BioXcel Therapeutics Expands Immuno-Oncology Partnership with Nektar into Clinical Development in Pancreatic Cancer

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Clinical partnership to develop triple combination of BioXcel Therapeutics' BXCL701, Nektar's NKTR-214 and a checkpoint inhibitor

NEW HAVEN, Conn., Sept. 24, 2018 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. ("BTI") (Nasdaq: BTAI), a clinical stage biopharmaceutical development company utilizing novel artificial intelligence approaches to identify the next wave of medicines across neuroscience and immuno-oncology, and Nektar Therapeutics (Nasdaq: NKTR) announced today that the companies are expanding their ongoing research collaboration into a new clinical partnership. The collaboration will clinically evaluate the novel combination of BTI's BXCL701, a small molecule immune-modulator, DPP 8/9 and FAP inhibitor; Nektar's NKTR-214, a CD122-biased agonist; and a checkpoint inhibitor as a potential therapy for pancreatic cancer.

Under the terms of the expanded collaboration agreement, BTI will be responsible for initiating and managing the clinical program. The primary objectives of the study are to evaluate safety and efficacy of the triplet combination of BXCL701, NKTR-214 and a checkpoint inhibitor for the treatment of patients with unresectable or metastatic pancreatic cancer. Additionally, correlative immune activation markers will also be evaluated in blood and tumor tissue.

"We are excited to expand our collaboration with Nektar to initiate a clinical program for this novel triplet combination regimen," said Vimal Mehta, Chief Executive Officer of BTI. "Mechanistically, we believe the action of BXCL701 on macrophages and neutrophils within the tumor tissue can activate the innate immune system and then in combination with NKTR-214 and an anti-PD1, we can then prime adaptive immune cells in order to trigger T-cell driven anti-cancer activity and the generation of T-cell memory. The exciting preclinical data presented at this year's ASCO Meeting highlighted the complementary mechanisms by which these three agents can synergize to generate durable responses in various animal models."

"We believe it is essential to target multiple dimensions of the immune system in parallel in order to address the multi-faceted etiologies underlying cancer cell growth in difficult-to-treat tumors such as pancreatic cancer," said Jonathan Zalevsky, Senior Vice President, Biology & Preclinical Development of Nektar Therapeutics. "This experimental triplet combination regimen of BXCL701, NKTR-214 and a checkpoint inhibitor is designed to leverage multiple mechanisms of action at once to better fight pancreatic cancer while potentially generating long-term cancer immunity. We're pleased to be working with BTI on this program."

BTI and Nektar Therapeutics initially announced a preclinical research collaboration in November 2017. This collaboration focused on utilizing the complementary mechanisms of BXCL701 and NKTR-214 to stimulate the body's own immune system to overcome immunosuppressive mechanisms in the tumor microenvironment.

About BioXcel Therapeutics, Inc.:
BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence approaches to identify the next wave of medicines across 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 two most advanced clinical development programs are BXCL501, a sublingual thin film formulation designed for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent designed for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer. For more information, please visit www.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, statements that relate to the advancement and development of BXCL701, the commencement of clinical trials, the availability of data from clinical trials and other information that is not historical information. When used herein, words such as "anticipate", "being", "will", "plan", "may", "continue", 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 BioXcel's current expectations and various assumptions. BioXcel believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. BioXcel 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, market conditions and the factors described under the caption "Risk Factors" in BioXcel's 10 Q for the Quarter ended June 30, 2018 and BioXcel's other filings made with the Securities and Exchange Commission. Consequently, forward-looking statements should be regarded solely as BioXcel's current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. BioXcel cannot guarantee future results, events, levels of activity, performance or achievements. BioXcel does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by law.

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