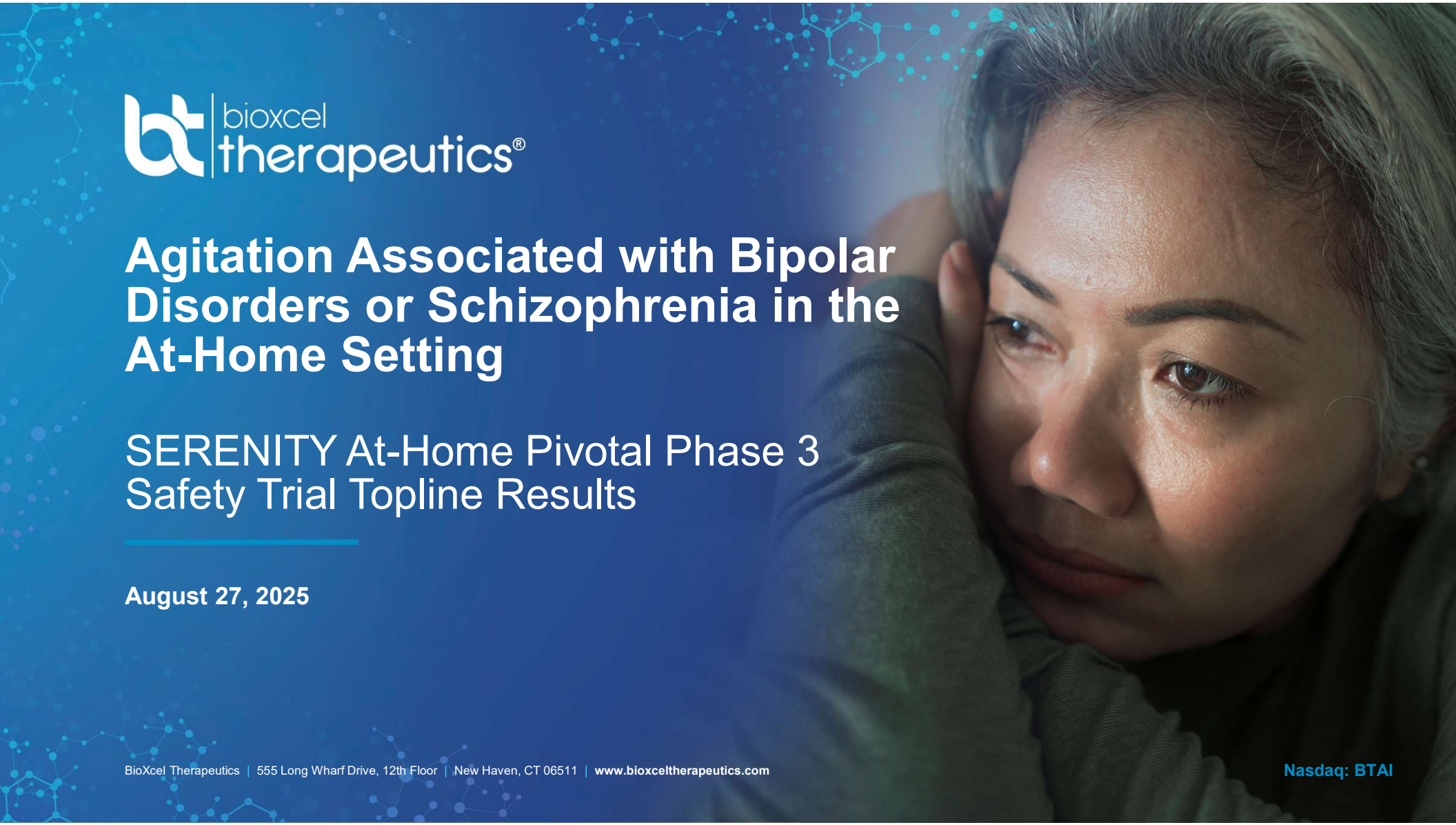

Agitation Associated with Bipolar Disorders or Schizophrenia in the At-Home Setting

SERENITY At-Home Pivotal Phase 3 Safety Trial Topline Results

August 27, 2025

BioXcel Therapeutics | 555 Long Wharf Drive, 12th Floor | New Haven, CT 06511 | **www.bioxceltherapeutics.com**

Nasdaq: BTAI

Forward-Looking Statements

This presentation includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. We intend 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 Company’s planned advancement of its SERENITY program; potential market opportunity for BXCL501; release of data from the SERENITY At-Home trial; the submission of an sNDA to the FDA; the supply of IGALMI® through existing distribution channels; the potential for the results from the Company’s completed, ongoing and proposed clinical trials to support regulatory approvals for its product candidates and change the treatment paradigm for agitation. 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; the number of episodes of agitation and the size of the Company’s total addressable market may be overestimated, and approval that the Company may obtain may be based on a narrower definition of the patient population; 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2024, 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 press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. 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 our 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.

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Agitation: A Clinical Burden With No Clear Solution[1]

Debilitating for Patients and Threatening for Healthcare Providers

Characterized by recurring episodes[1]

Symptoms differ by patient, vary between episodes, and range from mild to severe[2-7]

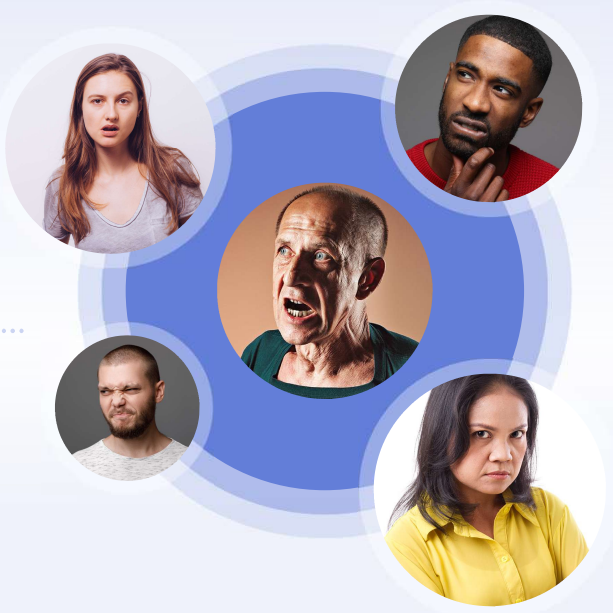
Multi-billion-dollar healthcare burden[8]

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 sedation[9]

Current treatment approaches:

- May involve physically restraining patients[10]
- Over-sedating therapies such as antipsychotics and benzodiazepines[10]



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..Dundar 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

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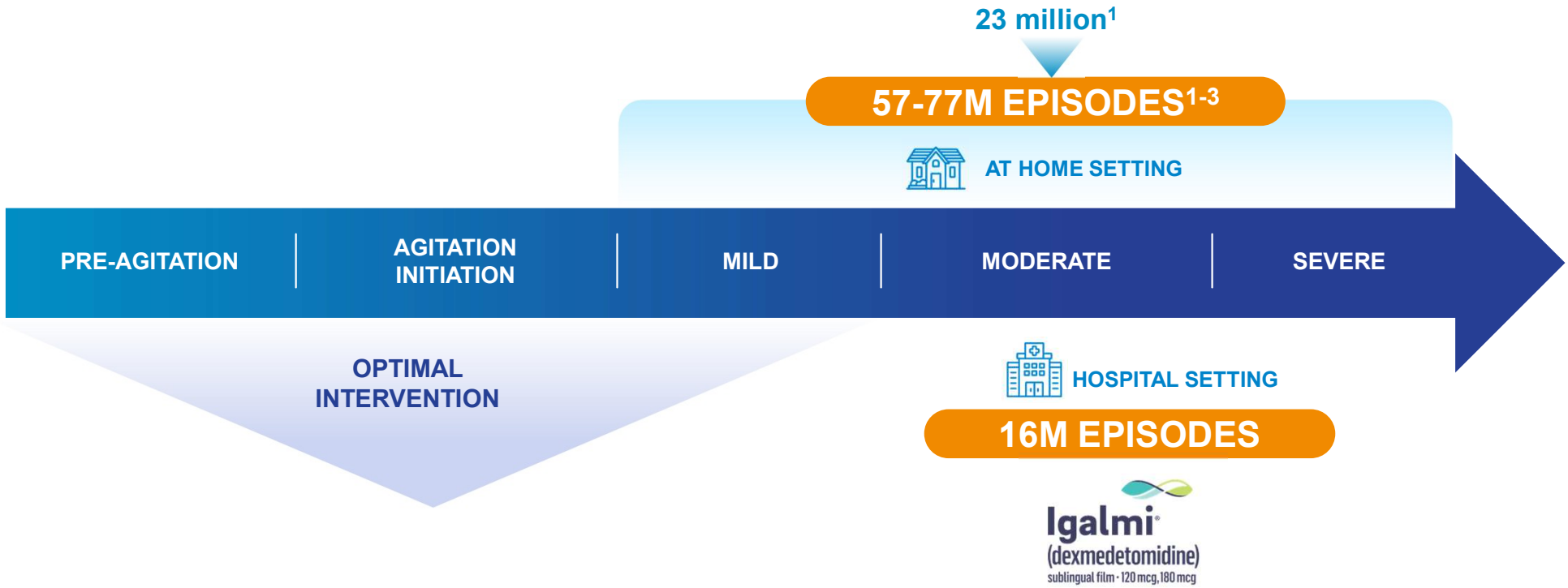
At-Home Intervention: Early Intervention May Prevent Severity Escalation

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

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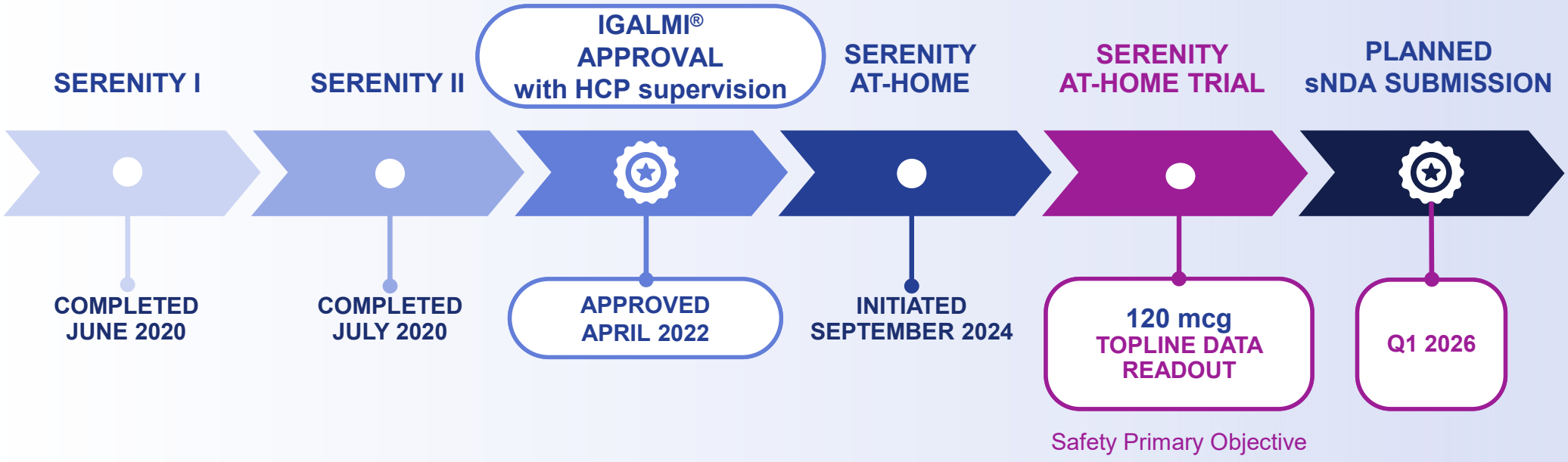
SERENITY Program Seeks IGALMI® Label Expansion

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

SERENITY Program Journey



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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

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.

Positive Topline Results: SERENITY At-Home Trial

Results are supportive of sNDA submission for label expansion of IGALMI®

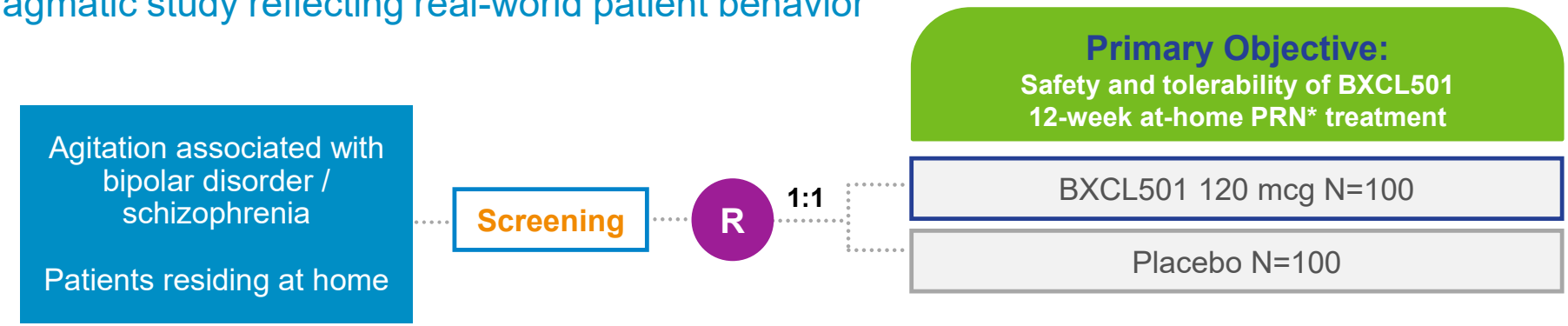
- **Data collected from 2,628 agitation episodes**
  - 2,437 episodes were treated in 208 patients
  - Patients self-administered the film for all treated episodes
- **Well tolerated with no drug-related serious adverse events**
  - No syncopes or falls reported in the BXCL501 arm
  - Adverse event profile consistent with approved IGALMI label and multiple clinical trials in institutional setting
  - Tolerability with repeat dosing remained similar throughout the trial
- **Preliminary results demonstrate continued effects and consistent benefit with repeat dosing across the course of the trial**
- **Submission of sNDA planned for Q1 2026**

SERENITY At-Home

Trial Design

SERENITY At-Home Safety Trial Design

Pragmatic study reflecting real-world patient behavior



- **Design:** Double-blind, placebo-controlled trial to evaluate the safety of a 120 mcg dose of BXCL501 in the home setting
- **Patients:** With or without co-resident family members/informants
- **Treatment:**
  - Single dose to treat agitation at levels that typically require intervention
  - Maximum of 1 dose of study medication within 12 hours
- **Alternative Interventions:** In addition to study treatment, patients could also use meditation, alcohol, cannabis, other medications etc. to reflect real-world coping strategies
- **Primary Objective:** Safety
- **Exploratory Objective**: Patients or caregivers/informants will complete a modified clinical global impression (mCGI) two hours after dosing to evaluate their impression of use in outpatient setting

* As needed

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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

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SERENITY At-Home

Topline Results

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

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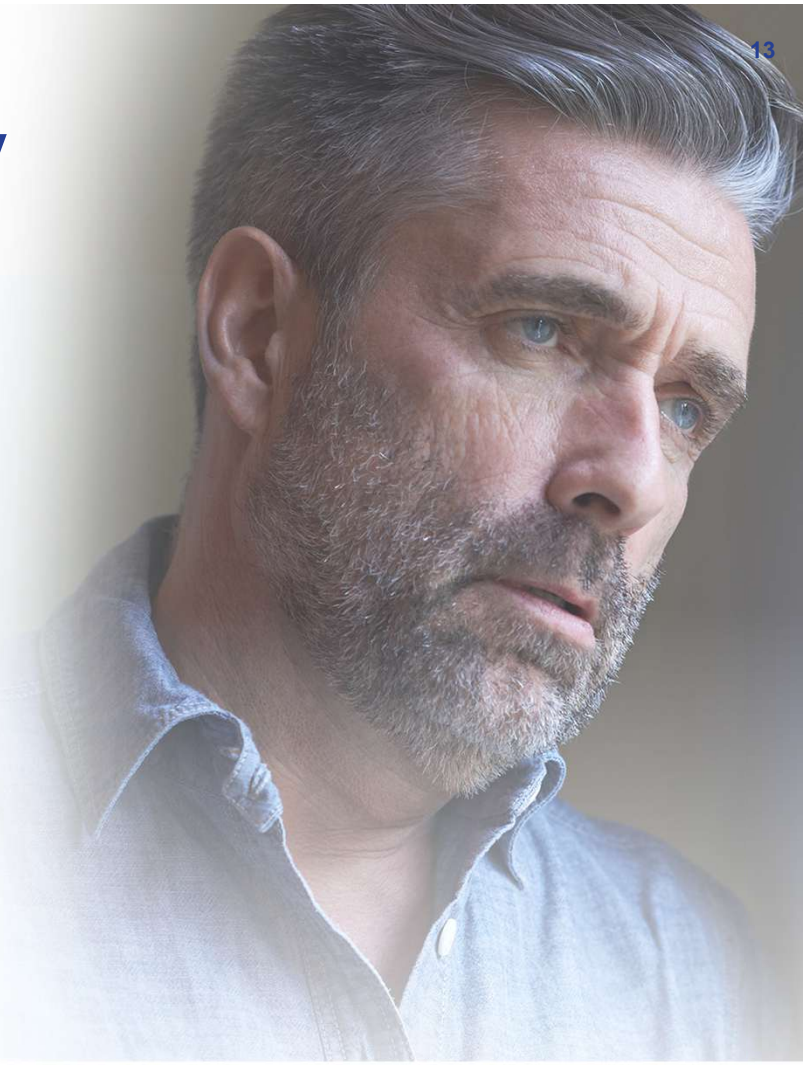
Agitation Episodes and Dosing Frequency

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

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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%)

[1]SERENITY 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.
[2]Percent of TEAE events per dosing episode
[3]Includes fatigue

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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%)

[1]Number of Dosed Episodes
[2]Percentage of Dosed Episodes
[3]Includes Fatigue

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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%)

[1]Number of dosed episodes
[2]Percentage of dosed episodes with an AE
[3]Includes Fatigue

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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**
- **Preliminary results from more than 2,400 episodes demonstrate continued treatment effect with repeat BXCL501 dosing across the course of the trial with no diminishing benefit with higher number of doses**
- **A greater percentage of patients experiencing mild, moderate or severe agitation had full resolution of symptoms in the BXCL501 arm compared with placebo**
- **Complete analyses of the full data set is ongoing and results will be shared in the near future**

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 syncopes
- **All patients successfully self-administered the film**
- **Continued effect and consistent benefit with repeat dosing across the course of the trial**
- **Results supportive of sNDA submission**

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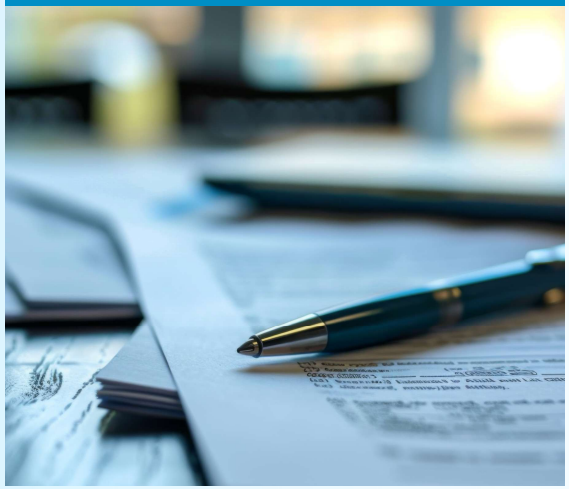
Planned Next Steps

Scientific conference data presentation

sNDA preparation and submission



Define commercialization strategy

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Thank you!

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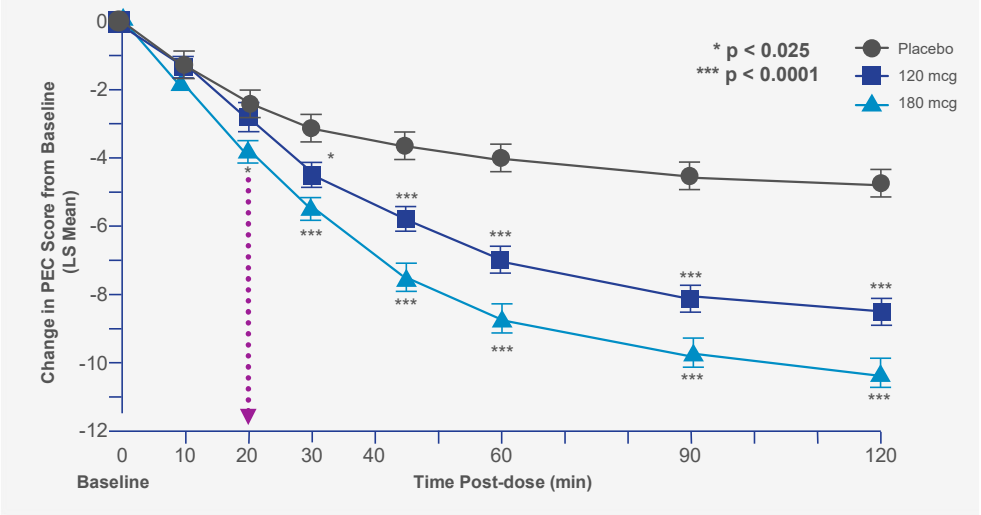
Appendix

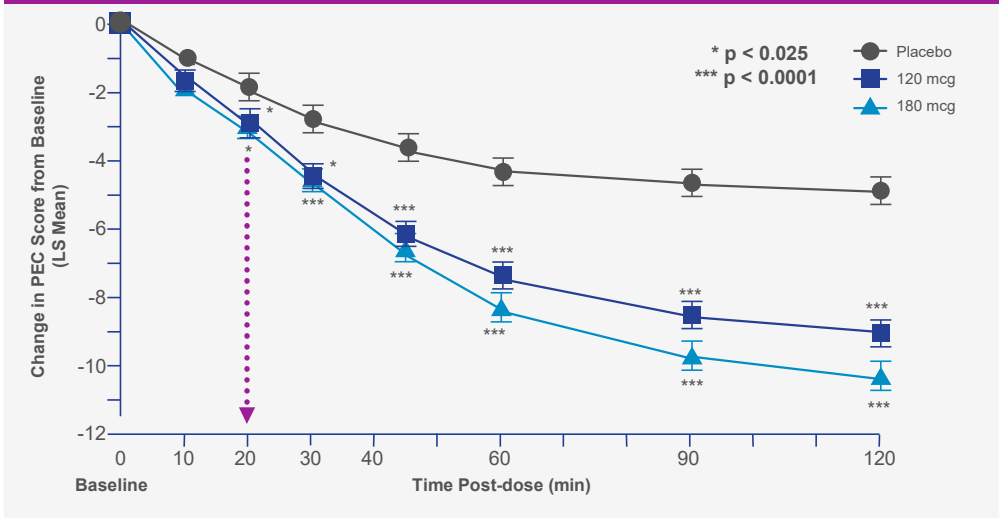
Building on Proven Efficacy of 120 mcg Dose

SERENITY I: Change in PEC Score from Baseline



Endpoint (120 min)	Placebo	120 mcg	180 mcg
PEC Total score Change from Baseline	-4.8	-8.5 ***	-10.3 ***
Response °	34%	79.1% ***	88.8% ***

SERENITY II: Change in PEC Score from Baseline



Endpoint (120 min)	Placebo	120 mcg	180 mcg
PEC total score change from Baseline	-5.0	-9.1 ***	-10.4 ***
Response °	37%	77.0% ***	90.5% ***

ITT analysis, Least Square Means +/-SEM
° Proportion achieving ≥ 40% PEC reduction

Proprietary & Confidential

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Safety Profile in Initial Pivotal Clinical Trials[1-3]

Adverse reactions reported in ≥2% of IGALMI-treated patients and greater than placebo in SERENITY I and II[1]

Adverse reaction	IGALMI 180 mcg (n=252)	IGALMI 120 mcg (n=255)	Placebo (n=252)
Somnolence*	23%	22%	6%
Oral paresthesia or oral hypoesthesia	7%	6%	1%
Dizziness	6%	4%	1%
Hypotension	5%	5%	0%
Orthostatic hypotension	5%	3%	<1%
Dry mouth	4%	7%	1%
Nausea	3%	2%	2%
Bradycardia	2%	2%	0%
Abdominal discomfort†	2%	0%	1%

*Somnolence includes the terms fatigue and sluggishness.[1]
†Abdominal discomfort includes dyspepsia and gastroesophageal reflux disease.[1]

1. IGALMI. Package insert. BioXcel Therapeutics, Inc.; 2022. **2.** Data on file. BXCL501-301 CSR (SERENITY I). BioXcel Therapeutics, Inc.; January 2021. **3.** Preskorn SH, et al. *JAMA*. 2022;327(8):727-736. **4.** Data on file. BXCL501-302 CSR (SERENITY II). BioXcel Therapeutics, Inc.; January 2021.

Please see Important Safety Information throughout this presentation.

- The majority of adverse reactions were mild to moderate in severity[2-4]
- No serious treatment-related adverse reactions were reported in clinical trials[2,4]
- Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or operating hazardous machinery, for at least 8 hours after taking IGALMI[1]
- There were no cases of syncope or falls reported in these trials.

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