BioXcel Therapeutics Announces European Patent Office's Grant of Patent for Method of Treating Agitation in Dementia Using Sublingual Dexmedetomidine

March 15, 2024

Newly granted patent aligns with Company's focus on expanding geographic coverage and strengthening intellectual property protection for BXCL501

NEW HAVEN, Conn., March 15, 2024 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience and immuno-oncology, today reported that the European Patent Office (EPO) granted the Company's European Patent No. 3,562,486 (the "486 patent") on March 13, 2024. The 486 patent covers the use of dexmedetomidine administered sublingually to treat agitation in individuals with dementia. The patent encompasses a broad range of dosage forms, including films such as BXCL501 (sublingual dexmedetomidine), wafers, and tablets, at dexmedetomidine doses ranging from 3 mcg to 100 mcg.

"We have made great progress in building our intellectual property portfolio, with more than 100 patent applications in prosecution and multiple patents issued to date," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "The 486 patent aligns with our focus on expanding our patent portfolio for BXCL501 into Europe, and, together with the United States and Japan, extends our BXCL501 franchise patent protection to three major markets. We believe this represents a strong foundation to potentially expand our commercialization of BXCL501 into additional geographies, if approved."

The 486 patent comes on the heels of the U.S. Patent and Trademark Office (USPTO) recently allowing U.S. Patent Application No. 17/496,470 with claims pertaining to methods of treating agitation in patients with Alzheimer's disease using the oromucosal administration of 60 mcg of dexmedetomidine in a water-soluble dosage form. The broad claims encompass film formulations such as BXCL501 (sublingual dexmedetomidine), tablets, or wafers.

Additionally, in the United States, the Company currently has eight patents for IGALMI™ listed in the United States Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"). The Company also received notice that the USPTO has allowed U.S. Patent Application No. 18/216,890 with claims pertaining to a method of treating agitation using an oromucosal formulation of dexmedetomidine or a pharmaceutically acceptable salt thereof through the administration of an initial dose of 60 mcg, 80 mcg, 90 mcg, 120 mcg or 180 mcg of dexmedetomidine and, after at least two hours, administering an oromucosal formulation of dexmedetomidine or a pharmaceutically acceptable salt thereof in a second dose of 40 mcg, 60 mcg, 80 mcg or 90 mcg of dexmedetomidine, where the patient has a QT interval of less than 470 msec. The patent, when issued, is expected to have an expiration date of July 17, 2040, subject to patent term adjustment, patent term extension, and terminal disclaimers. The Company expects that this patent, when issued, will be submitted for listing in the Orange Book with the eight currently listed U.S. patents for IGALMI™ (dexmedetomidine) sublingual film. Collectively, these nine patents will in general extend patent protection for IGALMI™ until January 12, 2043.

About IGALMI™ (dexmedetomidine) sublingual film

INDICATION

IGALMI™ (dexmedetomidine) sublingual film is a prescription medicine, administered under the supervision of a health care provider, which 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 at igalmi.com.

About BXCL501
In indications other than those approved by the U.S. Food and Drug Administration (FDA) as IGALMI™ (dexmedetomidine) sublingual film, BXCL501 is an investigational proprietary, orally dissolving film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist. BioXcel Therapeutics believes that BXCL501 potentially targets an important mediator of agitation, and the Company has observed anti-agitation results in multiple clinical trials across several neuropsychiatric disorders. BXCL501 is under investigation by BioXcel Therapeutics for the acute treatment of agitation associated with dementia due to probable Alzheimer's disease and for the acute treatment of agitation associated with bipolar I or II disorder or schizophrenia in the at-home setting. The safety and efficacy of BXCL501 for these investigational uses have not been established. BXCL501 has been granted Breakthrough Therapy designation by the FDA 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.

About BioXcel Therapeutics, Inc.
BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience. Its wholly owned subsidiary, OnkosXcel Therapeutics, is focused on the development of medicines in 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 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 and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, the Company's expectations as to the timing and benefits of patent protection relating to BXCL501 and IGALMI, in the EU, Japan and the U.S.; and the Company's potential addressable market for treatment with its products and product candidates. When used herein, words including "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: that it is difficult and costly to protect our proprietary rights; obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies; and we may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property, as well as the important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, as such factors may be updated from time to time in its other filings with the SEC, including without limitation its Annual Report on Form 10-K for the fiscal year ended December 31, 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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Source: BioXcel Therapeutics, Inc.

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