BioXcel Therapeutics Forms Neuroscience Clinical Advisory Board to Support Global Development of BXCL501

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Prominent clinicians and neuroscientists to guide advancement of lead programs and emerging neuroscience pipeline

NEW HAVEN, Conn., July 10, 2018 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. ("BTI") (Nasdaq:BTAI), a clinical stage biopharmaceutical development company utilizing novel artificial intelligence to identify the next wave of medicines across neuroscience and immuno-oncology, today announced the formation of a Clinical Advisory Board (CAB) to provide strategic counsel to the Company as it advances the development of BXCL501, a first-in-class sublingual thin film formulation of Dexmedetomedine, for the treatment of agitation. Additionally, the CAB will support the advancement of further candidates in BTI's emerging neuroscience pipeline identified through its artificial intelligence (AI) innovation lab partnership with BioXcel Corporation.

The initial members of the CAB include: Prof. Sheldon H. Preskorn, M.D.; Prof. Stephen Marder, M.D.; Dr. George Grossberg, M.D. and Prof. Alan Breier, M.D. The Company expects to add other neuroscience leaders going forward.

Dr. Vimal Mehta, Founder and Chief Executive Officer of BTI, commented, "Drs. Preskorn, Marder, Grossberg and Breier are leaders in psychopharmacology and neuroscience. We are honored to have their guidance and support in the development of our lead program, BXCL501 and future neuroscience programs. I believe their collective expertise and significant experience will be invaluable as we advance and expand our clinical pipeline."

Dr. Frank D. Yocca, Chief Scientific Officer of BTI, "Recently, BTI announced positive data from the Phase 1b study evaluating the intravenous administration of Dexmedetomedine to establish an optimal dose for BXCL501 which achieved mild sedation without producing any clinically meaningful effects of blood pressure and / or heart rate. We are now preparing to initiate further clinical studies to advance the development of BXCL501. We are very excited to have such distinguished clinicians on our clinical advisory board who will play a crucial role in providing counsel on study designs, regulatory and medical affairs as well as the commercialization strategy for BXCL501."

Sheldon H. Preskorn, M.D., is President and Chief Executive Officer, Worldwide Psychopharmacology Consultants and Professor of Psychiatry, University of Kansas School of Medicine-Wichita (KUSM-W). He is one of the world's leading experts in psychiatric drug development. His career has included wide-ranging experience in both drug development research and clinical psychiatry. He has worked with many pharmaceutical, biotechnology, device and diagnostic companies around the world and has participated in every phase of human drug development and preclinical pharmacology. Over the last 25 years, Dr. Preskorn has been a principal investigator on numerous antidepressant and antipsychotic medications marketed in the United States. He has served on the US Food and Drug (FDA) Psychopharmacology Advisory Committee and presented 12 New Drug Applications to 8 different FDA Advisory Committees. His clinical experiences include: supervising physician for an acute psychosis ward, chief of psychiatry for a university affiliated Veterans Administration Medical Center, director of the KUSM-W Outpatient Psychiatric Clinic and Chair of the KUSM-W Department of Psychiatry. He has lectured on six continents and has published over 500 articles, book chapters and books. He is a member of American College of Neuropsychopharmacology in addition to other professional societies.

Stephen R. Marder, M.D. is the Daniel X. Freedman Professor of Psychiatry, the Vice Chair for Education, and the Director of the Section on Psychosis at the UCLA Semel Institute for Neuroscience and Human Behavior. He is also the Director of the VISN 22 Mental Illness Research, Education Clinical Center (MIRECC) for the Department of Veterans Affairs. He joined the staff at the Brentwood VA Medical Center and the faculty at UCLA in 1977. Dr. Marder's research has focused on the development of pharmacological, psychosocial, and rehabilitation approaches for improving functioning and quality of life. He led the NIMH MATRICS (Management and Treatment Research to Improve Cognition in Schizophrenia) initiative which provided guidance for the development of pharmacologic agents to improve cognition and motivation in schizophrenia. He also led an NIMH Network for trials of medications for improving cognition in schizophrenia. He was the former President of the International Society of CNS Clinical Trials and Methodology and is considered an expert on clinical trials methods for complex CNS disorders, particularly schizophrenia. He holds an A.B. from the University of Pennsylvania and medical degree from the State University of New York at Buffalo. Dr. Marder has received several awards including the Exemplary Psychiatrist Award from the National Alliance for the Mentally Ill, the Stanley Dean Research Award of the American College of Psychiatry and others.

Dr. George Grossberg, M.D. treats geriatric patients with neurocognitive disorders, including Alzheimer's disease. His areas of clinical expertise include late-life depression, delirium, psychiatry in the nursing home setting, and geriatric psychopharmacology. His research interests include behavioral symptoms in Alzheimer's disease and new treatments for neurocognitive disorders. Dr. Grossberg has served as a consultant for central nervous system disorders to companies such as Abbott, Astra-Zeneca, Bayer, Forest, Janssen, Lilly, Novartis, Organon, Omnicare and Synthelabo. He completed his medical degree and residency at Saint Louis University School of Medicine and is a member of the American Medical Directors Association. In addition, Dr. Grossberg is the Samuel W. Fordyce professor and director of Geriatric Psychiatry division at Saint Louis University School of Medicine. He is also President of the American Association for Geriatric Psychiatry and the International Psychogeriatric Association. Dr. Grossberg has written and edited 15 textbooks and has published over 500 papers and abstracts in the medical literature.

Alan Breier, M.D. is a Professor of Psychiatry and the Vice-Chair for Clinical Research at Indiana University School of Medicine. Additionally, he is the Chief of the Indiana University Psychotic Disorders Program and Chief, Prevention and Recovery Center for Early Psychosis (PARC). Dr. Breier previously served as a Chief Medical Officer and Vice President, Medical at Eli Lilly and Company; where he had worked since first joining as a Research Fellow in 1997. Dr. Breier's research is focused on testing innovative therapeutics for schizophrenia and elucidating the underlying disease process of psychotic disorders by implementing genetic analyses and brain imaging. He received his bachelor's degree (summa cum laude) from

University of Toledo, medical degree from University of Cincinnati College of Medicine and trained in psychiatry at Yale University School of Medicine. He is the member of American Psychiatric Association, Society of Biological Psychiatry and American College of Neuropsychopharmacology.

About BioXcel Therapeutics, Inc.:
BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence 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.

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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 BXCL501 and 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 prospectus dated March 7, 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.

Source: BioXcel Therapeutics, Inc.