BioXcel Therapeutics Establishes Immuno-Oncology Clinical Advisory Board to Advance BXCL701 Development

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Appoints world renowned immuno-oncology clinicians and scientists

NEW HAVEN, Conn., Aug. 22, 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, today announced the formation of an immuno-oncology clinical advisory board (CAB). The newly formed CAB will play an integral role in the development of BXCL701, a first-in-class DPP8/9 and FAP inhibitor, currently being developed for the treatment of pancreatic and treatment emergent neuroendocrine prostate cancer (tNEPC). BXCL701 is designed to stimulate both the innate and acquired immune systems by inhibiting DPP8/9 and blocking immune evasion by inhibiting Fibroblast Activation Protein (FAP). The CAB will also support BTI’s future immuno-oncology candidates identified through the Company’s artificial intelligence (AI) innovation lab partnership with BioXcel Corporation.

Members of the CAB are preeminent experts in developing drugs for pancreatic and prostate cancer and are at the forefront of advancing new therapies through clinical research to improve patient outcomes. The founding US members of the immuno-oncology CAB include:

- Pancreatic cancer advisors:
  - Louis Weiner, M.D.; Georgetown Lombardi Comprehensive Cancer Center, Chair; National Cancer Institute (NCI's) Board of Scientific Counselors
  - Daniel Von Hoff, M.D., F.A.C.P.; Translational Genomics Research Institute (TGen), HonorHealth, McKesson Specialty Health, Mayo Clinic, former President of ASCO, former AACR board member, instrumental in development of gemcitabine (Gemzar®), nab-paclitaxel (ABRAXANE®), irinotecan liposome injection (CAMPTOSAR®) and many other approved drugs

- Neuroendocrine prostate cancer advisors:
  - Eric Small, M.D.; University of California, San Francisco (UCSF), involved in development of abiraterone (ZYTIGA®), apalutamide (ERLEADA™), sipuleucel T (PROVENGE®), and ipilumimab (YERVOY®)
  - Emmanuel S. Antonarakis, M.D.; Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, co-principal investigator for the KEYNOTE-199 trial (Pembrolizumab (KEYTRUDA®) for treatment of metastatic castration resistant prostate cancer).

Dr. Vimal Mehta, Founder and Chief Executive Officer of BTI, commented, “We are pleased to have distinguished thought leaders such as Drs. Weiner, Von Hoff, Small, and Antonarakis join BTI’s immuno-oncology CAB. Each has made outstanding contributions in developing treatments for pancreatic and prostate cancer. Their clinical experience, coupled with their deep expertise in the broader immuno-oncology arena will be invaluable to BTI. Our lead immuno-oncology candidate, BXCL701, has the potential to improve clinical benefit in patients suffering from pancreatic cancer and tNEPC."

Dr. Vincent J. O’Neill, Senior Vice President and Chief Medical Officer of BTI, commented, “BXCL701 is being developed to treat pancreatic cancer and tNEPC, an aggressive form of prostate cancer which is currently untreatable, creating a novel therapeutic option for patients. We continue to be excited about BXCL701’s therapeutic potential in these, and potentially other, types of cancer. We are looking forward to utilizing the expertise and knowledge of such notable experts."

Louis M. Weiner, M.D., is the Director of Georgetown Lombardi Comprehensive Cancer Center, associate vice president at Georgetown University Medical Center, chair of the oncology department at Georgetown’s School of Medicine, and clinical director of cancer services at MedStar Georgetown University Hospital. Prior to joining Georgetown Lombardi, Dr. Weiner served as chairman of the medical oncology department and vice president for translational research at Fox Chase Cancer Center in Philadelphia. Dr. Weiner is an internationally recognized medical oncologist specializing in the treatment of gastrointestinal cancers and an accomplished researcher developing novel immunotherapy treatments in his laboratory. He serves as chair of the NCI’s Board of Scientific Counselors – Clinical Sciences and Epidemiology, and as a member of its Clinical Trials and Translational Research Advisory Committee. He is a standing member of the Cancer Immunopathology and Immunotherapy Study Section of the National Institutes of Health. Dr. Weiner earned his bachelor’s degree in biology with honors from the University of Pennsylvania and his medical degree from Mount Sinai School of Medicine at New York University. After completing his internship, residency and service as chief medical resident at the University of Vermont’s Medical Center Hospital, he held clinical and research fellowships in hematology and oncology at Tufts University School of Medicine in Boston.

Daniel Von Hoff, M.D., F.A.C.P., is the distinguished professor, physician-in-chief, and director of molecular medicine at the TGen in Phoenix, Arizona. He also holds the Virginia G. Piper Distinguished Chair for Innovative Cancer Research at HonorHealth Clinical Research Institute in Scottsdale, Arizona. Dr. Von Hoff also serves as the Medical Director of Research at McKesson Specialty Health and the Chief Scientific Officer for US Oncology Research specializing in phase I clinical trials. Additionally, he is a Professor of Medicine at the Mayo Clinic. Dr. Von Hoff’s major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He was involved in the development of many FDA approved cancer treatments now in routine use. Notably, he was involved in the development of 3 of the 4 drugs used for treatment of advanced pancreatic cancer.

Currently, Dr. Von Hoff is focused on the development of molecularly targeted therapies for advanced pancreatic cancer. Dr. Von Hoff is the past President of the American Association for Cancer Research, a fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. From 2004-2010, he served on President George W. Bush's National Cancer Advisory Board. Dr. Von Hoff received his medical degree from Columbia University and completed his residency in internal medicine at University of California, San Francisco.

Eric J. Small, M.D., is a professor of medicine and urology at the University of California, San Francisco, where he is leader of the Prostate Cancer Program, and Deputy Director and Chief Scientific Officer in the Helen Diller Family Comprehensive Cancer Center. His patient care and research is focused on prostate cancer, immunotherapy and the mechanisms of resistance to standard therapies, most recently focusing on the development of treatment associated small cell/neuroendocrine prostate cancer (t-SCNC). Dr. Small was principal investigator for the Stand Up to Cancer West Coast Prostate Cancer Dream Team, and has been involved with the development of a number of therapeutics including abiraterone, apalutamide, sipuleucel T, and ipilumimab. Dr. Small is a member of the Board of Directors of the American Society of Clinical Oncology (ASCO). Dr. Small earned a bachelor's degree from Stanford University and a medical degree from Case Western Reserve University School of Medicine. While in medical school, he completed a fellowship in pathology. He completed post-graduate residency training in internal medicine at Beth Israel Hospital (Boston) and a fellowship in hematology and oncology at UCSF before joining the UCSF faculty.

Emmanuel S. Antonarakis, M.D., is an Associate Professor of Oncology and Urology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. He is also an attending physician and translational researcher at Johns Hopkins. Dr. Antonarakis' clinical interest is the management of prostate cancer and other genitourinary malignancies. His research focuses on developing novel androgen-directed therapies as well as immunotherapies for men with recurrent or advanced prostate cancer, as well as biomarker development. He is currently the principal investigator on several Phase II and III prostate cancer trials, and is an active member of the Prostate Cancer Clinical Trials Consortium (PCCTC) and the Eastern Cooperative Oncology Group (ECOG) as well as the NCI Prostate Cancer Task Force. Dr. Antonarakis is also the co-principal investigator for the KEYNOTE-199 trial. He obtained his medical degree from the University of Wales College Of Medicine and completed a Residency in Internal Medicine at the Johns Hopkins Bayview Medical Center, followed by a fellowship in Medical Oncology at the Johns Hopkins Hospital and Sidney Kimmel Cancer Center.

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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