April 26, 2021

BioXcel Therapeutics Announces Presentations on SERENITY I & II at the 2021 American Psychiatric Association Annual Meeting

NEW HAVEN, Conn., April 26, 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 data from its two pivotal Phase 3 trials (SERENITY I & II) of BXCL501 for the acute treatment of agitation associated with schizophrenia and bipolar disorders I and II will be presented at the upcoming American Psychiatric Association ("APA") Annual Meeting. The meeting will be held virtually on May 1-3, 2021.

Poster Presentations:

Title: A Novel Rapidly Effective Treatment of Agitation for Schizophrenia With the Oral Dissolving Film BXCL501
Presenter: Leslie L. Citrome, MD, MPH, Clinical Professor of Psychiatry and Behavioral Sciences at New York Medical College

Title: Novel Rapidly Effective Treatment of Agitation in Patients with Bipolar Disorders: BXCL501 – An Oral Dissolving Film
Presenter: Sheldon H. Preskorn, MD, Professor, Department of Psychiatry and Behavioral Sciences at the University of Kansas School of Medicine-Wichita

The posters will be presented within a virtual poster hall and will be available through the conference portal from May 1, 2021 to June 1, 2021. The posters will also be available in the "News & Media" section of the Company's website at www.bioxceltherapeutics.com.

About Schizophrenia and Bipolar Disorder Related Agitation

Agitation is a common and difficult to manage symptom associated with multiple neuropsychiatric conditions, including schizophrenia and bipolar disorders I and II. These two disease states alone have an estimated U.S. prevalence of approximately 9 million adults with more than 3 million experiencing agitation each year. On average, patients with these conditions experience more than a dozen episodes per year, the majority requiring pharmacologic treatment. Early identification and prompt intervention to relieve agitation are essential to avoid symptomatic escalation and the emergence of aggression. Expert consensus best-practice guidelines have recommended that agitation should be treated by a combination of behavioral calming techniques, verbal de-escalation, and medications that are voluntarily accepted by patients without coercion, with the pharmacologic goal of

“calming without excessive sedation.” A non-invasive therapy that causes rapid and sustained symptom relief may be helpful to avoid the costly and traumatic use of coercive techniques, like physical restraint and seclusion, which may result in admission and prolonged hospitalization.

About SERENITY I and SERENITY II

The SERENITY studies were randomized, double-blinded, placebo-controlled parallel group adaptive trials in a total of 759 patients, 18 to 75 years of age. SERENITY I (n=381) enrolled patients with agitation associated with schizophrenia or schizoaffective disorder, with arms randomized to receive BXCL501 at 120 micrograms, or 180 micrograms or matching placebo, respectively. SERENITY II (n=378) enrolled patients with agitation associated with bipolar disorders, in three treatment arms randomized to receive BXCL501 at 120 micrograms, 180 micrograms or placebo, respectively. The primary endpoint of the trials was the reduction in acute agitation measured by the Positive and Negative Syndrome Scale - Excitatory Component (“PEC”) change from baseline compared to placebo. The secondary endpoint was determination of the earliest time where an effect on agitation is apparent as measured by the change from baseline in PEC total score.

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 potentially targets a causal agitation mechanism, and the Company has observed anti-agitation results in multiple clinical studies across several neuropsychiatric disorders, including schizophrenia related agitation (SERENITY I), bipolar disorder related agitation (SERENITY II) and dementia related agitation (TRANQUILITY). BXCL501 has been granted Breakthrough Therapy designation for the acute treatment of agitation associated with dementia and Fast Track designation for the acute treatment of agitation associated with schizophrenia, bipolar disorders and dementia. The Company recently submitted its New Drug Application to the FDA for BXCL501 for the acute treatment of agitation associated with schizophrenia and bipolar disorders. BXCL501 is also currently being evaluated in a Phase 2 trial (PLACIDITY) for the treatment of agitation associated with delirium. The safety and efficacy of BXCL501 has not been established.

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.

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