BioXcel Therapeutics to Host Virtual Key Opinion Leader Event to Highlight BXCL501 as a Potential Treatment for Agitation and Opioid Withdrawal Symptoms

February 12, 2021

Live webcast to be held on February 19th from 11:00 am ET to 2:00 pm ET

NEW HAVEN, Conn., Feb. 12, 2021 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (“BioXcel” or the “Company”) (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced that the Company will host a virtual Key Opinion Leader (“KOL”) event on Friday, February 19, 2021 from 11:00 am ET to 2:00 pm ET. The event aims to highlight BXCL501, the Company’s investigational, proprietary, orally dissolving thin film formulation of dexmedetomidine (“Dex”), and its potential as a treatment option for multiple neuropsychiatric conditions.

BioXcel’s management team will be joined by leading experts for each indication to discuss the significant unmet medical need and BXCL501’s potential to change the treatment paradigm.

KOL Presenters Include:

Schizophrenia/Bipolar Related Agitation

- Scott Zeller, MD, is an Assistant Clinical Professor of Psychiatry at the University of California-Riverside and Touro University medical schools. He served as Chief of Psychiatric Emergency Services of the Alameda Health System for twenty years, as well as founded Project BETA, which revolutionized the care approach for agitated individuals worldwide; he has also authored several books and numerous research articles on Agitation. Dr. Zeller is the Past President of the American Association for Emergency Psychiatry and Past Chair of the multidisciplinary National Coalition on Psychiatric Emergencies.

Dementia Related Agitation

- Alan Breier, MD, is a Mental Health Research and Education Senior Professor of Psychiatry at Indiana University School of Medicine. Additionally, at the University, he is Vice-Chair for Clinical Research, the Chief of IU Psychotic Disorders Program, and the Director of the Prevention and Recovery Center for Early Psychosis. Previously, he served as the Chief Medical Officer and Vice President of Pharmaceutical Products at Eli Lilly, where he was also the product team leader for the antipsychotic drug Zyprexa®.

- Larry Ereshefsky, PharmD, FCCP, BCPP, is a founding member of the International Society for CNS Clinical Trials and Methodology, serving as Chair of the Behavioral and Psychological Symptoms of Dementia Steering Committee and Co-Chaired the Agitation and Apathy sub-groups. He is a retired Regents Professor of Pharmacy, Psychiatry, and Pharmacology at the University of Texas/UT Health Science Center and has designed and conducted more than 80 CNS clinical trials evaluating treatments for Alzheimer’s and other neurodegenerative disorders, contributing to several drug approvals spanning neurology and psychiatry. He serves as the Chief Scientific Officer for APEX Innovative Sciences and for Follow the Molecule LLC, where he focuses on translational drug development strategies.

Opioid Withdrawal Symptoms

- Thomas R. Kosten, MD, is the JH Waggoner Chair and Professor of Psychiatry, Pharmacology, Immunology, Pathology, and Neuroscience of the Dan Duncan Institute for Clinical and Translational Research at Baylor College of Medicine. He has directed a national NIDA Medications Development Center since 1988, was previously the Research Director of the VA National Substance Use Disorders Quality Enhancement Research Initiative at the Michael E. DeBakey VA Medical Center and is the founder of the Division of Substance Abuse at Baylor College of Medicine and at Yale University School of Medicine.

Delirium Related Agitation

- E. Wesley Ely, MD, MPH, is a subspecialist in Pulmonary and Critical Care Medicine who conducts health services research as a Professor of Medicine in the Division of Allergy, Pulmonary, and Critical Care Medicine at Vanderbilt University Medical Center. He is a practicing intensivist with a focus on Geriatric ICU Care, as the Associate Director for Research for the VA Tennessee Valley Geriatric Research and Education Clinical Center. Dr. Ely is also the co-director of the Center for Critical Illness, Brain Dysfunction, and Survivorship, where his team developed the primary tool used to

measure delirium clinically and in ICU-based trials.

A live webcast of the event will be accessible through the Investors section of the Company's website at www.bioxceltherapeutics.com on February 19th at 11:00 am ET. Following the event, the webcast will be archived on the Company's website for at least 30 days.

About BXCL501

BXCL501 is an investigational, proprietary, orally dissolving thin film formulation of dexmedetomidine, a selective alpha-2a receptor agonist for the treatment of agitation and opioid withdrawal symptoms. BioXcel believes that BXCL501 directly targets a causal agitation mechanism, and the Company has observed anti-agitation results in multiple clinical studies across several neuropsychiatric disorders. BXCL501 has been granted Fast Track Designation by the U.S. Food and Drug Administration for the acute treatment of agitation in patients with schizophrenia, bipolar disorders, and dementia. BXCL501 has been studied in two Phase 3 trials (SERENITY I and II) for the acute treatment of schizophrenia related agitation and bipolar disorder related agitation, respectively, and in a Phase 1b/2 trial (TRANQUILITY) for the acute treatment of dementia related agitation. This product candidate is also currently being evaluated in a Phase 1b/2 study (RELEASE) for the treatment of opioid withdrawal symptoms, with plans to initiate a Phase 2 trial in hospitalized patients suffering from delirium related agitation within the next several months.

BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology. BioXcel'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 indices. BioXcel's two most advanced clinical development programs are BXCL501, an investigational, proprietary, orally dissolving thin film formulation of dexmedetomidine for the treatment of agitation and opioid withdrawal symptoms, and BXCL701, an investigational, orally administered, systemic innate immunity activator in development for the treatment of aggressive forms of prostate cancer and advanced solid tumors that are refractory or treatment naïve to checkpoint inhibitors. For more information, please visit www.bioxceltherapeutics.com.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to BXCL501's potential as a treatment option for multiple neuropsychiatric conditions. When used herein, words including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. 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 BioXcel's current expectations and various assumptions. BioXcel believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel 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; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of BXCL501 and BXCL701 and other product candidates; 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 BioXcel's product candidates; its approach to the discovery and development of product candidates based on EvolverAI is novel and unproven; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, 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 www.sec.gov and the Investors section of our website at www.bioxceltherapeutics.com.

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 BioXcel 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 BioXcel's views as of any date subsequent to the date of this press release.

Contact Information:

BioXcel Therapeutics, Inc.

www.bioxceltherapeutics.com

Investor Relations:

Mary Coleman
BioXcel Therapeutics, VP of Investment Relations
MColeman@bioxceltherapeutics.com
1.475.238.6837

John Graziano
Solebury Trout
jgraziano@soleburytrout.com
1.646.378.2942

Media:

Julia Deutsch
Solebury Trout
jdeutsch@soleburytrout.com
1.646.378.2967

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