BioXcel Therapeutics Announces Enrollment of First Patients in U.S. Department of War-Funded Study of BXCL501 (Sublingual Dexmedetomidine) for Treatment of Acute Stress Reactions

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DoW-funded Phase 2a trial led by University of North Carolina at Chapel Hill (UNC) Institute for Trauma Recovery

Positive outcomes from trial can potentially impact Veteran Affairs/Department of War Clinical Practice Guidelines for management of acute stress reactions (ASR)

NEW HAVEN, Conn., April 08, 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 enrollment of the first patients in a U.S. Department of War (DoW)-funded Phase 2a clinical trial evaluating BXCL501 (sublingual dexmedetomidine) for the treatment of acute stress reactions (ASR), also known as acute stress disorder (ASD). The trial is being led by the University of North Carolina at Chapel Hill (UNC) Institute of Trauma Recovery and marks a significant milestone in the collaboration between BioXcel Therapeutics and UNC.

The double-blind, placebo-controlled trial (NCT06943404) is designed to enroll 100 patients experiencing ASRs following motor vehicle collisions and will evaluate the potential of BXCL501 to reduce ASR symptom severity, improve neurocognitive function, and prevent the progression to chronic posttraumatic neuropsychiatric symptoms. BioXcel Therapeutics is supplying BXCL501 for the trial.

ASR symptoms occur in the days and weeks after trauma, and include anxiety, sleep disturbance, concentration difficulty, pain, and somatic symptoms such as dizziness and lightheadedness. Chronic adverse posttraumatic neuropsychiatric symptoms occur when acute stress reactions do not resolve, and include persistent pain, posttraumatic stress, and depressive symptoms. ASRs are common among service men and women, police and other first responders, and survivors of shootings and natural disasters. ASRs affect more than 40 million Americans who seek emergency department care annually after traumatic stress exposure (e.g., motor vehicle collision).[1,2]

"Supporting service men and women resilience and effectively treating ASRs is an urgent military priority," said Samuel McLean, M.D., MPH, Professor of Psychiatry and Emergency Medicine and Director of the Institute for Trauma Recovery at the UNC School of Medicine, and Principal Investigator of the study. "We are excited to evaluate BXCL501 as a potential treatment to address this critical unmet need of service men and women and civilians experiencing ASRs."

"We look forward to supporting Dr. McLean and his team at UNC on this important study evaluating BXCL501 for the treatment of ASRs," Vimal Mehta, Ph.D., Chief Executive Officer of BioXcel Therapeutics, added. "The results from this study could have clinical benefit for this patient population and support BXCL501's potential as a pipeline-in-a-product."

The 2023 VA/DoW Clinical Practice Guidelines for management of PTSD and ASR recommend trauma-focused psychotherapy, specifically cognitive-behavioral therapy (CBT), as the primary treatment to reduce ASR symptoms and prevent PTSD. Pharmacotherapy is generally not recommended for treating ASR, and benzodiazepines are contraindicated. A positive outcome from this trial could contribute to a reassessment of those guidelines and establish a pharmacological treatment pathway for patients suffering from ASR and have an immediate and critical need for treatment.[3]

The ASR research is supported by the DoW under award number HT9425-24-1-1108. The content presented in this release is solely the responsibility of the authors and does not necessarily represent the official views of the DoW.

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.

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: potential future

development of BXCL501 in ASR; BXCL501's potential as a "pipeline within a product"; the potential for updates to the VA/DoW Clinical Practice Guidelines for management of PTSD and ASR recommend trauma-focused psychotherapy; and a potential reassessment of those guidelines and establish a pharmacological treatment pathway for patients suffering from ASR. 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.

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

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References

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2 Lewis, Gemma C., et al. "Incidence and predictors of acute psychological distress and dissociation after motor vehicle collision: A cross-sectional study." Journal of Trauma & Dissociation, vol. 15, no. 5, 30 Sept. 2014, pp. 527–547, https://doi.org/10.1080/15299732.2014.908805.

3 "Va.Gov: Veterans Affairs." Management of Posttraumatic Stress Disorder and Acute Stress Disorder 2023, 3 June 2009, www.healthquality.va.gov/guidelines/mh/ptsd/.