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Cabaletta Bio Expands Scientific Regulatory, and Cell Therapy Manufacturing Expertise with Scientific Advisory Board Additions

-- Carl June, M.D., who led discovery and development of the breakthrough CAR T platform at the University of Pennsylvania

-- Jay Siegel, M.D., former head of Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research at FDA & retired Chief Biotechnology Officer at Johnson & Johnson

-- Gwendolyn Binder, Ph.D., Chief Technology Officer at Adaptimmune and expert in T cell product development, translational research and GMP manufacturing

RADNOR, Pa., Nov. 15, 2018 (GLOBE NEWSWIRE) -- Cabaletta Bio Inc., a biopharmaceutical company focused on the discovery and development of cellular therapies for B cell-mediated autoimmune diseases, has appointed three highly accomplished and experienced individuals, Carl June, M.D., Jay Siegel, M.D. and Gwendolyn Binder, Ph.D., to its Scientific Advisory Board (SAB). The new members join a prestigious SAB co-chaired by Cabaletta co-founders Michael Milone, M.D., Ph.D. and Aimee Payne, M.D., Ph.D.

“Cabaletta Bio was recently spun out from the University of Pennsylvania (“Penn”) to develop chimeric autoantibody receptor (CAAR) T cell products for the treatment of B cell-mediated autoimmune diseases. Our products are directly related to the chimeric antigen receptor (CAR) T cell platform discovered and developed at Penn,” said Steven Nichtberger, M.D., co-founder, CEO and Chairman of Cabaletta Bio. “The addition of these exceptionally accomplished individuals to our SAB brings directly relevant experience in multiple disciplines from individuals who will be engaged and invaluable advisors as we pursue our objective of rapidly advancing truly innovative treatments for patients suffering from B cell-mediated autoimmune diseases.”

Dr. June, the Richard W. Vague Professor of Immunotherapy in the Department of Pathology and Laboratory Medicine at Penn, Director of the Center for Cellular Immunotherapies at the Perelman School of Medicine and Director of the Parker Institute for Cancer Immunotherapy at Penn, led the research team that discovered and developed the first Food and Drug Administration (FDA) approved CAR T cell therapy, tisagenlecleucel (Kymriah®, Novartis). Dr. Michael Milone was a post-doctoral fellow in Dr. June’s laboratory and a co-inventor of tisagenlecleucel with responsibility for advising preclinical development efforts. Dr. June is a graduate of the Naval Academy in Annapolis and Baylor College of Medicine in Houston. He is board certified in Internal Medicine and Medical Oncology, has published more than 450 manuscripts and is the recipient of numerous prizes and honors.

Dr. Siegel, has extensive experience both as a leader in pharmaceutical product

development and in regulation at the FDA. He recently retired from Johnson & Johnson (J&J) where he was Chief Biotechnology Officer and Head of Scientific Strategy and Policy. During his tenure at J&J, including as Group President of R&D for Biotechnology, Immunology and Oncology, the groups he led were responsible for overseeing the discovery and development of several products including STELARA®, SIMPONI®, SYLVANT® as well as certain indications for REMICADE®. He had also served as Head of Pharmaceutical Global Regulatory Affairs, Group President for R&D and President of Centocor R&D. Prior to joining J&J, Dr. Siegel served more than 20 years at the U.S. FDA Center of Biologics Evaluation and Research (CBER) in positions of increasing responsibility for regulating certain biotechnology products in the US, ultimately as the head of therapeutic review and approval at CBER.

Dr. Siegel is currently co-chair of the working group on regenerative medicine at the National Academies of Sciences, Engineering and Medicine which has oversight for gene and cell therapy products. He is also a fellow with the American College of Physicians and the Society for Clinical Trials and has authored numerous publications in the areas of clinical trial design, biotechnology, immunology and drug development policy. Dr. Siegel earned his M.D. from Stanford University School of Medicine and is a recipient of numerous honors including the United States Public Health Service's highest honor, the Distinguished Service Medal and, twice, the U.S. Health & Human Services Secretary's Award for Distinguished Service.

Dr. Binder has served on the SAB since October. She brings more than 17 years of industry and academic leadership in translational research and development, T cell manufacturing and the early development of engineered T cell therapies. Dr. Binder serves as Chief Technology Officer at Adaptimmune, where she established regulatory, manufacturing, compliance and clinical operations. Dr. Binder led Adaptimmune's early internal manufacturing and process development teams for vector and cell manufacturing. She also set and executed the strategic plan for the company's currently operational GMP facility. Prior to Adaptimmune, Dr. Binder was a Director in the Translational Research Program at Penn, working under the direction of Dr. June and Dr. Milone. During her time at Penn, she oversaw the opening of five INDs for novel engineered T cell therapy products. Dr. Binder earned her Ph.D. from the Johns Hopkins University in Cellular and Molecular Medicine, with a focus in viral immunology.

Editor's Note: Drs. June, Milone, Payne and Nichtberger are Penn faculty members and hold equity stakes in the Company, and the University of Pennsylvania is an equity holder and investor in the Company. In addition, both Penn and the inventors of the licensed technology may receive additional financial benefits under the license in the future.

About CAAR T Cell Therapy

Chimeric autoantigen receptor (CAAR) T cells are believed to work by binding and destroying only disease-causing B cells, while sparing the normal B cells which are essential for human health. CAAR T cells are based on revolutionary chimeric antigen receptor (CAR) T cell technology developed at the University of Pennsylvania and are related to the technology platform that resulted in the first FDA-approved CAR T cell therapy. Rather than a CD19-targeting molecule, CAAR T cells express the autoantibody-targeted antigen on their surface. The 4-1BB co-stimulatory domain and the CD3-zeta signaling domain carry out the same activation and cytotoxic functions as in the CAR T setting. Thus, Cabaletta's CAARs

direct the patient's T cells to kill only the B cell population that produces self-reactive antibodies, potentially leading to complete and durable remission of specific autoimmune disease while sparing other B cell populations that provide beneficial immunity from infection.

About Cabaletta Bio
Cabaletta Bio is a biopharmaceutical company focused on the discovery and development of cellular therapies for B cell-mediated autoimmune diseases. Cabaletta's therapeutic platform produces highly selective autologous chimeric autoantibody receptor (CAAR) T cells that bind and destroy only disease-causing B cells, while sparing healthy B cells which are essential for human health. Cabaletta has signed an exclusive licensing agreement and other sponsored research agreements with Penn focused on treating B cell-mediated autoimmune diseases with CAAR T cells. Cabaletta was founded by Dr. Michael Milone, Dr. Aimee Payne and Dr. Steven Nichtberger. Dr. Milone and Dr. Payne are physician/scientists at Penn and also serve as co-chairs of Cabaletta's Scientific Advisory Board. The company's lead therapeutic program is a potential treatment for a prototypical B cell-mediated autoimmune disease, mucosal pemphigus vulgaris (mPV). mPV is a rare skin disorder that causes painful blisters and sores on mucous membranes such as the mouth, nose, throat, and genitals, leading to severe and sometimes debilitating and life-altering effects. For more information, visit www.cabalettabio.com.

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