BioXcel Therapeutics to Host IGALMI™ Commercial Day on October 18, 2022

October 5, 2022

NEW HAVEN, Conn., Oct. 05, 2022 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced that it will host a Commercial Day presentation for the investment community to provide an update on its recently launched product, IGALMI™ (dexmedetomidine) sublingual film, on Tuesday, October 18, 2022 beginning at 11:00 a.m. Eastern Time.

Vimal Mehta, Ph.D., Founder and Chief Executive Officer, and Matt Wiley, Chief Commercial Officer, will be joined by healthcare experts to discuss clinical insights, treatment perspectives, market opportunities, and launch progress. IGALMI was approved by the U.S. Food and Drug Administration in April 2022 for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults.[1]

Participating healthcare experts will include and discuss:

- **Dr. Sheldon Preskorn, M.D.:** *The Mechanism of Agitation*

  Dr. Sheldon Preskorn is President and CEO, World-Wide Clinical Psychopharmacology Consultation. He has been principal investigator on more than 250 clinical trials, including drug-development work that has spanned all phases of psychiatric drug development from preclinical research through registration studies, including all antidepressants and antipsychotics marketed in the U.S. over a 25-year period. He also has extensive experience with the drug-registration process, having worked on 16 successful New Drug Applications, including 8 of the 12 antidepressants marketed in the U.S. over a 25-year period and the only implantable device approved for treatment of a psychiatric illness. His clinical and administrative experience includes serving as supervising physician for an acute psychosis ward, chief of psychiatry for a university-affiliated Veterans Administration Medical Center, and supervisor of a residency teaching clinic seeing adult psychiatric outpatients with a diverse range of psychiatric disorders.

- **Karen Sands, MSN, APRN-BC, ANP, CCRN, FCCM:** *The Front Lines of Agitation*

  Karen Sands is an Adult Nurse practitioner and is currently serving as faculty preceptor for several NP programs including Duke University School of Nursing, University of South Alabama School of Nursing, and Chamberlin University College of Nursing. She has 34 years of nursing experience, with the last 32 years dedicated to the medical and surgical critical care arena and hospital medicine.

- **Jacob Hanaie, Pharm. D., APh:** *The Hospital Formulary Process*

  Dr. Jacob Hanaie is an Advanced Practice prescribing pharmacist, Director of Pharmacy, and distinguished Chairman of the Pharmacy and Therapeutics Committee at Kedren Psychiatric Hospital and Community Mental Health Center in Los Angeles. In addition to research and clinical experience in schizophrenia, depression, bipolar, ADHD/ADD, and dependence, Dr. Hanaie's expertise includes pharmacology, pharmacokinetics, and pharmacodynamics, along with an in-depth understanding of the complex mental health system at federal, state, and county levels.

Investors interested in attending the in-person event should RSVP by contacting Brennan Doyle at bdoyle@bioxceltherapeutics.com. To access a live webcast of the Commercial Day presentation and accompanying presentation materials, please visit "News/Events" within the Investors & Media section of the Company's website beginning 15 minutes prior to the start time of the presentation. A webcast replay will be available on the website following the event.

About IGALMI™ (dexmedetomidine) sublingual film

INDICATION

IGALMI is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.

IMPORTANT SAFETY INFORMATION

IGALMI can cause serious side effects, including:

- Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under

the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart rate) and alertness after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell their healthcare provider if they feel dizzy, lightheaded, or faint.

- Heart rhythm changes (QT interval prolongation). IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.
- Sleepiness/drowsiness. Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.
- Withdrawal reactions, tolerance, and decreased response/efficacy. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full Prescribing Information.

About BioXcel Therapeutics, Inc.
BioXcel Therapeutics, Inc. is a biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology. The Company'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. The Company's commercial product, IGALMI™ (developed as BXCL501), is a proprietary, sublingual film formulation of dexmedetomidine approved for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. BXCL501 is under investigation for the acute treatment of agitation associated with probable Alzheimer's disease, and as an adjunctive treatment for major depressive disorder. The Company is also developing BXCL502 as a potential therapy for chronic agitation in dementia. Under its subsidiary, OnkosXcel Therapeutics, the Company is developing BXCL701, an investigational, orally administered, systemic innate immune activator for the treatment of aggressive forms of prostate cancer. For more information, please visit 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 date, time and content of the Company's Commercial Day event for IGALMI. When used herein, words including "anticipate," "will," "plan," "may," "continue," "intend," "designed," "goal" 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 the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. The Company 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, the important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, 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 the Company 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 the Company's views as of any date subsequent to the date of this press release.

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References and Notes

1. IGALMI™ (dexmedetomidine) [package insert]. New Haven, CT: BioXcel Therapeutics, Inc.; 2022.