September 18, 2019

BioXcel Therapeutics Announces BXCL501 Program Initiative for Prevention and Treatment of Acute Agitation using Wearable Digital Devices

Neuropsychiatric patients are vulnerable to multiple agitation episodes; Alzheimer's dementia patients specifically require integrated patient management solutions

Expands market potential of BXCL501, if approved, beyond traditional treatment paradigms to preventative therapy

Initial study to develop proprietary algorithms using multi-parametric analysis to predict the onset of agitation

NEW HAVEN, Conn., Sept. 18, 2019 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. ("BTI" or the "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical development company utilizing novel artificial intelligence approaches to identify and advance the next wave of medicines in neuroscience and immuno-oncology, today announced a strategic plan to investigate the development of using wearable digital device technology such as the Apple Watch, with the goal of enhancing the prevention and treatment of agitation including, if approved, the administration of BXCL501 prior to the onset of agitation.

BioXcel Therapeutics plans to conduct a feasibility study with potential applications for uses in commercially available wearable digital devices to measure nervous and motor system activity relevant to both agitation and the mechanism of action of the Company's drug candidate, BXCL501. BTI plans to leverage its core drug development expertise in neuroscience and the AI expertise of its parent company, BioXcel Corporation, and to collaborate with both clinical investigators and a third-party digital solutions provider. The goal of this collaborative effort is to use these data to develop an integrated patient management solution, which may enable early intervention for agitation via an analytic algorithm that predicts and identifies agitation. If successfully developed, such technology could potentially be used in conjunction with BXCL501 for prevention and early identification of agitation in patients with Alzheimer's dementia and other medical conditions including delirium and PTSD.

"Utilizing predictive algorithms and developing related wearable device technology may enable the administration of BXCL501 prior to the onset of an agitation episode, which, if BXCL501 is approved, may reduce the burden on the patient and caregiver," noted George Grossberg, Samuel W. Fordyce Professor and Director of Geriatric Psychiatry in the Department of Psychology at Saint Louis University School of Medicine. "By identifying the early onset of agitation, BXCL501 could potentially be administered more efficiently and, consequently, we believe has the potential to reduce medical costs and improve patient

management with lower doses, applicable to a broader set of institutionalized elderly patients."

Approximately 5.8 million people in the U.S. are afflicted by Alzheimer's dementia. Many patients diagnosed with the disease will experience agitation, which is characterized by verbal and physical aggression, excessive motor activity, restlessness, and wandering. Agitation is the principle reason why patients move from home-based care to supervised living, to residential care and then to nursing homes, as they exceed the capacity of their care setting to manage agitation. Each transition being of escalating financial burden, predicting agitation would enable patients to be managed in the least restrictive lowest cost setting, potentially delaying the necessity to transition care. There are no predictive technologies for agitation and FDA approved treatments to help the agitation associated with Alzheimer's disease or other forms of dementia.

"BioXcel Therapeutics is very pleased to further develop the BXCL501 program with integrated preventive treatment approaches," said Frank Yocca, Chief Scientific Officer of BioXcel Therapeutics. "Our goal is to both prevent and reduce agitation episodes by proactively and safely administering BXCL501. We are excited to partner our 501 program with predictive technologies to develop non-invasive solutions that are designed to be easy to administer, well tolerated and provide rapid relief without excessive sedation."

About Digital Wearable Devices

According to third party research, the smartwatch market is primarily controlled by 3 vendors: Apple (NASDAQ:AAPL), Fitbit (NYSE:FIT), and Samsung (005930.KS). In 2018, 45 million smartwatches were shipped globally with Apple Watches accounting for 22.5 million of those units. Fitbit shipped 5.5 million units while Samsung shipped 5.3 million units. Overall, global smartwatch shipments grew 54% from 2017 to 2018.

About BXCL501:

BXCL501 is an investigational, proprietary sublingual thin film of dexmedetomidine, a selective alpha2 A -adrenergic agonist designed 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 multiple clinical studies across multiple neuropsychiatric indications. BXCL501 is currently being developed for agitation associated with schizophrenia and bi-polar disorders followed by Alzheimer's/dementia.

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence approaches to identify and advance the next wave of medicines 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 the Company’s wearable digital device initiative and related feasibility study, clinical development initiatives and trials for BXCL501 and the efficacy of BXCL501 in the treatment of agitation. 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; 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 June 30, 2019 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.

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.

Contact Information:

BioXcel Therapeutics, Inc.
www.bioxceltherapeutics.com
The Ruth Group
Carol Ruth / James Salierno
646-536-7004 / 7028
cruth@theruthgroup.com

jsalierno@theruthgroup.com

Source: BioXcel Therapeutics, Inc.