BioXcel Therapeutics Presents New Data from SERENITY At-Home Phase 3 Trial for Agitation Associated with Bipolar Disorders or Schizophrenia at 2026 ASCP Annual Meeting

May 28, 2026

NEW HAVEN, Conn., May 28, 2026 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience, today announced the presentation of new positive data from the Phase 3 SERENITY At-Home trial evaluating BXCL501 (sublingual dexmedetomidine) for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting at the 2026 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, taking place May 26 – 29 in Miami, FL.

Positive primary results from the randomized, double-blind, placebo-controlled Phase 3 SERENITY At-Home safety trial have been presented previously. The current presentation describes new analyses of exploratory efficacy outcomes from this trial, which evaluated BXCL501 in patients with agitation associated with bipolar disorders or schizophrenia in the at-home setting. Patients self-administered the study drug during agitation episodes over a 12-week period and assessed symptom severity using the modified Clinical Global Impression-Severity (mCGI-S) scale before dosing and two hours post-dose. The analyses demonstrated that BXCL501 reduced agitation compared to placebo across all levels of baseline symptom severity, including severe, moderate and mild agitation, with the most pronounced treatment effect observed in patients experiencing severe agitation episodes. Importantly, benefit was maintained with repeated dosing throughout the study period regardless of baseline agitation severity.

The U.S. Food and Drug Administration has assigned a Prescription Drug User Fee Act (PDUFA) target action date of November 14, 2026, for the Company's supplemental New Drug Application (sNDA) for IGALMI® for at-home use in the acute treatment of agitation associated with bipolar disorders or schizophrenia, which was accepted earlier this year.

"These new analyses from the SERENITY At-Home Phase 3 trial further strengthen the growing body of evidence supporting BXCL501 as a potential treatment option for acute agitation associated with bipolar disorders or schizophrenia in the at-home setting," said Dusan Kostic, Ph.D., SVP, Clinical and Medical Affairs at BioXcel Therapeutics. "If approved, BXCL501 could become the first FDA-approved treatment for acute agitation in the at-home setting, significantly impacting the lives of patients."

Presentation Details

Title: Efficacy of Sublingual Dexmedetomidine in the Home Setting for Reduction in Agitation Across Baseline Severity of Symptoms in Patients with Schizophrenia or Bipolar Disorder
Session Date and Time: Thursday, May 28, 11:30 a.m. – 1:15 p.m.
Co-Authors: Michael De Vivo, Lavanya Rajachandran, Heather Robison, Rashmi Deshpande, Dusan Kostic

Poster Number: T118

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company built on artificial intelligence ("AI") 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.

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.

Forward-Looking Statements

This press release 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 press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: approval by the FDA of the sNDA and expanded label for IGALMI, IGALMI's ability to make a transformative impact on the lives of a large patient population, ability to advance a strategic option to maximize shareholder value and advance the commercial and development plans for IGALMI. 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, 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 and the Investors section of the Company's website at. 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 press release.

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