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BioXcel Therapeutics Announces Compassionate Use Program at Massachusetts General Hospital for BXCL501 to Treat COVID-19 Patients Suffering from Delirium and Agitation

Company providing BXCL501 to evaluate its activity in patients with COVID-19 that may require calming or arousable sedation following intubation

NEW HAVEN, Conn., July 09, 2020 (GLOBE NEWSWIRE) -- BioXcel Therapeutics (“BTI” or “Company”) (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to identify and advance the next wave of medicines in neuroscience and immuno-oncology, today announced that the Company has initiated an expanded access program at Massachusetts General Hospital (“MGH”) to provide its investigational drug, BXCL501, the Company’s proprietary sublingual thin-film formulation of dexmedetomidine (“Dex”), to critically ill patients diagnosed with COVID-19 in the intensive care unit ("ICU") that may require calming or arousable sedation.

“We are pleased to support clinicians at MGH as they manage an in-flux of COVID-19 patients,” commented Vimal Mehta, Ph.D., Chief Executive Officer of BTI. “COVID-19 primarily affects the respiratory system, with the severely ill often requiring mechanical ventilation. As a result of critical illness and the medical coma that is necessary for mechanical ventilation, patients frequently develop delirium and agitation, causing worse clinical outcomes and extended hospital stays. BXCL501 is being studied in advanced clinical trials to treat acute agitation, and we believe it has the potential, if approved, to help physicians treat patients that may be struggling with agitation or delirium.”

Facilitated by the U.S. Food and Drug Administration (“FDA”), expanded access, also known as compassionate use, provides an opportunity for patients to receive an investigational treatment prior to regulatory approval when there are no comparable or satisfactory therapeutic alternatives available.

“Being on the frontlines of this pandemic, our intensivists have witnessed firsthand the high numbers of critically ill patients diagnosed with COVID-19 and ICU delirium,” added Seun Johnson-Akeju, M.D., M.M.Sc., Anesthetist-in-Chief of the Department of Anesthesia, Critical Care and Pain Medicine at the Massachusetts General Hospital. “The COVID-19 surge caused an acute shortage of medications for managing agitation. We are hopeful that BXCL501 will improve the clinical outcomes of critically ill patients diagnosed with COVID-19 that are struggling with agitation and ICU delirium.”

About BXCL501

BXCL501 is a potential first-in-class, proprietary sublingual thin film of dexmedetomidine, a selective alpha-2a receptor agonist for the treatment of acute agitation. BTI believes that BXCL501 directly targets a causal agitation mechanism and the Company has observed anti-agitation effects in clinical studies across multiple neuropsychiatric indications. BXCL501 has also been granted Fast Track Designation by the U.S. Food and Drug Administration for the acute treatment of mild to moderate agitation in schizophrenia, bipolar disorder, and dementia.

A Phase 1b safety and efficacy study of BXCL501 yielded positive dose-response data. BXCL501 is being evaluated in the SERENITY program, consisting of two Phase 3 studies for the acute treatment of agitation in patients with schizophrenia (SERENITY I) and bipolar disorder (SERENITY II). BXCL501 is also being evaluated in the Phase 1b/2 TRANQUILITY trial for the treatment of agitation associated with dementia, as well as the Phase 1b/2 RELEASE trial for the treatment of opioid withdrawal symptoms.

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical-stage biopharmaceutical company utilizing artificial intelligence to identify improved therapies in neuroscience and immuno-oncology. BTI's drug re-innovation approach leverages existing approved drugs and/or clinically evaluated 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 sublingual thin film formulation in development for acute treatment of agitation resulting from neuropsychiatric disorders, and BXCL701, an investigational orally administered systemic innate immunity activator in development for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer in combination with other immuno-oncology agents. For more information, please visit http://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 evaluation of the Company’s investigational drug, BXCL501, in the treatment of COVID-19 patients. 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; 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as supplemented by its Current Report on Form 8-K filed on April 14, 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 page of its 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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