BioXcel Therapeutics to Host Virtual Roundtable Featuring Leading Medical Experts Addressing Latest Developments in Treatment of Acute Agitation in Alzheimer's Dementia

February 19, 2026

Discussion will focus on the high unmet need and the lack of FDA-approved treatment options associated with acute agitation episodes in Alzheimer's dementia

Large patient population affected by Alzheimer's agitation, with approximately ~100 million annual episodes [1]

KOL Roundtable to be held on Friday, February 27, at 2:00 p.m. EST

NEW HAVEN, Conn., Feb. 19, 2026 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience, today announced it will host a virtual key opinion leader (KOL) roundtable on Friday, February 27, from 2:00 to 3:00 p.m. EST.

The event is a continuation of the Company's awareness and educational initiatives focused on addressing acute agitation episodes associated with neuro-psychiatric diseases. The discussion will center on acute agitation episodes in Alzheimer's dementia, highlighting the large unmet need for treatment options for this patient population and caregivers across a variety of settings. Acute agitation episodes related to Alzheimer's dementia impacts a substantial patient population, accounting for approximately 100 million episodes annually.[1]

The panelists will also explore the potential role of BXCL501 as a differentiated treatment option in this disease area. BXCL501 is a late-stage product candidate being evaluated for the treatment of acute agitation episodes in Alzheimer's dementia. There are no FDA-approved therapies for the treatment of acute agitation episodes in Alzheimer's dementia.

Currently, the Company is advancing preparations for the initiation of the TRANQUILITY In-Care Phase 3 trial, a second double-blind, placebo-controlled study to evaluate BXCL501 for the treatment of acute agitation episodes in Alzheimer's dementia.

The roundtable event will be moderated by Anjalee Khemlani, an award-winning healthcare journalist and podcast host (Give It To Me Straight, Doc), known for her in-depth reporting on the industry, most recently at Yahoo Finance.

The roundtable will feature the following medical professionals:

- George T. Grossberg, MD, Inaugural Henry & Amelia Nasrallah Endowed Professor, Director Division of Geriatric Psychiatry, Department of Psychiatry & Behavioral Neuroscience, Saint Louis University School of Medicine
- Anton P. Porsteinsson, MD, William B. and Sheila Konar Professor of Psychiatry, Neurology, Neuroscience, and Medicine, Director, Alzheimer's Disease Care, Research and Education Program (AD-CARE), University of Rochester School of Medicine and Dentistry
- Angela Sanford, MD, Professor of Internal Medicine-Geriatrics, Saint Louis University School of Medicine

Webcast Details:

To register for the webcast, click here. A replay of the event will be available on the BioXcel Therapeutics website following the live presentation.

Attendees may submit questions via written Q&A during the event. Attendees are encouraged to log in approximately 10 minutes prior to the scheduled start time.

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 TRANQUILITY In-Care Phase 3 Trial

The TRANQUILITY In-Care trial is designed as a double-blind, placebo-controlled study to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 over a 12-week period for agitation associated with Alzheimer's dementia in the care setting. The trial is expected to enroll approximately 200 patients 55 years and older who have mild, moderate, or severe dementia with mini-mental state examination scores of 0 to 25 and who reside in skilled nursing facilities, memory care units, or assisted living facilities. Patients will self-administer 60 mcg of BXCL501 or placebo when episodic agitation episodes occur over the trial period. The primary endpoint is expected to be a change from baseline in the Positive and Negative Syndrome Scale-Excitatory Component (PEC) total score at two hours post-first dose. Additional PEC and Clinical Global Impressions – Improvement Scale measurements will also be obtained during the trial.

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: the virtual KOL roundtable centered on acute agitation episodes in Alzheimer's dementia; the potential role of BXCL501 as a differentiated treatment option in this disease area; and the initiation of the TRANQUILITY In-Care Phase 3 trial, a second double-blind, placebo-controlled study to evaluate BXCL501 for the treatment of acute agitation episodes in Alzheimer's dementia. 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 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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References

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