



IGALMI Commercial Opportunity in the At-Home Setting for Bipolar Disorders and Schizophrenia

February 2026

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

NASDAQ: BTAI

Forward-Looking Statements

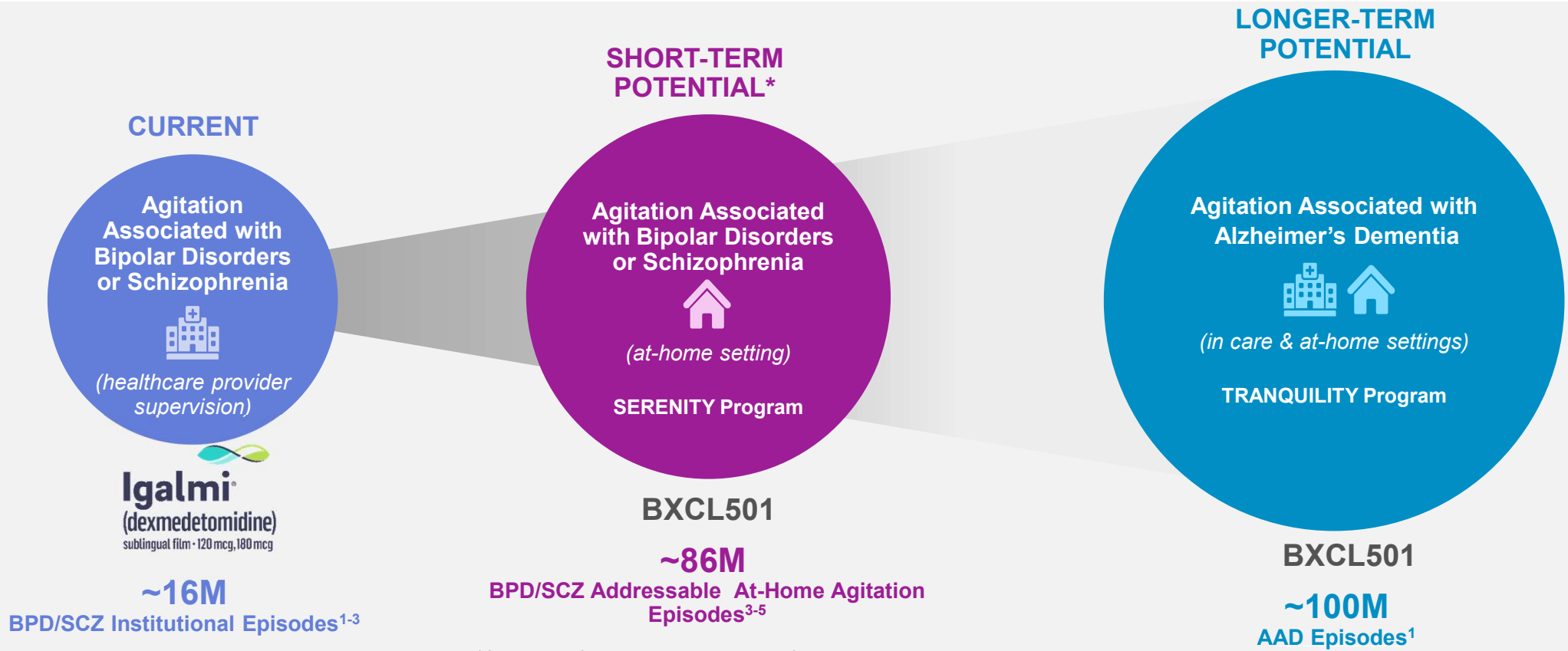
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Unless otherwise indicated, information contained in this presentation concerning our industry and the markets in which BioXcel Therapeutics operates, including its general expectations, market position and market opportunity, is based on its management’s 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.

IGALMI® and BXCL501 Market Expansion Potential

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



*Contingent of FDA review and approval of submitted sNDA

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. IGALMI Demand Study Quant | N=125 Psychs, 55 Psych-like PCPs | Dec-Jan 2026
 6. Data on file; BioXcel Therapeutics, Serenity At-Home study

Agitation Associated with Bipolar Disorder and Schizophrenia is a Behavioral Emergency With Highly Variable Clinical Definition, Diagnoses, and Treatments

Agitation is Characterized by:



ICD-10 Codes Consistent With Agitation^{1,2}

- Restlessness
- Nervousness
- Tension
- Irritability
- Hostility
- Violence
- Impulsiveness
- Overactivity



Emotional Signs and Symptoms³

- Hyperresponsiveness
- Racing thoughts
- Emotional tension



Behavioral Signs and Symptoms³

- Inability to stay calm or still
- Motor and verbal hyperactivity
- Communication impairments

Currently No Approved Treatment

Treatments Used Off-Label⁴

- First generation antipsychotics
- Benzodiazepines (alone or combined with other therapies)
- Second generation antipsychotics
- Other combination therapies
- No treatment

While the manifestations of agitation and treatment options are relatively well-established, there was a need to validate and further characterize the unmet needs experienced in bipolar disorder, schizophrenia, and schizoaffective disorder

1. Roberts J, et al. *BMC Psychiatry*. 2018;18(1):104.

2. International Statistical Classification of Diseases and Related Health Problems 10th Revision. <https://icd10cmtool.cdc.gov/?fy=FY2021>. Accessed August 26, 2021.

3. Martínez-Raga J, et al. *Front Psychiatry*. 2018;9(54).

4. IGALMI Demand Study Quant | N=125 Psychs, 55 Psych-like PCPs | Dec-Jan 2026

There are ~2.3M treated Bipolar and Schizophrenia Patients who Experience Frequent Acute Agitation in the At-Home Setting, of whom ~1.8M may be Eligible for Treatment with IGALMI*

★ Informed by Primary Research¹

★ Informed by Secondary Research

2025 Inputs	SCZ	SZD	BP-I	BP-II	Total
★ Diagnosed Patients (#) ^{2,3}	1.3M	800K	4.8M	1.2M	~8.1M
★ Treated Patients (#) ^{2,3}	1.2M	775K	3.8M	745K	~6.5M
★ Share Living at Home (%) ^{4,5}	80%	80%	90%	90%	
★ Share with Agitation (%) ¹	50%	50%	38%	33%	
Treated Patients Experiencing Agitation at Home (#)	480K	310K	1.3M	220K	~2.3M
★ Share Eligible for IGALMI ¹	77%	77%	78%	79%	-
Addressable Patients	~0.37M	~0.24M	~1.01M	~0.17M	~1.8M
★ Average Annual Episodes ^{1,6,7}	48	48	48	48	
Addressable Annual Episodes	17.7M	11.5M	48.7M	8.4M	~86.2M

*Based on inclusion/exclusion criteria for the Serenity At-Home Study

¹IGALMI Demand Study Quant | N=125 Psychs, 55 Psych-like PCPs | Dec-Jan 2026

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

³<https://www.yalemedicine.org/conditions/schizoaffective-disorder>

⁴Bareis et al. *J Affect Disord.* 2024 Aug 25;366:317–325

⁵Uggerby et al., *Schizophr Res* 2011 Sep;131(1-3):120-6

⁶Roberts J, et al. *BMC Psychiatry.* 2018;18(1):104

⁷Data on file; BioXcel Therapeutics, Serenity At-Home study

Early Intervention At Home May Prevent Severity Escalation

Potentially reduced ER visits, hospitalizations, or first responder interventions



Updated total addressable episodes estimates based on recently completed commercial opportunity assessment

¹IGALMI Demand Study (Jan 2026) | ²Kwong, M et al., Presented at the Academy of Managed Care Pharmacy Nexus 2021, October 18-21, 2021; Symphony claims data.

Testimonial from Leading Mental Health Advocate and Bipolar Disorder Patient, Gabe Howard

“

Living with acute agitation episodes can have many negative outcomes. It can be dangerous.

”

“

Nobody ends up in a hospital setting or being treated for serious mental illness because it's a good day and they're in control.

”



“

[Having a treatment option for the outpatient setting] would dramatically change my life. And anything I could do to lead a better life, to protect myself, my career, my friends, my family. It's a game-changer.

”

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[®]
(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.

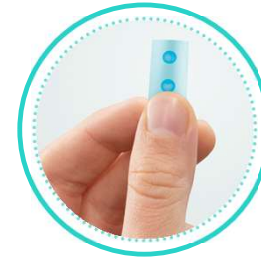
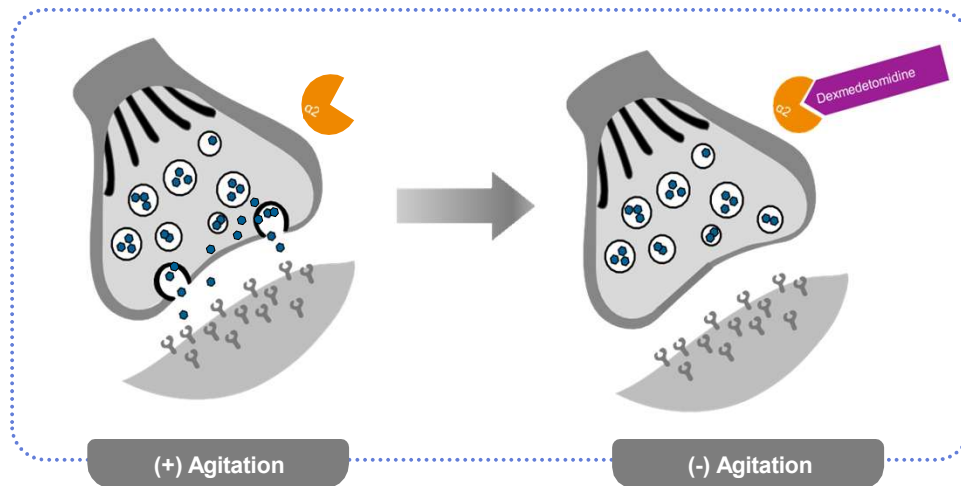
Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@biocelltherapeutics.com.

Please see full [Prescribing Information](#).

IGALMI (Dexmedetomidine) Sublingual Film

Dexmedetomidine MoA addresses agitation

- ✓ 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.

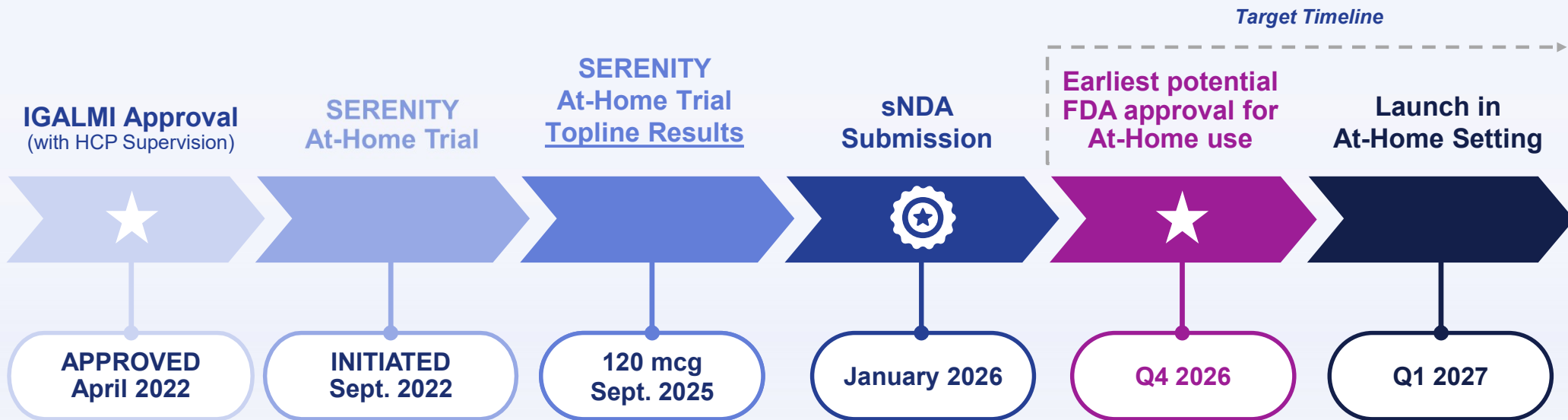


- **Patient-administered** under supervision of healthcare provider
- **Absorption** into the bloodstream and quantifiable in plasma after 5 to 20 minutes with a T-max of 2 hours and half life of 2.8 hours
- IGALMI® **significantly reduced agitation** as early as 20-30 minutes following administration
- Mucoadhesive, so it **cannot be spit out or swallowed**
- **Sublingual** or **buccal** placement
- IGALMI® is **non-scheduled**
- Manufactured and supplied by ARx in Glen Rock, PA

SERENITY At-Home Trial Provides Opportunity for Label Expansion

No FDA-approved therapies for acute agitation associated with Bipolar Disorder or Schizophrenia in the at-home setting

SERENITY Program Journey



SERENITY At-Home Trial

Topline Results



SERENITY At-Home Trial Characteristics

Large safety database generated to support sNDA submission

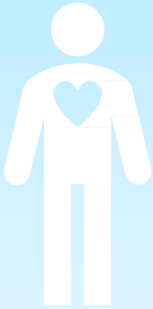
- **120 mcg dose of IGALMI vs placebo over 12-week period**
- **2,437 agitation episodes were treated in 208 patients**
 - 55% Schizophrenia, 45% bipolar; mean (SD) age 47 years (12.9), Years since diagnosis, 17.4 (11.8)
 - 168 (81%) treated patients completed the full 12-week study
 - An average of 11.7 agitation episodes were recorded per treated patient (Average of ~4 episodes per month)
- **All patients were able to successfully self-administer the film**
- **Data collected for 2,628 agitation episodes in 215 patients***
- **A total of 246 patients were randomized****

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



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

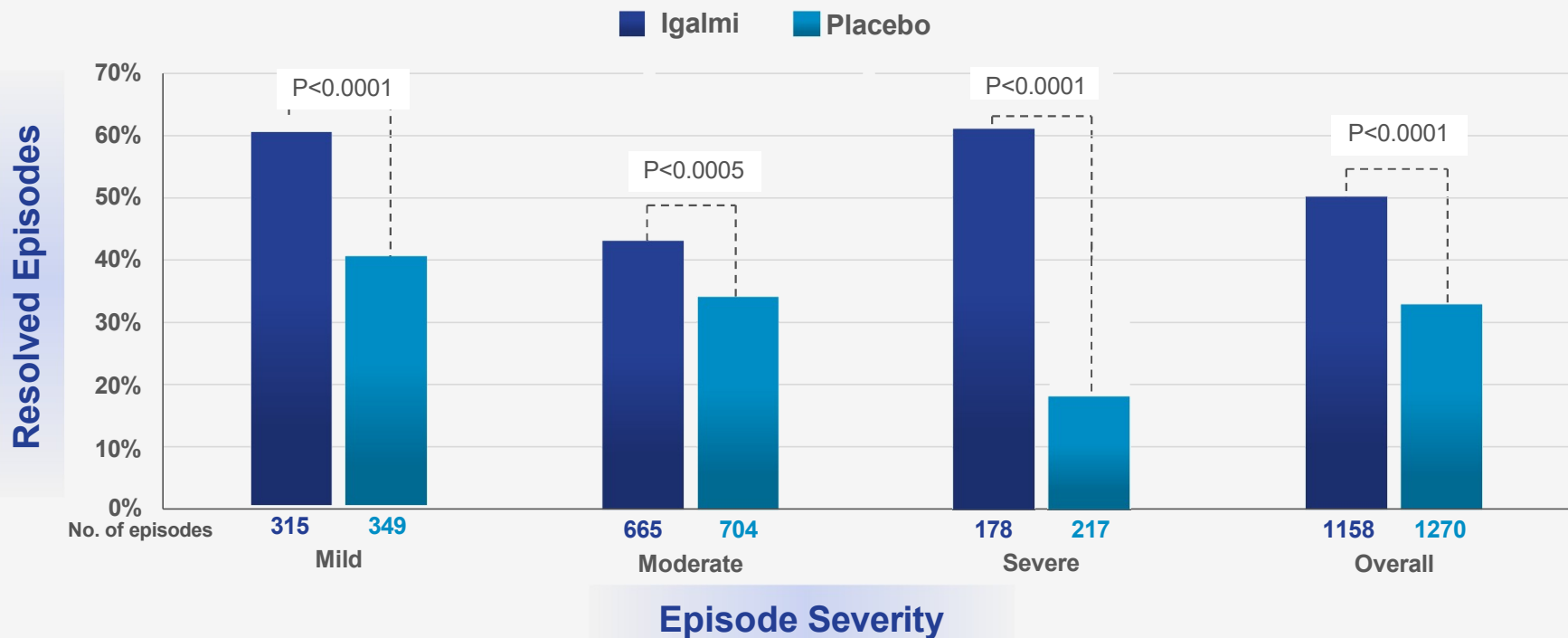
IGALMI was Well Tolerated with No Falls or Syncope Reported during the Trial

Primary objective of the pivotal safety trial was met

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

IGALMI Demonstrated Significant Treatment Benefit Over Placebo Regardless of Agitation Episode Severity

PERCENT OF FULLY RESOLVED EPISODES BY BASELINE SEVERITY



Patient Perspectives

Market Research Performed February 2023



Qualitative and Quantitative Patient and Caregiver Research was Completed in 2022 and 2023

The research included **Bipolar and Schizophrenia patients and caregivers** who have experienced an episode of agitation in the past year. A summary of the sample is below.



Respondent Type

BPD Patient	35
BPD Caregiver	25
SCH Patient	11
SCH Caregiver	9



Current Rx

Anti-psychotics	38
Anti-depressants	38
Anti-anxiety	32
Mood stabilizers	25



Years Since Diagnosis

<2 years	4
2-5 years	14
6-10 years	17
10+ years	44
Don't know/ not sure	1

Bipolar and Schizophrenia Patients' Perspectives of Agitation

Difficult for patients to articulate; patients feel a sense of helplessness

Overall Quality Descriptors



- Beyond their control
- Different from ordinary fear and anger
- Feeling a lack of agency over their own thoughts and actions
- Likely to escalate
- Emotional experience of agitation likely makes it harder to make concrete, proactive decisions on when to seek help



Patient Quote

CLICK FOR VOICE



[I]t feels like there's something inside of me telling me **there's something wrong**, and I can't sit still, and I feel like my body's about to jump out of my skin. It's just really annoying, and **you get short-tempered** because of it and angry and snappy at people. **It's hard to describe** because you can't get it to go away, and it's just there, and **you're stuck with it**, and **there's nothing you can do** to make it go away.”

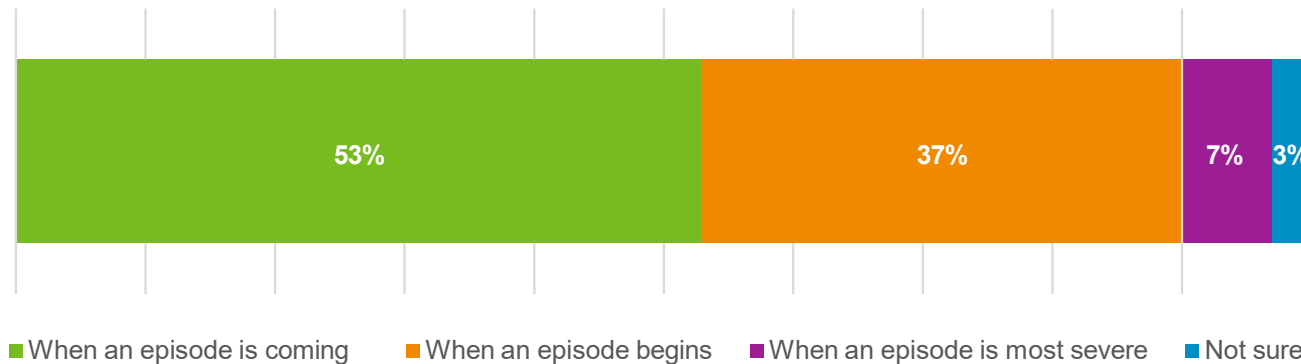
(Q1, R10, PT, SCZ)

Question 1: Take a moment to describe what it is like to experience an episode of agitation associated with schizophrenia or bipolar disorder. How do you (or your loved one) feel during these times, both physically and emotionally?
Source: InVibe July 2022 (N=240 Bipolar and Schizophrenia patients)

Episode Intervention Target

Patients indicate that they want to manage the episode with IGALMI either just before or at the first sign of escalation in the at-home setting.

Best Time To Take IGALMI
(% PTs/CGs n=80)

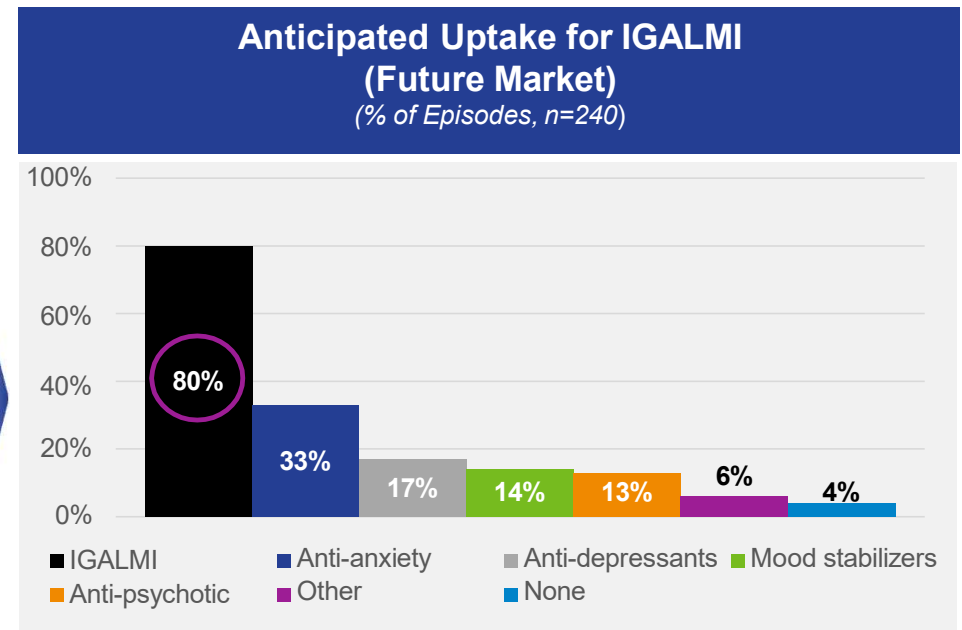
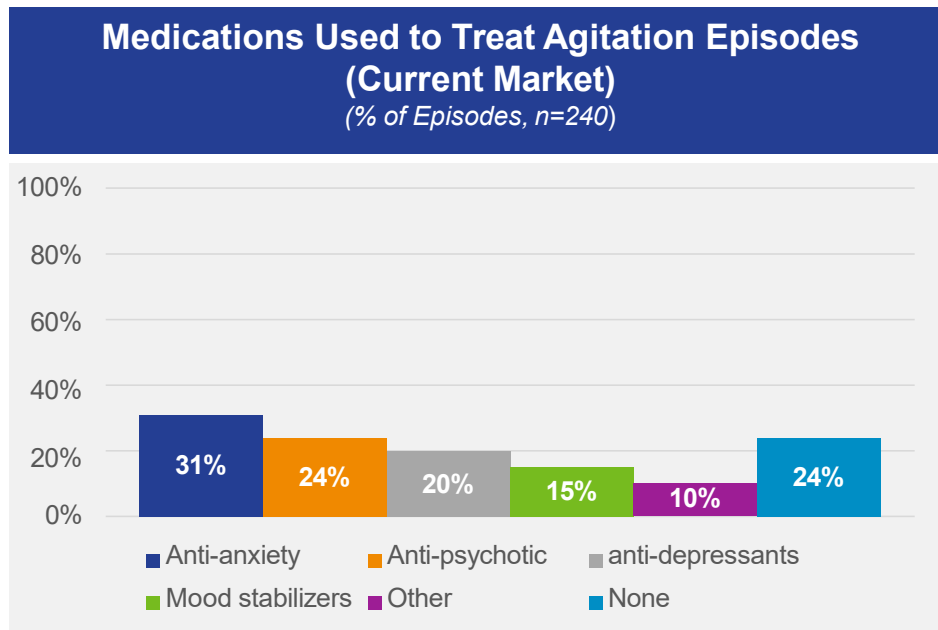


“ I would love to be able to have it available **when I knew an episode was coming**. That it would help bite it in the butt, so to say. That would be such a benefit for me. ”

(VR4, R8, PT, BPD, age 57)

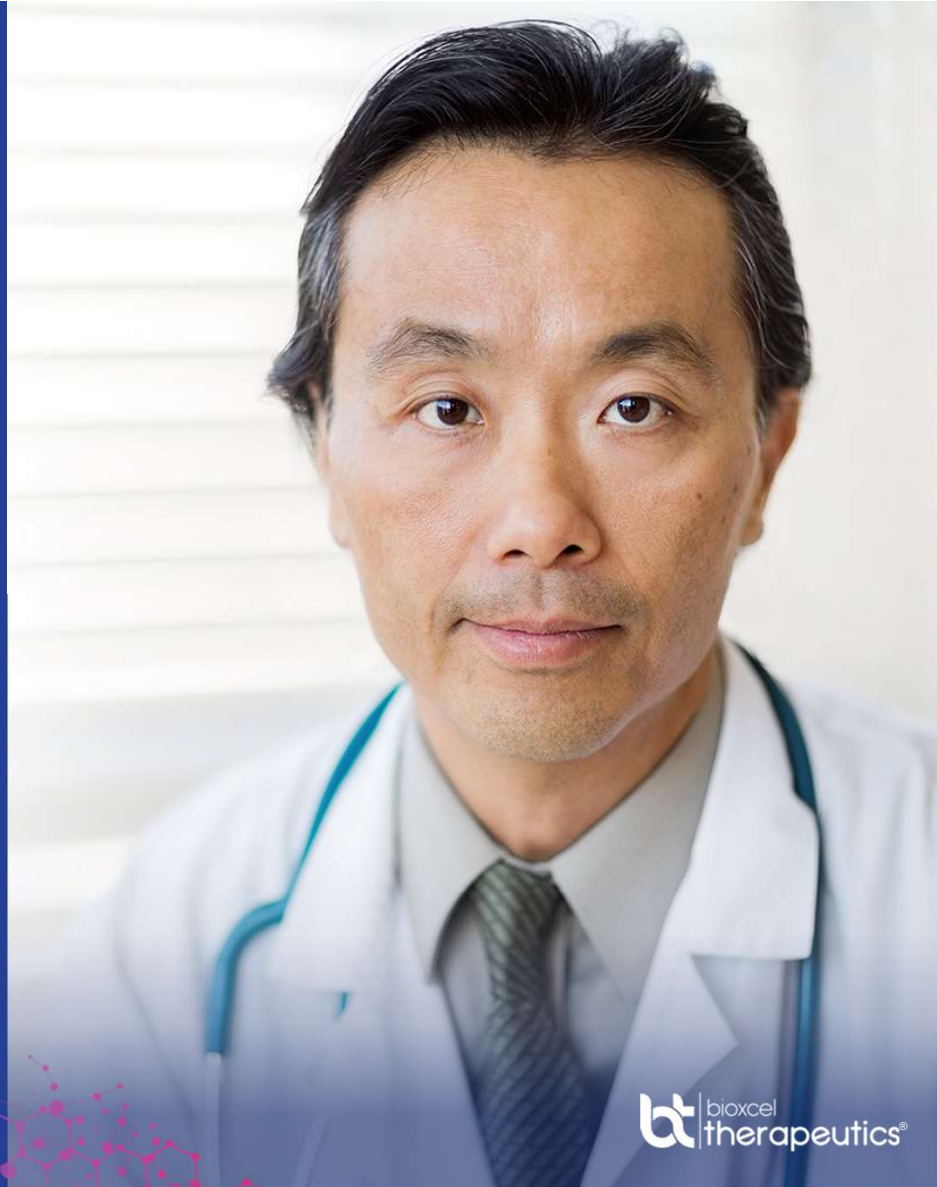
Patients Preference Estimate

Based on a target product profile, patients say they would use IGALMI for 80% of their episodes



HCP Perspectives

Third-Party Market Research
Performed December 2025 - January 2026



Qualitative and Quantitative Research with HCPs and Payers was Completed in Q1 2026

Phase 1: Qualitative Interviews

- **N=20, 60-minute web-assisted telephone interviews**
 - N=10 Psychiatrists
 - N=5 Psych-like PCPs
 - N=5 Payers (All payers served on P&T and belong to a plan covering >1M lives)

	Mean # of Patients Experiencing Frequent ¹ Acute Agitation Episodes	
	Bipolar Disorder	Schizophrenia
Psychiatrists	151	113
Psych-like PCPs	112	35

Phase 2: Quantitative Survey

- **N=180 HCPs, Psychs (125); Psych-like PCPs (55)**
- **Conducted via ~15-minute online survey**

	Mean # of Patients Experiencing Frequent ¹ Acute Agitation Episodes	
	Bipolar Disorder	Schizophrenia
Psychiatrists	91	102
Psych-like PCPs	84	65

The Prevalence of Frequent* At-Home Acute Agitation Episodes Is Reported to Be More Common in Schizophrenia vs Bipolar Disorder

Proportion of Patients Who Experience Frequent Acute Agitation Episodes
(in % of patients; n=180 base: all)

Median % of Patients Experiencing Frequent Acute Agitation

Bipolar Disorder

36%






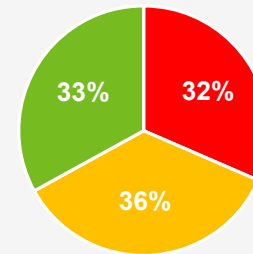
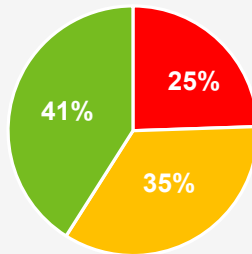
Schizophrenia

50%



Distribution Of Patients by Agitation Severity

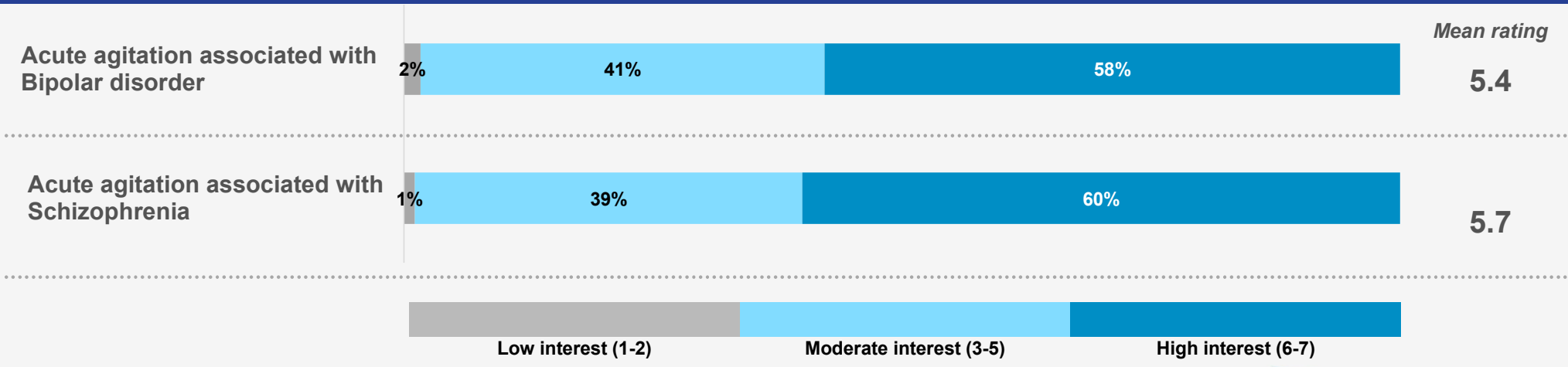
Severe	
Moderate	
Mild	



*Frequent defined as 10-15 episodes per year
 Source: IGALMI Demand Study Quant | N=125 Psychs, 55 Psych-like PCPs | Dec-Jan 2026 |

HCPs Perceive the Unmet Need Associated with Acute Agitation to be Moderate to High in Patients with Schizophrenia and Bipolar Disorder

Current Perceived Level of Unmet Need for an FDA-Approved Therapy
(in % of respondents; n=180 base: all)



No significant differences by specialty

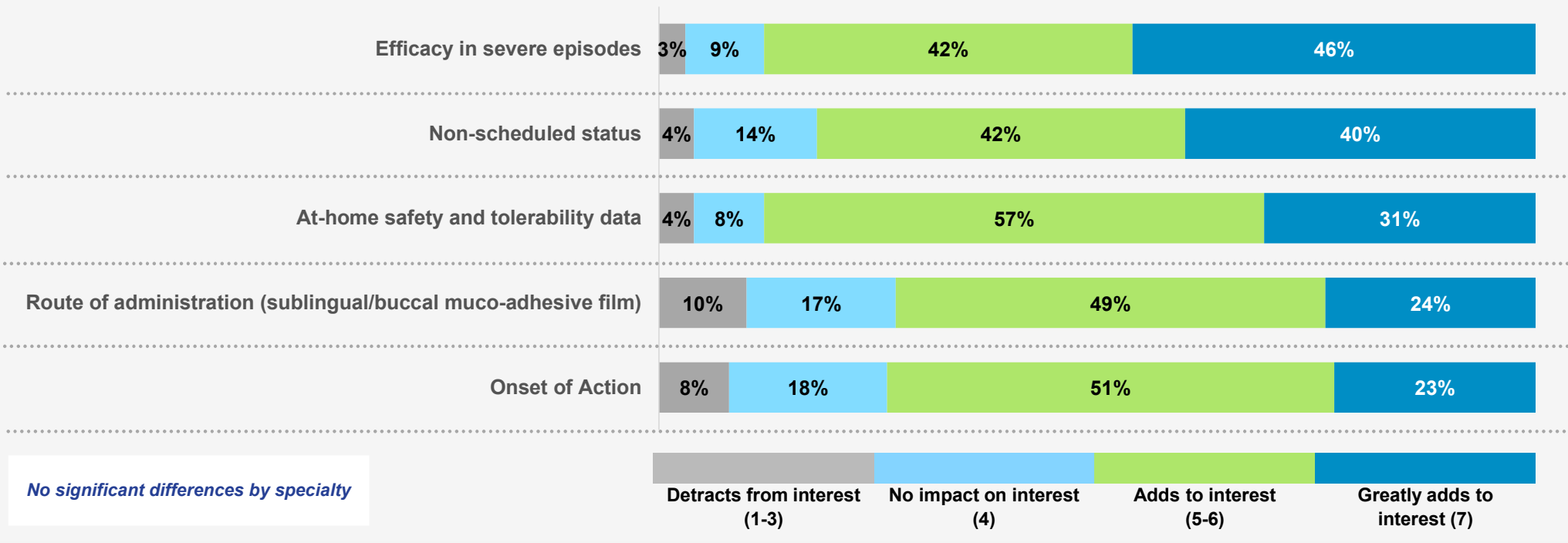
“We tend to rely on benzodiazepines a lot and because those have addictive potential, I think there’s some unmet need for a reliable, quick, calming agent that doesn’t have habit forming potential...I think there’s a bit of an unmet need for fast reacting formulations for home use”
 – Psych

“Even with all the stuff that we have, there are still quite a few people who are not getting taken care of. But it’s not purely the lack of medications. It’s also that these are conditions where treatment is undesirable from the patient standpoint... they’re afraid to take the medications for a variety of reasons”
 – Psych-like PCP

Most Impactful Brand Attributes Centered Around Efficacy, Non-Scheduled Status, and Onset of Action, All Driving Interest for ~75% of Respondents

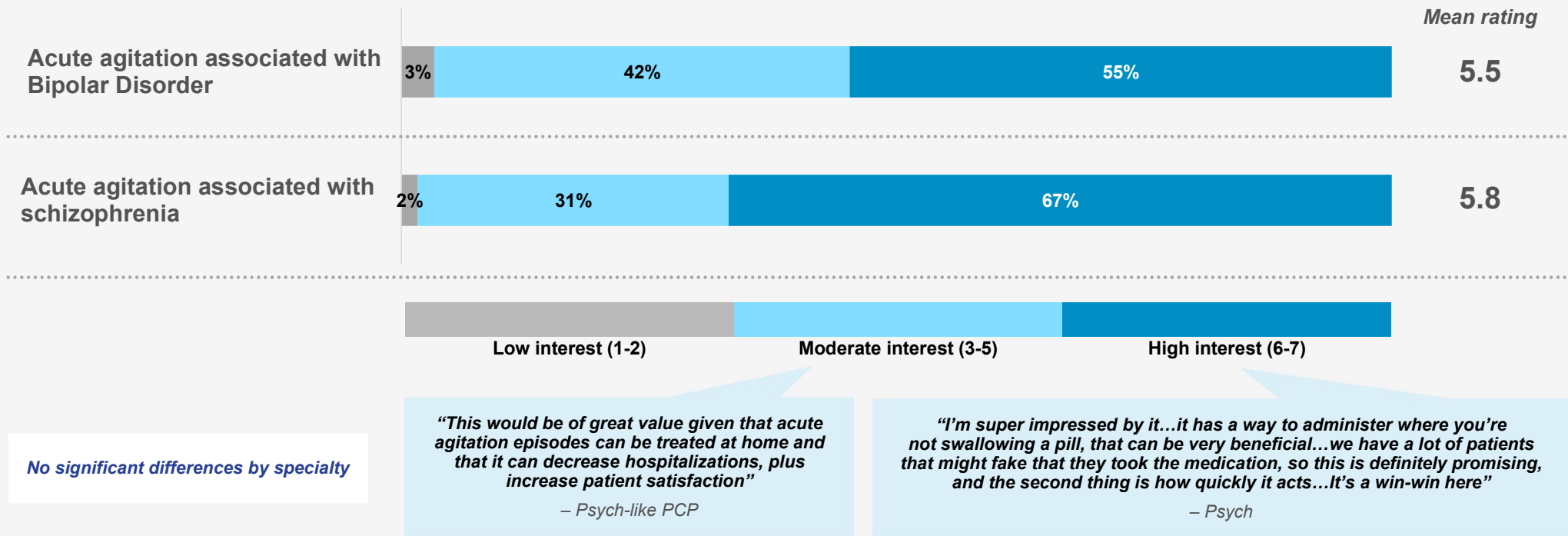
Impact of IGALMI Attributes on Interest (Most Positive Impact)

(in % of respondents; n=180; base: all; ordered by greatly adds to interest rating)



HCPs Expressed Moderate-to-High Interest in IGALMI Across Conditions; Interest Was Slightly Higher in Schizophrenia

Level of Interest in IGALMI *(in % of respondents; n=180; base: all)*

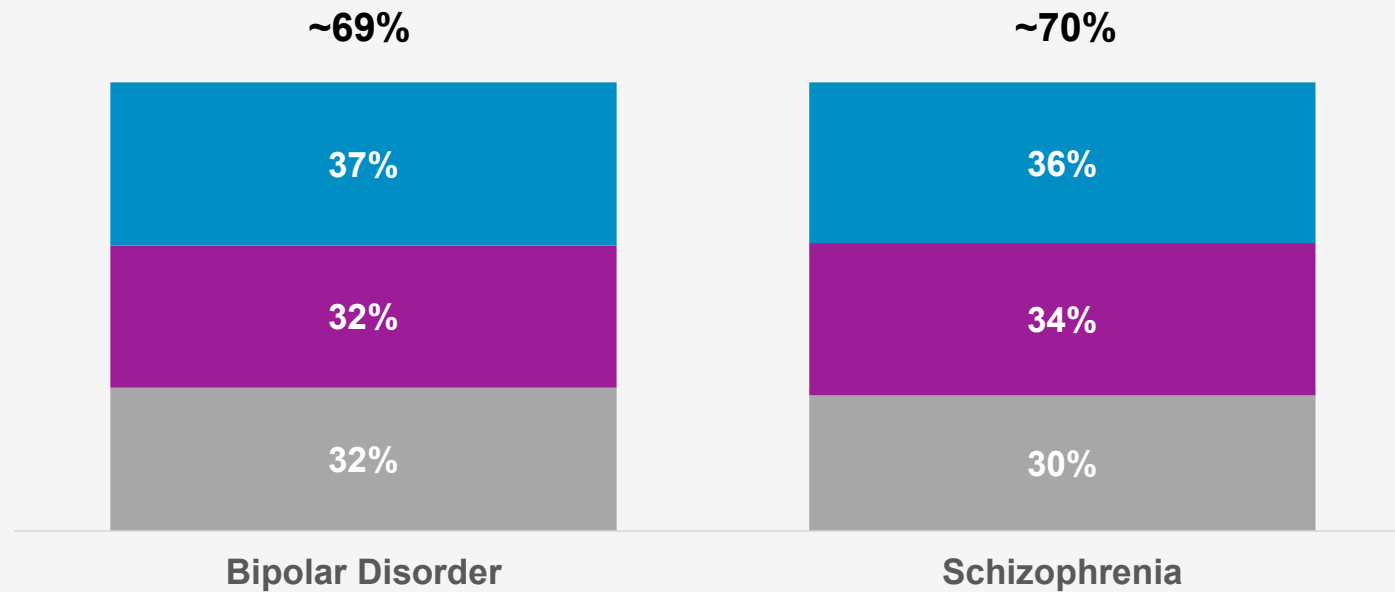
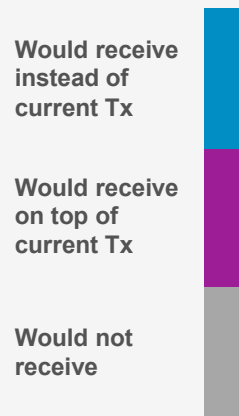


HCPs Expect That up to 70% of Patients Would Receive IGALMI as Either a Replacement for, or in Combination with Their Current Treatment

Future Treatment if IGALMI Were Available

(in % of patients; base: out of HCPs who have patients with the designated disease)

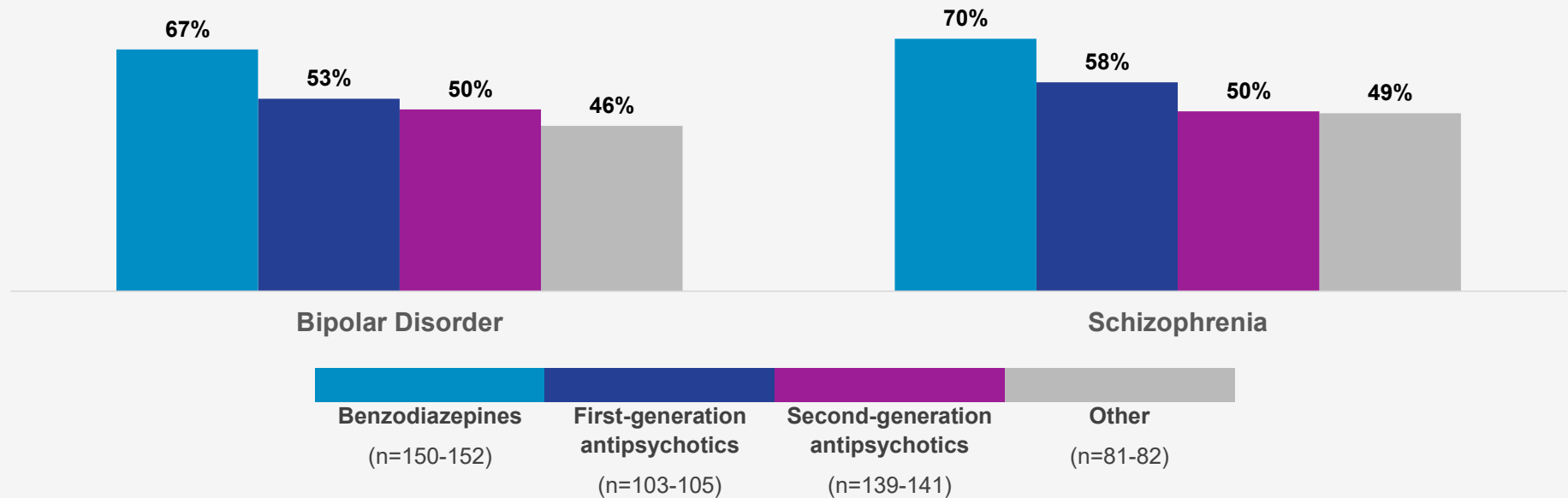
Total % who would receive:



HCPs See Potential for IGALMI to Replace Benzodiazepine Use, Allowing Patients to be Treated for Agitation without Risk of Addiction

Treatment That IGALMI Would Replace

(in % of respondents (select multiple); base: at least 1 patient whose treatment would be replaced and using treatment)



Payer Perspectives



Payers Echoed HCPs' Positive Reactions Toward IGALMI



Key Takeaway:

Overall, payers reacted positively to the IGALMI TPP and expect it to be added to their organization's formulary, expressing interest in an FDA-approved therapy that demonstrates strong efficacy with minimal safety concerns

Current Perceptions	Expectations for IGALMI
<p>Many frequently-used agitation treatments are generic and thus not strictly managed, even with combo usage</p> <p><i>Excludes branded atypical antipsychotics, which often require step-through</i></p>	<p>IGALMI is expected to have formulary coverage with access restrictions</p> <ul style="list-style-type: none"> • Prior authorizations, quantity limits and/or step-through generics are expected, with restrictions in place consistent with criteria of the study • Quantity limits may be determined by the number of acute agitation episodes that patients are experiencing (like in migraine), or by what was seen in the clinical trial (4 doses per month), which would be highly limiting • Potential for exceptions for severe patients (e.g., those with a history of hospitalization) • IGALMI may fall under the mental health carve out with Medicaid and Medicare
<p>Hospitalizations due to agitation are recognized but not salient</p>	<p>A treatment that demonstrates a reduction in hospitalizations would be accepted if demonstrated in the data</p> <ul style="list-style-type: none"> • While payers were intrigued by data showing the cost of hospitalization in schizophrenia and bipolar disorder, they may also need the treatment to show a reduction (vs. an implied reduction)
<p>Agitation frequency not well understood</p>	<p>Additional detail on agitation frequency may be needed to help payers evaluate potential utilization and cost to their plan</p> <ul style="list-style-type: none"> • Since episodes happen at home, payers do not currently manage or have access to this information

Commercial Launch Planning



Key Commercial Insights Shaping Launch Planning

- Acute agitation in SCZ/SZD and BP-I/BP-II at home is common and current treatments are unapproved and recognized as deficient ('26 HCP Qual/Quant)
 - ⇒ **Initiate HCP education on acute agitation and the existing medical need**
- HCPs reacted positively to IGALMI Target Product Profile (TPP) based on Serenity At-Home data projecting use in ~70% of Bipolar/Schizophrenia patients ('26 HCP Qual/Quant)
 - ⇒ **Begin HCP education on IGALMI features**
 - ⇒ **Ensure robust publication of data from the study**
- Patients / Caregivers reacted very positively to TPP for at-home use, selecting IGALMI for 80% of future episodes of acute agitation ('23 Consumer Study)
 - ⇒ **Commence consumer outreach once prescribers are fully educated about the label expansion**
- Payers reacted positively to IGALMI TPP and expect formulary placement with prior authorization to approved label ('25 Payer Qual)
 - ⇒ **Develop value proposition and market access strategy for formulary placement discussions starting 3 months prior to approval**

Preparing for Commercialization

Detailed launch playbook being developed

HCPs

- Develop go-to-market strategy
- Identify key market shaping activities
- Prescriber segmentation and salesforce sizing



Consumers

- Define segments
- Create disease state awareness program
- Design patient assistance program



Payers

- Create value proposition
- Develop cost-offset story supported by HEOR data
- Assess market access strategy for the at-home market



Thank you!



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