BioXcel Therapeutics Receives Permanent J-Code for IGALMI™ (dexmedetomidine) Sublingual Film from Centers for Medicare & Medicaid Services

October 30, 2023

Standardizes and improves product reimbursement process

New HCPCS Level II code J1105 to be effective January 1, 2024

NEW HAVEN, Conn., Oct. 30, 2023 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience, today announced that the Centers for Medicare & Medicaid Services (CMS) has issued a permanent and product-specific J-Code for IGALMI™ (dexmedetomidine) sublingual film, which is approved for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults[1,2]. Under the Healthcare Common Procedure Coding System (HCPCS) process, the IGALMI J-Code J1105 will become effective January 1, 2024.

J-codes are permanent codes used by healthcare providers, commercial insurance plans, and government payers to help standardize the reimbursement process. Compared to a miscellaneous or unlisted product code, a J-code simplifies claims submission, which in turn streamlines the billing and reimbursement process.

“Beginning next year, IGALMI will be separately reimbursed under a direct and predictable J-Code for the hospital outpatient setting, which we expect will help remove economic barriers that may have impacted formulary approval decisions and product utilization to date,” said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. “Ultimately, we believe this commercial milestone will facilitate additional patient access to this important therapeutic option for the treatment of bipolar disorder- or schizophrenia-associated agitation.”

The J-code for IGALMI has been published online in the CMS HCPCS Application Summaries and Coding Recommendations, Third Quarter, 2023 HCPCS Coding Cycle.

About Agitation Associated with Bipolar Disorder and Schizophrenia

Agitation is a relatively common and difficult-to-manage symptom associated with bipolar I or II or schizophrenia in adults.[3,4] Prompt identification of agitation related to schizophrenia and bipolar disorders can help de-escalate the situation before aggressive or violent behaviors emerge.[5,6] 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.[4] Medication used in this manner to treat agitation is consistent with the goal to calm the patient enough so they can be assessed, while avoiding unarousable sedation.[5,6] In many settings, physical restraints and forcible injections of heavily sedating medications are used, which can create a hostile and adversarial relationship between clinicians and patients[4,7-8]

About IGALMI™ (dexmedetomidine) sublingual film

INDICATION

IGALMI™ (dexmedetomidine) sublingual film is a prescription medicine, administered under the supervision of a health care provider, that is placed under the tongue or behind the lower lip and is used for the acute treatment of agitation associated with schizophrenia and bipolar disorder I or II in adults. The safety and effectiveness of IGALMI has not been studied beyond 24 hours from the first dose. It is not known if IGALMI is safe and effective in children.

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. (Nasdaq: BTAI) is a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience. 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 indications. 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. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements regarding: the CMA's issuance of a permanent and product-specific J-Code for IGALMI, and the potential benefits, expectations and impact from the J-Code on formulary wins, patient access and the commercialization strategy of IGALMI. The words "anticipate," "believe," "can," "continue," "could," "designed," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. 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, its limited operating history; risks associated with the strategic reprioritization; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; its lack of experience in marketing and selling drug products; the risk that IGALMI or the Company's product candidates may not be accepted by physicians or the medical community in general; undesirable side effects caused by the Company's product candidates; its exposure to patent infringement lawsuits; its reliance on third parties; 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, 2023, 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

1. IGALMI™ (dexmedetomidine) [package insert]. New Haven, CT: BioXcel Therapeutics, Inc.; 2022
2. Centers for Medicare & Medicaid Services. Accessed October 23, 2023. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/current-prior-years-level-ii-coding-decisions.
3. Sacchetti E, Amore M, Di Sciascio G, et al. Psychomotor agitation in psychiatry: an Italian expert consensus. Evidence-based Psychiatric Care. 2017;1:1-24.
4. Wilson MP, Pepper D, Currier GW, et al. The psychopharmacology of agitation: consensus statement of the American Association for Emergency Psychiatry Project Beta Psychopharmacology Workgroup. West J Emerg Med. 2012;13(1):26-34.
5. Richmond JS, Berlin JS, Fishkind AB, et al. Verbal de-escalation of the agitated patient: consensus statement of the American Association for Emergency Psychiatry Project BETA De-escalation Workgroup. *West J Emerg Med.* 2012;13(1):17-25. doi:10.5811/westjem.2011.9.6864
6. Martinez-Raga J, Amore M, Di Sciascio G, et al. 1st international experts' meeting on agitation: conclusions regarding the current and ideal management paradigm of agitation. *Front Psychiatry.* 2018;9:54. doi:10.3389/fpsyt.2018.00054
7. Zeller SL, Citrome L. Managing agitation associated with schizophrenia and bipolar disorder in the emergency setting. West J Emerg Med. 2016;17(2):165-172.
8. Holloman GH Jr, Zeller SL. Overview of Project BETA: Best practices in evaluation and treatment of agitation. West Emerg Med. 2012;13(1):1-2.