July 7, 2020

BioXcel Therapeutics Announces Notice of Allowance for U.S. Patent Application Covering Formulation for BXCL501 and Methods of Treating Agitation

Patent is expected to extend IP protection until 2039

NEW HAVEN, Conn., July 07, 2020 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. ("BTI" or "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence to identify improved therapies in neuroscience and immuno-oncology, today announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office ("USPTO") for patent application No. 16/453,679 related to BXCL501, the Company's proprietary sublingual thin-film formulation of dexmedetomidine ("Dex"). The patent is expected to cover film formulations containing Dex and methods of treating agitation using such film formulations.

"The allowance of this patent substantially strengthens our intellectual property position, an important milestone for BXCL501's development and potential commercialization," commented Vimal Mehta, Ph.D., Chief Executive Officer of BTI. "With a significant need for an effective therapy that addresses the underlying cause of agitation, BXCL501 has the potential to fill this gap, while also providing a unique and favorable delivery method for treating patients. As we prepare to report topline data from our pivotal SERENITY trials this month, we are thrilled to have received this patent allowance for film formulations containing Dex, an essential step in creating value for our shareholders."

A Notice of Allowance is issued after the USPTO makes a determination that a patent should be granted from an application. The patent, which is expected to be issued in the third quarter of 2020, will have a term that expires no earlier than 2039. After issuance, BioXcel plans to list the U.S. patent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book.

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 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 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 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 receipt of patent approval for BXCL501, the Company’s intellectual property strategy, the timing and data from clinical development initiatives and trials for BXCL501, the potential commercialization of BXCL501 and BTI’s corporate strategy. 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.

These forward-looking statements are based on management’s current expectations and beliefs. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause BTI’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: 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 March 31, 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 Investors sections 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 its 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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