



BioXcel Therapeutics Submits Pre-Supplemental New Drug Application Meeting Package in Support of Potential Label Expansion for IGALMI®

July 21, 2025

Company focused on obtaining approval for outpatient (at-home) use of IGALMI® for the acute treatment of agitation associated with bipolar disorders or schizophrenia

Pre-Supplemental New Drug Application meeting with FDA scheduled for August 20, 2025

NEW HAVEN, Conn., July 21, 2025 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience, today announced the submission of a pre-supplemental New Drug Application (pre-sNDA) meeting package to the U.S. Food and Drug Administration (FDA) for IGALMI® in support of a potential label expansion for outpatient use for the acute treatment of agitation associated with bipolar disorders or schizophrenia.

The primary purpose of the pre-sNDA meeting, scheduled for August 20, 2025, is to gain alignment with the FDA regarding the content and format of the planned sNDA submission, which the Company is preparing. Additionally, the Company plans to reconfirm the understanding reached during the Type C meeting with the FDA on March 6, 2024, that FDA views the Company's current development plans as a reasonable approach to support expanding the label to include at-home (outpatient) use of 120 mcg BXCL501 for the acute treatment of agitation associated with schizophrenia or bipolar disorders in the at-home setting.

"We are on track with our clinical development and regulatory submission plan for BXCL501 (IGALMI®)," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "Our clear focus continues to be bringing for the first time to patients an at-home treatment for acute agitation associated with schizophrenia or bipolar disorders. We have received two favorable recommendations from the Data Safety Monitoring Board (DSMB), are nearing completion of the SERENITY At-Home Pivotal Phase 3 trial, and expect to report top-line results from the study this quarter."

An estimated 23 million annual episodes of agitation associated with bipolar disorders or schizophrenia occur in the at-home setting annually in the U.S.¹⁻³. However, there are no FDA-approved therapies for the acute treatment of agitation in this setting.

Additional information on the SERENITY At-Home trial is included in a [corporate presentation](#) in the Investors section of the Company's website: bioxceltherapeutics.com.

About BXCL501

Outside of its approved indication by the U.S. Food and Drug Administration as IGALMI® (dexmedetomidine) sublingual film, BXCL501 is an investigational proprietary, orally dissolving film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist. BXCL501 is under investigation by BioXcel Therapeutics for the acute treatment of agitation associated with Alzheimer's dementia and for the acute treatment of agitation associated with bipolar I or II disorder or schizophrenia in the at-home setting. The safety and efficacy of BXCL501 for these investigational uses have not been established. BXCL501 has been granted Breakthrough Therapy designation by the FDA for the acute treatment of agitation associated with dementia and Fast Track designation for the acute treatment of agitation associated with schizophrenia, bipolar disorders, and dementia.

About the SERENITY At-Home Phase 3 Trial

The SERENITY At-Home Phase 3 trial is a double-blind, placebo-controlled study designed to evaluate the safety of a 120 mcg dose of BXCL501 for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting. The trial is designed to evaluate 200 patients with a history of agitation episodes residing at home either alone or with caregivers/informants. Patients are self-administering 120 mcg of BXCL501 or placebo when agitation episodes occur over the 12-week trial period, with safety data (adverse events) collected during the trial. In addition, patients or caregivers/informants will complete a modified global impression of severity (mCGIs) and a clinical global impression of change (mCGI-C) two hours after dosing as an exploratory endpoint to evaluate use in the outpatient setting.

About IGALMI® (dexmedetomidine) sublingual film

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 at lgalmi.com.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience. Its wholly owned subsidiary, OnkosXcel Therapeutics, is focused on the development of medicines in immuno-oncology. The Company's drug re-innovation approach leverages existing approved drugs and/or clinically validated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. For more information, please visit bioxceltherapeutics.com.

Forward-Looking Statements

This current report 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 current report other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: the Company's upcoming sNDA meeting and sNDA submission. 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 the factors discussed under the caption "Risk Factors" in its most recent Quarterly Report on Form 10-Q, as such factors may be updated from time to time in its other filings with the SEC. 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 current report. 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 current report.

Contact Information

Corporate/Investors

Russo Partners

Nic Johnson

nic.johnson@russopartnersllc.com

1.303.482.6405

Media

Russo Partners

David Schull

david.schull@russopartnersllc.com

1.858.717.2310

Source: BioXcel Therapeutics, Inc.

IGALMI® is a registered trademark of BioXcel Therapeutics, Inc.

References

1. Data on file relating to agitation episodes associated with schizophrenia or bipolar I or II disorder. BioXcel Therapeutics, Inc. New Haven, CT December 2020. Episode estimations may not reflect potential treatable episodes, and actual addressable market may be smaller.
2. Data from Wu EQ, Shi L, Birnbaum H, et al. Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach. *Psychol Med.* 2006;36(11):1535-1540. Estimates based on whether indications are approved for at-home use for the intended patient population and such patients are treatable. Episode estimations may not reflect potential treatable episodes, and actual addressable market may be smaller.
3. National Institute of Mental Health. Prevalence of bipolar disorder in adults. November 2017. Accessed December 16, 2022. <https://www.nimh.nih.gov/health/statistics/bipolar-disorder>. Episode estimations may not reflect potential treatable episodes, and actual addressable market may be smaller.