BioXcel Therapeutics Strengthens Clinical Development Leadership to Advance Late-Stage Programs

December 11, 2023

Vincent J. O'Neill, M.D., promoted to Executive Vice President, Chief of Product Development and Medical Officer

Rajiv Patni, M.D., appointed Strategic Clinical Advisor to CEO and Board of Directors

NEW HAVEN, Conn., Dec. 11, 2023 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company utilizing artificial intelligence to develop transformative medicines in neuroscience and immuno-oncology, today announced a key executive promotion and a clinical advisor appointment as part of the Company's strategic reprioritization focused on the advancement of its late-stage clinical programs and emerging pipeline candidates.

Vincent J. O'Neill, M.D., Senior Vice President and Chief Research & Development Officer of OnkosXcel Therapeutics, has been promoted to Executive Vice President, Chief of Product Development and Medical Officer of BioXcel Therapeutics. He will lead clinical, regulatory and medical affairs to provide a fully integrated approach to product development. Additionally, Rajiv Patni, M.D., has been appointed to the newly created position of Strategic Clinical Advisor to the BioXcel Therapeutics Chief Executive Officer and Board of Directors.

"Our strategic focus has shifted to expanding the market opportunities for our lead program BXCL501 in the at-home setting, which we believe represent key value drivers for the Company. We are adding to the strength of our existing team and expanding our clinical leadership in line with our prioritization of late-stage TRANQUILITY and SERENITY III programs for BXCL501's potential use to treat Alzheimer's, bipolar disorder, and schizophrenia-related agitation," said Vimal Mehta, Ph.D., CEO of BioXcel Therapeutics. "We are also excited to advance development candidates identified through our AI-driven approach as part of our efforts to build a sustainable R&D pipeline. The promotion of Vince and the appointment of Rajiv are in support of our clinical execution, and we welcome their strong leadership as we look to progress in 2024."

Vincent J. O'Neill, M.D.: Executive Vice President, Chief of Product Development and Medical Officer

Dr. O'Neill has significant expertise in therapeutic and diagnostic product development. He joined BioXcel Therapeutics in 2017 as Vice President and Chief Medical Officer, later Senior Vice President and Chief Medical Officer, and played an instrumental role in the Company's SERENITY I and II trials of BXCL501, which contributed to the FDA approval of IGALMI™ (dexmedetomidine) sublingual film for the acute treatment of agitation associated with schizophrenia and bipolar I or II disorder in adults. He also led the Company's immuno-oncology program and the successful human proof of concept trials for BXCL701, an investigational, orally administered systemic innate immune activator for the treatment of refractory forms of prostate cancer. In 2022, he became Senior Vice President and Chief Research & Development Officer of the Company's wholly owned OnkosXcel Therapeutics subsidiary.

Prior to joining BioXcel Therapeutics, Dr. O'Neill held senior leadership roles at several leading global pharmaceutical companies, including Sanofi, Genentech, and GlaxoSmithKline. Most recently, he served as Chief Medical Officer at Mirna Therapeutics and Exosome Diagnostics. He was instrumental in the expanded approvals of Genentech's oncology therapeutics, Avastin® and Tarceva®. At GSK, he oversaw the signal transduction discovery unit and led the first IND application and clinical trial of the MEK inhibitor, MEKINIST®. Dr. O'Neill has authored several peer-reviewed publications and conference presentations. He received his M.D. and B.Sc. in Molecular Pathology from the University of Glasgow, Scotland, and is a member of the Royal College of Physicians.

Rajiv Patni, M.D.: Strategic Clinical Advisor to the BioXcel Therapeutics CEO and Board of Directors

Dr. Patni was Chief Research and Development Officer at Reata Pharmaceuticals, a commercial-stage company recently acquired by Biogen. Previously, he was a successful Chief Medical Officer at several public, small-cap, commercial-stage biopharmaceutical companies: Adamas, Portola, and Global Blood Therapeutics. He joined these companies at an inflection point in their R&D growth trajectories and contributed to their acquisition by larger companies. Earlier in his career, Dr. Patni had roles of increasing responsibility at Pfizer, Roche, and Actelion.

Over his 23-year industry tenure in global product development, Dr. Patni has contributed to the development of 21 NCEs for both common and, most recently, rare diseases. His experience in fostering successful team efforts at these different companies contributed to the approval of 10 medicines, from the U.S. FDA, EMA, and other regulatory agencies. Dr. Patni received his M.D. degree from the Mount Sinai School of Medicine in New York City as part of an accelerated B.S. /M.D. program. He completed his internal medicine residency and adult cardiology fellowship at the Albert Einstein College of Medicine, also in New York City, where he continued as an attending physician-scientist before joining the biopharmaceutical industry.

"I have been impressed by the Company's AI-based discovery and development of BXCL501, which was approved as IGALMI, and their continued development of this asset for potential at-home treatment of agitation associated with Alzheimer's dementia, bipolar disorders, and schizophrenia," said Dr. Patni. "I look forward to working with the BioXcel leadership team in continuing to address the unmet medical needs of patients and caregivers and advance the Company's product-development goals."

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 at igalmi.com.

About BioXcel Therapeutics, Inc.
BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company utilizing artificial intelligence 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 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, its expectations regarding its development programs and anticipated contributions of Drs. O'Neill and Patni. 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, 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, 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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