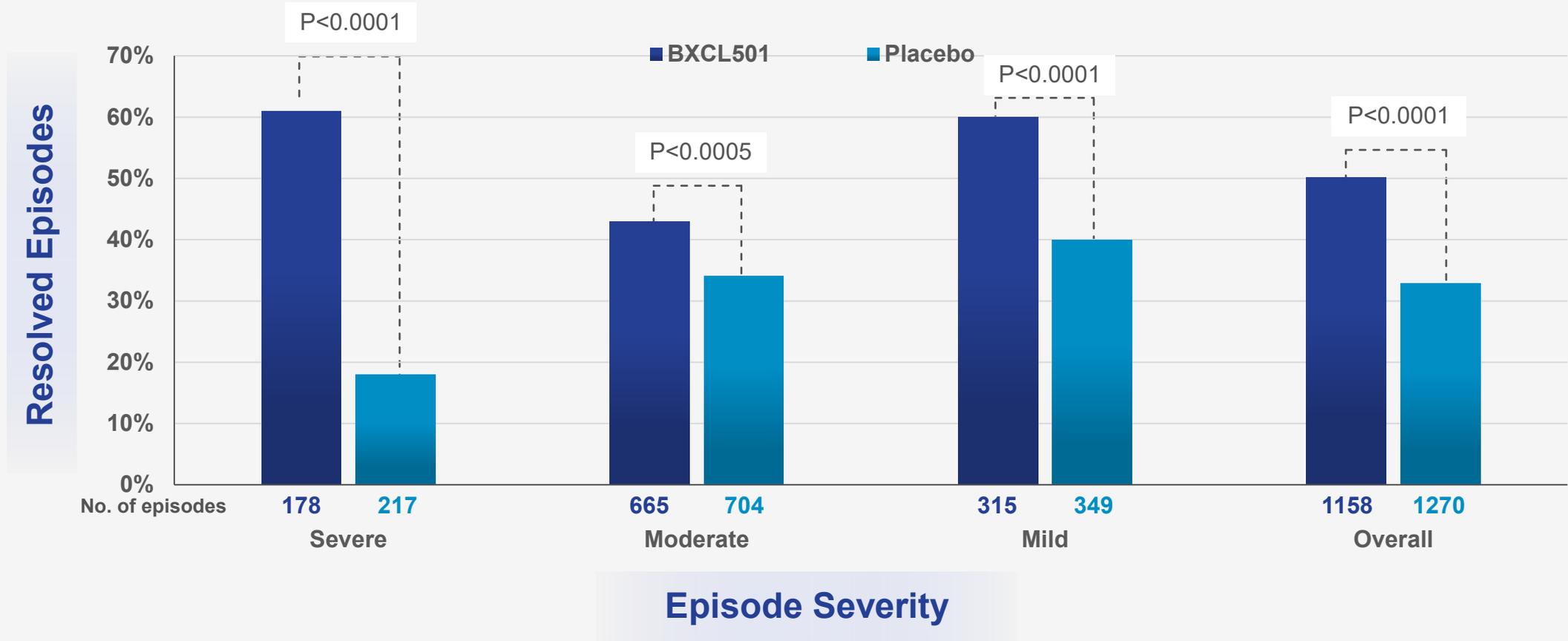
Similar reductions in symptom severity with repeat dosing over a 12-week period

- The efficacy of 120 mcg dose for a single dose administration proven and approved as IGALMI®
- The primary objective of this trial was safety and the exploratory objective was to assess the continued benefit of BXCL501 with repeat dosing
- BXCL501 demonstrated a significant mean reduction in mCGI-S score from baseline compared to placebo at 2 hours across 2,433 treated episodes ($P < .05$)*
- Complete resolution of agitation was significantly higher with BXCL501 compared to placebo across agitation episode severity ($P < .0001$)
- BXCL501 showed a similar reduction in agitation symptoms over both the duration of the trial and number of treated episodes

* Four patients did not record full efficacy information.

The Benefit of BXCL501 Over Placebo Across Episode Severities

PERCENT OF FULLY RESOLVED EPISODES BY BASELINE SEVERITY



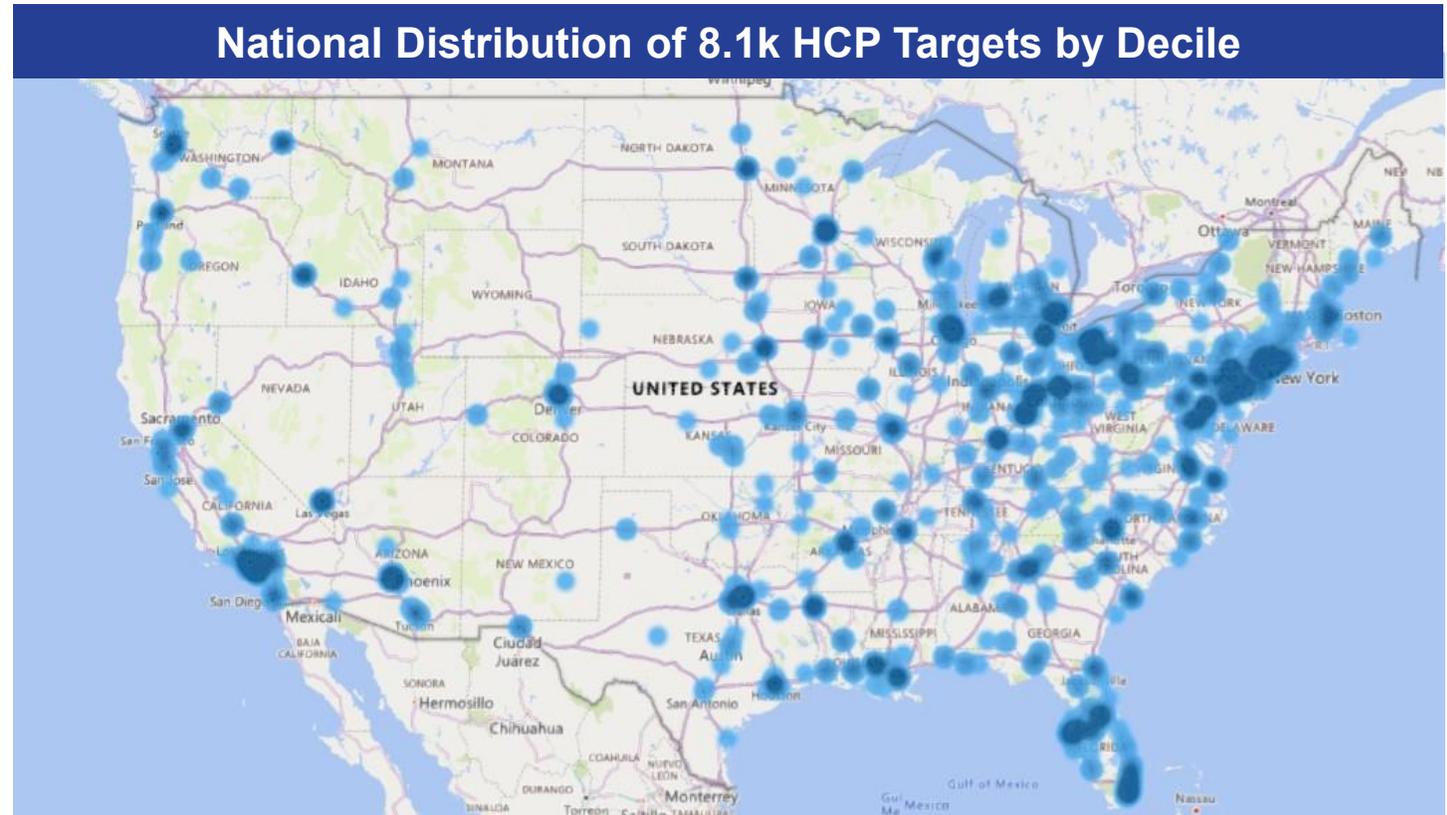
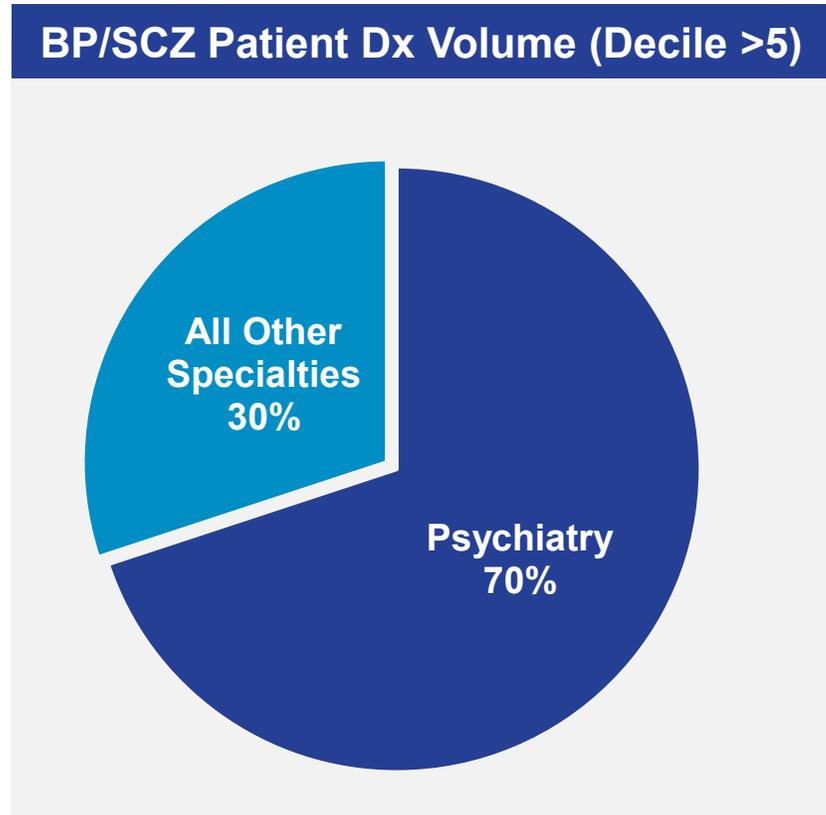
Clinical Summary



- **Well tolerated with repeat dosing across the trial duration**
- **Safety profile** consistent with prior inpatient SERENITY trials
 - No discontinuations due to TEAEs in the BXCL501 arm
 - No serious drug-related adverse events
 - No falls or syncope
- **All patients successfully self-administered the film**
- **Benefit was maintained over time**, with no attenuation of effect on agitation symptoms across multiple episodes
- **Results supportive of sNDA submission**

Provisional Targeting Model

Among the highest deciles of Bipolar & Schizophrenia patient Dx volume, 70% are managed by psychiatrists, with 8.1k total HCP targets. 50-70 discrete field FTEs can cover these targets



BXCL501 for Agitation Associated with Alzheimer's Dementia (AAD)

AAD is Debilitating for Patients and a Burden for Caregivers

Agitation is the primary reason for patients to live in long-term care facilities versus a home setting

- Nearly 7 million Alzheimer's dementia patients in the U.S., with approximately 50% suffering from agitation.
- AD-related agitation typically worsens over time
 - Both the number and severity of agitation episodes increase
 - Often places significant burden on caregivers
- No FDA-approved therapeutic options for an as-needed (PRN) acute treatment of agitation in Alzheimer's patients



Strategic Opportunity for BXCL501 in AAD Treatment Market

PRN therapy could potentially address breakthrough episodes – favorable chronic treatment companion

Perceptual Map

No Boxed Warning

- **Brexpiprazole**

- After treatment, the mean CMAI scores indicated still clinically significant agitation due to “breakthrough” episodes¹⁻³
- For some symptoms, these episodes occur a couple of times a week on average⁴

- **AXS-05**

- 44% of patients did not have long-term control of agitation⁵
- In both Phase 3 studies, the mean CMAI score showed that even among “responders” a substantial proportion is still clinically significantly agitated^{5,6}

- Neither treatment is indicated PRN and neither prevents agitation episodes, only reduces frequency

- PRN treatment would still be needed even with chronic daily therapy



Source: Mizuho Securities April 17th 2023 and BREXPIPIRAZOLE sNDA for Agitation Associated with Alzheimer’s Dementia (AAD) April 14, 2023 Psychopharmacologic Drugs Advisory Committee and Peripheral and Central Nervous System Drugs Advisory Committee Otsuka Pharmaceutical Co. Lundbeck Inc.

TRANQUILITY II: Multi-Center, Randomized, Double-Blind, Placebo-controlled Efficacy and Safety Study

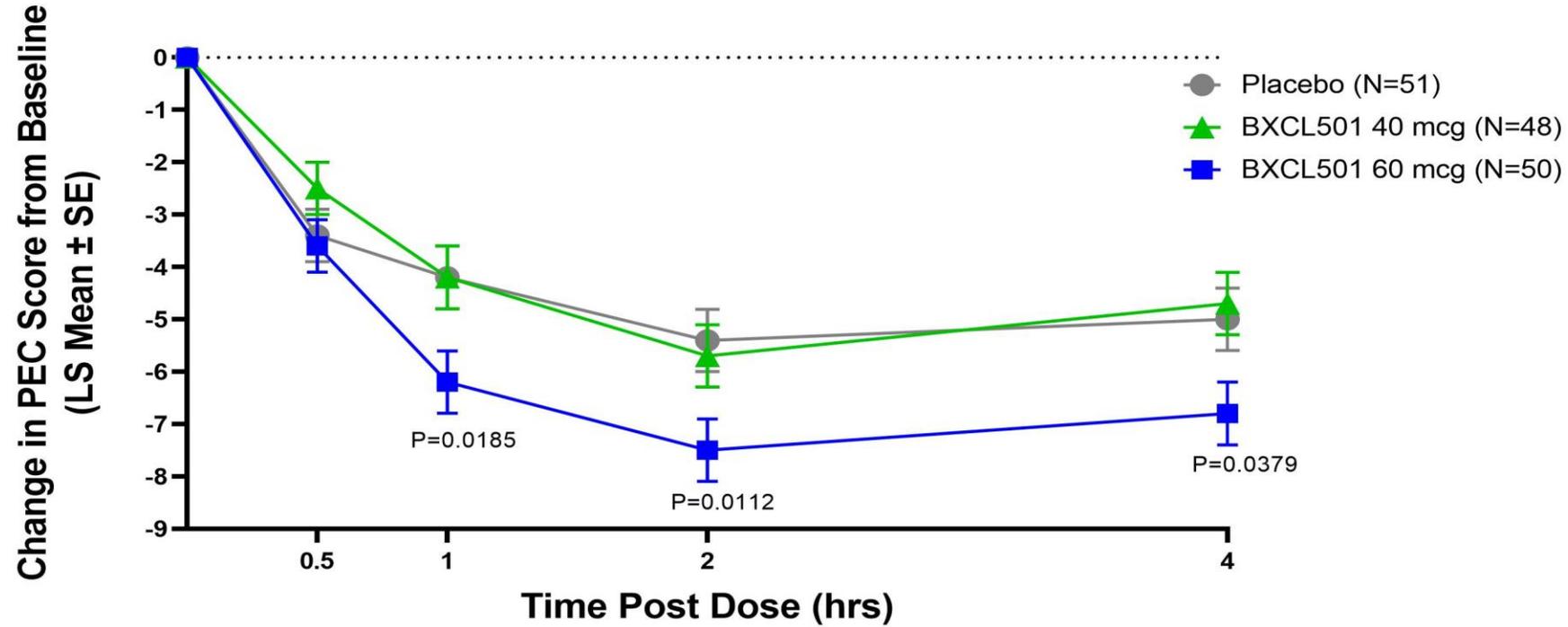
PRN dosing of BXCL501 over a 12-week period in subjects with agitation associated with dementia



Major Findings

- Treatment with 60 μg BXCL501 showed efficacy in reducing symptoms of agitation.
- BXCL501 was generally well-tolerated at doses of 60 μg and 40 μg .
- BXCL501 has potential as a treatment option for AAD.

Change From Baseline in PEC Total Score Compared to Placebo for the First Episode of Agitation



PEC = The Positive and Negative Syndrome Scale - Excited Component Scale; LS = least square; SD = standard deviation; SE = standard error

Mean (SD) baseline PEC scores in the Placebo, BXCL501 40 mcg, and BXCL501 60 mcg groups were: 17.5 (2.62), 17.3 (2.26), and 18.0 (2.18), respectively.

ENDPOINT	BXCL501 60 mcg (N=50)	BXCL501 40 mcg (N=48)	PLACEBO (N=51)
Change from baseline [LS Mean (SE)] @ 1 hour	-6.2 (0.6) p = 0.0185	- 4.2 (0.6) p = 0.9590	- 4.2 (0.6)
Change from baseline [LS Mean (SE)] @ 2 hours	-7.5 (0.6) p = 0.0112	- 5.7 (0.6) p = 0.7648	- 5.4 (0.6)
Change from baseline [LS Mean (SE)] @ 4 hours	-6.8 (0.6) p = 0.0379	- 4.7 (0.6) p = 0.7100	-5.0 (0.6)

The trial met its primary endpoint for the 60 mcg dose with statistically significant (p=0.0112) reduction in agitation at 2 hours.

BXCL501 Was Well Tolerated

Treatment-emergent adverse events of special interest (AESI) occurring within 24 hours after first dose and over entire trial period

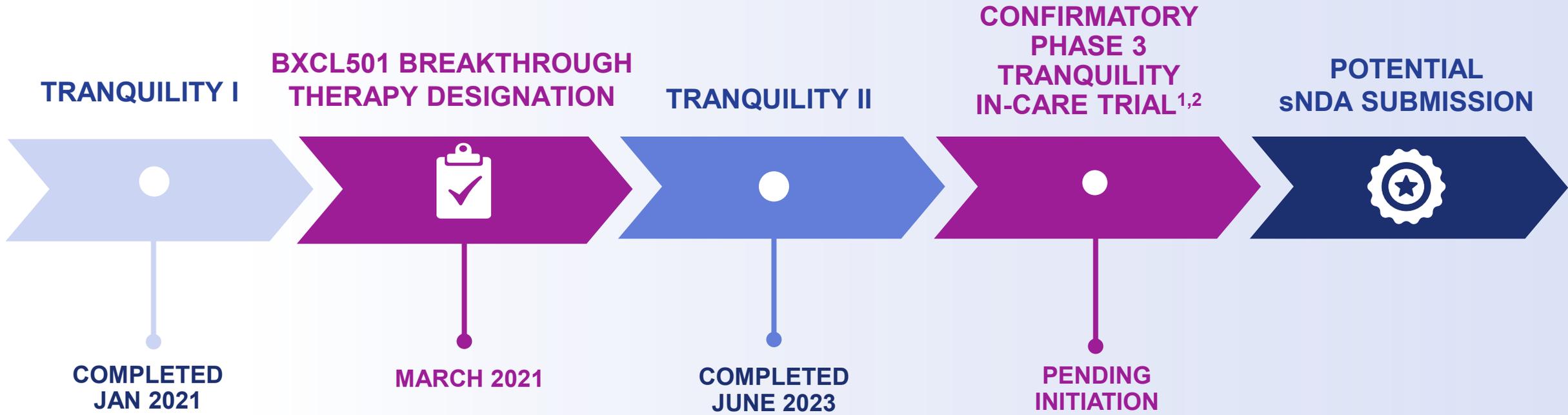
		AEs within 24 hours of first dose			AEs during 12-week trial (443 doses)		
Adverse Event	Severity	BXCL501 60 mcg n=50 (%)	BXCL501 40 mcg n=48 (%)	Placebo n=51 (%)	BXCL501 60 mcg n=50 (%)	BXCL501 40 mcg n=48 (%)	Placebo n=51 (%)
Somnolence*	Mild	8 (16.0)	6 (12.5)	2 (3.9)	8 (16.0)	9 (18.8)	2 (3.9)
	Moderate	1 (2.0)	2 (4.2)	0	3 (6.0)	2 (4.2)	0
Lethargy	Mild	2 (4.0)	1 (2.1)	1 (2.0)	4 (8.0)	1 (2.1)	1 (2.0)
	Moderate	1 (2.0)	1 (2.1)	0	1 (2.0)	1 (2.1)	0
Hypotension	Mild	7(14.0)	4 (8.3)	2 (3.9)	7(14.0)	8(16.7)	2 (3.9)
	Moderate	1 (2.0)	0	0	4 (8.0)	0	1 (2.0)
Bradycardia	Mild	3 (6.0)	0	0	4 (8.0)	3 (6.3)	1 (2.0)
	Moderate	1 (2.0)	1 (2.1)	0	2 (4.0)	1 (2.1)	0
Orthostatic Hypotension	Mild	2 (4.0)	2 (4.2)	1 (2.0)	5 (10.0)	8 (16.7)	2 (3.9)
	Moderate	2 (4.0)	1 (2.1)	0	2 (4.0)	2 (4.2)	0

*Somnolence was primarily mild and no subject was unarousable.

The adverse events of special interest (AESI) are defined as those related to mechanism of action of the drug. Those that are listed were observed within 24 hours after the first dose and occur with a frequency of at least 2% and greater than with placebo. Subjects are counted once at highest severity for each preferred term.

TRANQUILITY Program Offers Potential Opportunity to Address a Significant Unmet Need in AAD

TRANQUILITY Program Journey

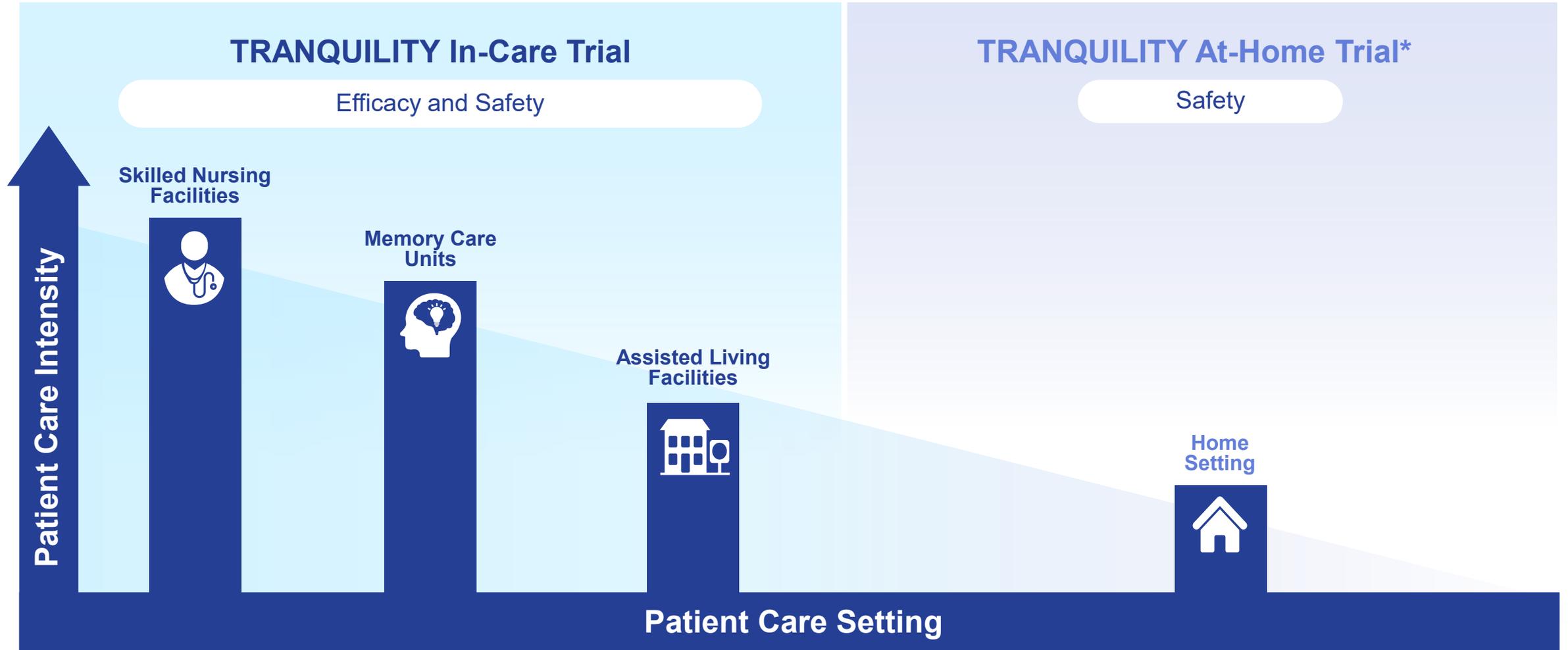


1 Trial design may be subject to change.

2 Per ICH guidelines, the company will be required to collect 6-month safety data from at least 300 patients and 1-year safety data from at least 100 patients.

Evaluating BXCL501 for AAD in High to Low Care Settings

Clinical trial strategy designed to maximize potential commercial opportunity across patient locations



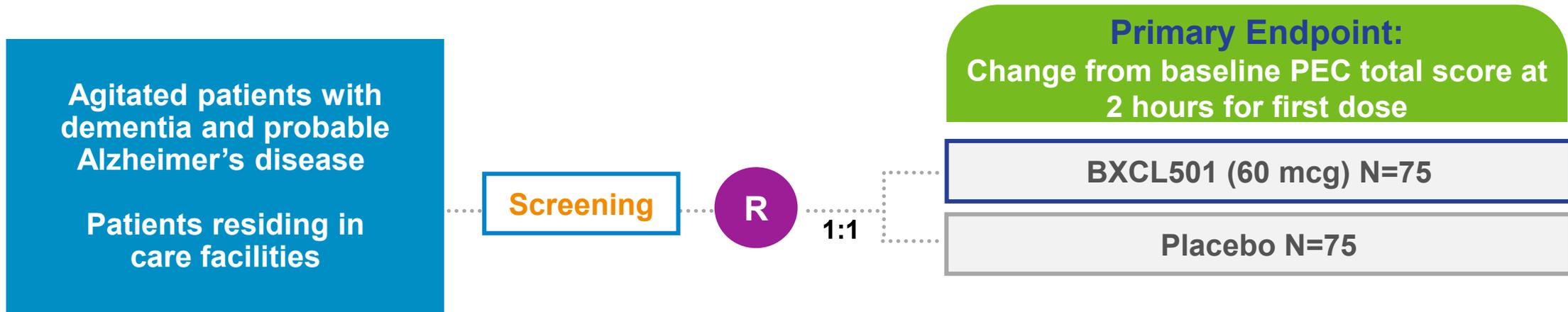
*Trial design may be subject to change

Skilled-Nursing Facilities: medical setting for patients with advanced health conditions who receive 24/7 skilled nursing care and medical monitoring

Memory Care Units: medical setting for patients with dementia who receive specialized care for symptom management

Assisted Living Facilities: residential setting for elderly patients who are largely independent but need help with ADLs (bathing, dressing, and other non-medical type assistance)

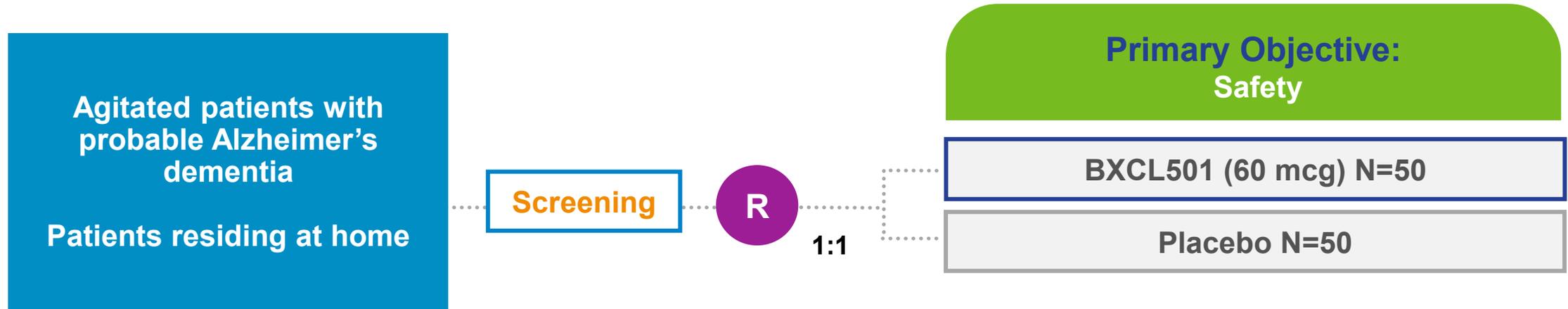
Second Phase 3 Trial: TRANQUILITY In-Care Study Design*



- **Design:** Randomized, double-blind, placebo-controlled, parallel group trial
- **Power:** Over 80% power
- **Inclusion Criteria**
 - Patients with probable AD (mild, moderate, or severe, MMSE \leq 25), who experience agitation, and residing in skilled nursing facilities, memory care units, or assisted living facilities
 - Patients with at least 3 episodes of agitation in the month prior to enrollment
 - PEC total score \geq 14 prior to randomization
- **Primary Endpoint:** Change from baseline of PEC total score at 2 hours for **first dose**
- **Study Duration:** 12 weeks with assessment of continued efficacy (up to 3 PECs)

*For illustrative purposes only: protocol under development and trial design may be subject to change.

Preliminary TRANQUILITY At-Home Study Design*



- **Study Design:** Randomized, double-blind, placebo-controlled, parallel group trial
- **Primary Objective:** Safety and tolerability of BXCL501 60 mcg
- **Inclusion Criteria**
 - Patients with mild, moderate, or severe probable AD who experience agitation, MMSE \leq 25
 - Patients with **not more than three episodes of agitation per week** in the month prior to enrollment
 - Patients with caregivers
- **Treatment**
 - BXCL501 60 mcg or placebo administered for agitation in at-home setting

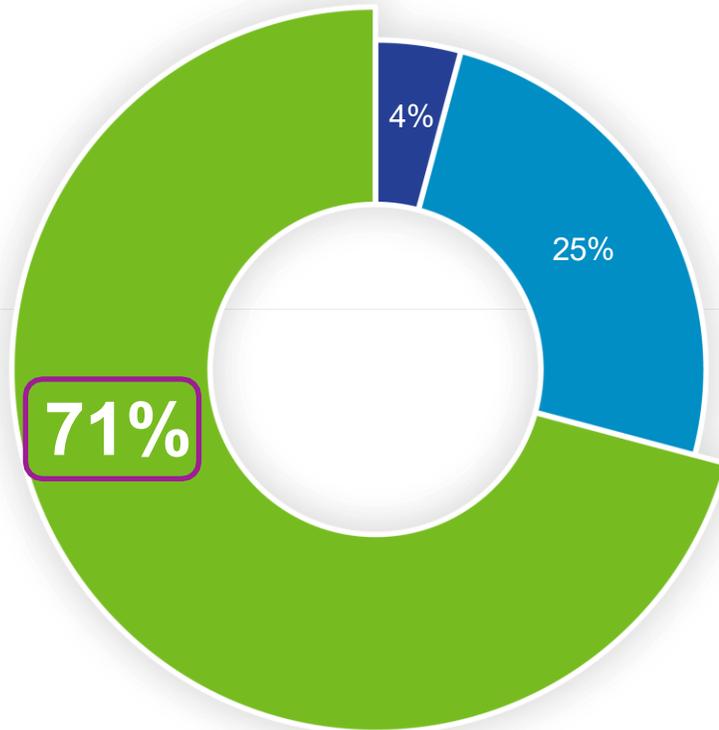
* For illustrative purposes only. Protocol under development and trial design may be subject to change. The FDA has not provided feedback on this trial.

Caregiver Impressions of BXCL501 Target Product Profile Have Been Favorable

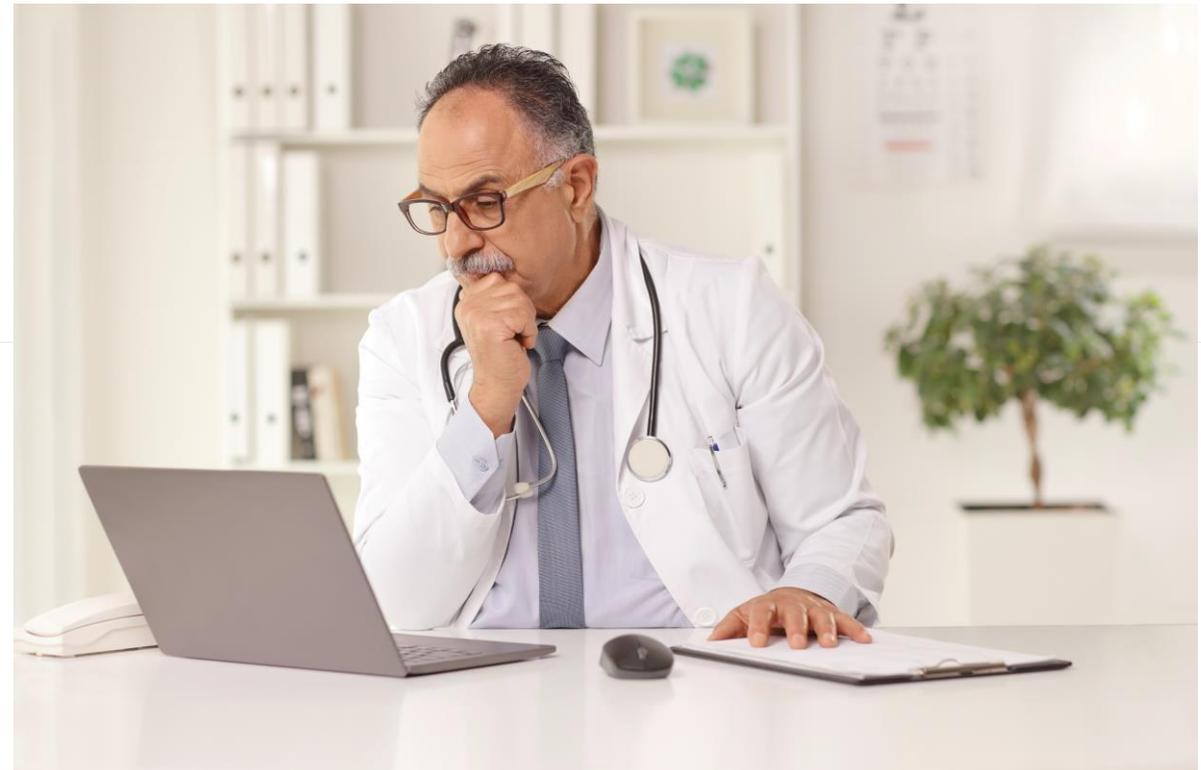
>70% of caregivers expressed high interest in BXCL501

Interest in BXCL501

(% of Total CGs, n=75)



■ Very interested (6-7) ■ Neutral (3-5) ■ Not interested (1-2)



Source: inVibe Market Research with ADA Caregivers (n=75), September 2022.

Key Company Milestones

Positive Business Momentum



Serenity At-Home safety and exploratory efficacy data announced

- Data analysis ongoing for clinical study reports



sNDA preparation in progress

- Content and format of sNDA aligned with FDA in August
- sNDA non-clinical section completed, clinical and CMC sections in-progress



Developing commercialization and partnering strategy for at-home setting



Agreement to TRANQUILITY In-Care trial design with FDA and evaluating CROs for trial initiation



Strengthened balance sheet

Thank you!
