

December 17, 2020



BioXcel Therapeutics to Present at the 39th Annual J.P. Morgan Healthcare Conference

Company to present corporate update and plans for 2021

Topline TRANQUILITY data expected to be reported by mid-January

NEW HAVEN, Conn., Dec. 17, 2020 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. ("BTI" or the "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence to identify improved therapies in neuroscience and immunoncology, today announced that Dr. Vimal Mehta, Founder and Chief Executive Officer of BTI, will present corporate updates and plans for 2021 at the 39th Annual J.P. Morgan Healthcare Conference on Thursday, January 14, 2021 at 8:20 AM Eastern Time.

"I am excited to share a preview of the transformative year ahead for the Company at the Annual J.P. Morgan Healthcare Conference," said Vimal Mehta, Chief Executive Officer of BTI. "In the first quarter, we are expecting to file our first New Drug Application with the FDA for BXCL501 and report topline data from the TRANQUILITY and RELEASE clinical studies. We believe these expected 2021 milestones will help us deliver the full potential and value of BXCL501 as a novel treatment for agitation across a wide range of neuropsychiatric disorders."

A live webcast of the presentation and accompanying presentation materials will be accessible through the Investors section of the Company's website at www.bioxccltherapeutics.com. Following the conference, 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. BTI believes that BXCL501 directly targets a causal agitation mechanism, and the Company has observed anti-agitation effects 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 agitation associated with schizophrenia and bipolar disorders. Also, the product is being evaluated in a Phase 1b/2 trial (TRANQUILITY) for the acute treatment of agitation associated with dementia, and in a Phase 1b/2 study (RELEASE) for the treatment of opioid withdrawal symptoms. The Company also plans to initiate a Phase 2 trial in hospitalized patients suffering from agitation associated with delirium within the next several months.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes artificial intelligence to identify improved therapies in neuroscience and immuno-oncology. BTI'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. BTI'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 the timing and data from clinical development initiatives and trials for BXCL501. 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 BTI's current expectations and various assumptions. BTI believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

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

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