Trovagene Investor Relations

Trovagene Announces the Addition of Dr. Sandra Silberman to its Clinical Advisory Board

Apr 13, 2017

SAN DIEGO, April 13, 2017 /PRNewswire/ -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, announced today that Dr. Sandra Silberman, a leading clinical researcher in hematology/oncology, has joined Dr. Jorge Cortes, Dr. Philip Janku and Dr. David Berz, as a member of Trovagene's Clinical Advisory Board (CAB). Dr. Silberman has extensive experience in the development of novel therapies for the treatment of hematologic cancers and will work with Trovagene through the clinical development process for PCM-075, an oral and highly selective polo-like kinase 1 (PLK1) inhibitor for the treatment of acute myeloid leukemia (AML).

"We are thrilled to have Dr. Silberman join our Clinical Advisory Board," said Bill Welch, Chief Executive Officer of Trovagene. "We are fortunate to have access to these industry leading physicians for guidance and collaboration as we work to achieve our goal to transform oncology with the development of precision cancer therapeutics."

Trovagene recently gained exclusive global development and commercialization rights for PCM-075 from Nerviano Medical Sciences, S.r.l., a major European oncology research and development company. A Phase 1 safety study of PCM-075 has already been successfully completed in patients with advanced metastatic cancers with data indicating an acceptable safety profile as well as antitumor activity. Trovagene believes that PCM-075 has pharmacokinetic and pharmacodynamic properties that provide advantages and may show improvement in clinical benefits over an earlier PLK1 inhibitor, for the treatment of patients with AML.

Trovagene plans to submit an investigational new drug (IND) application to the FDA in the second quarter of 2017. This submission will include a Phase 1/2 clinical protocol that will identify the safety of PCM-075 in AML patients, provide a preliminary assessment of response, study the effect of different clinical dosing regimens, as well as explore the potential of correlative biomarker analyses to select patients more likely to respond.

"I am excited to join Trovagene's Clinical Advisory Board," said Dr. Silberman. "I look forward to contributing my experience gained from leading the clinical development of imatinib (Gleevec®), the first targeted therapy for chronic myelogenous leukemia, to the development process for PCM-075."

Background on Clinical Advisory Board Members

Jorge Eduardo Cortes, MD

Dr. Cortes is a Deputy Chair and Professor of medicine in the Department of Leukemia at The

Dr. Cortes is a Deputy Chair and Professor of medicine in the Department of Leukemia at The University of Texas MD Anderson Cancer Center, Houston Texas where he directs the CML Program. He is chief editor of Hematological Malignancies Reports and Clinical Leukemia and serves in the Editorial Board of the Journal of Clinical Oncology, Leukemia, Clinical Cancer Research, Leukemia and Lymphoma and the American Journal of Hematology. Over the course of his 25-year career specializing in leukemia research, Dr. Cortes served several prestigious academic appointments at the University of Texas, including associate professor in the Department of Leukemia at the Graduate School of Biomedical Sciences and Chair of the CML section at the MD Anderson Cancer Center. He has received numerous awards including the Faculty Scholar Award from MD Anderson Cancer Center in 2003, the Annual Celgene Young Investigator Achievement Award for Clinical Research in Hematology in 2005, The Dr. John J. Kenny Award from The Leukemia & Lymphoma Society in 2006, the Service to Mankind Award from The Leukemia & Lymphoma Society in 2007 and the Otis W. and Pearl L. Walters Faculty Achievement Award in Clinical Research from MD Anderson Cancer Center in 2007.

Filip Janku, MD, PhD
Dr. Janku serves as an Assistant Professor in the Department of Investigational Cancer Therapeutics (Phase I Program) at MD Anderson Cancer Center. Dr. Janku's research focuses on proof-of-concept clinical trials that possess a pivotal correlative component especially those involving liquid biopsies, molecular profiling of cell-free DNA, the PI3K/AKT/mTOR pathway and therapeutic use of oncolytic bacteria. Dr. Janku received multiple awards for his research efforts, including Sidney Kimmel Scholar award, several ASCO Merit Awards as well as an American Association for Cancer Research Scholar-in-Training Award.

Sandra L. Silberman, MD, PhD
Dr. Silberman is an independent industry consultant, who has advised many major companies, including Bristol-Myers Squibb, AstraZeneca, Imclone, and Roche, in their various oncology programs. She began her career in clinical development at Pfizer, Inc., where she initiated the company's first program in clinical oncology and oversaw the introduction of erlotinib (Tarceva®) into clinical trials. She led the global development of Gleevec®, an innovative drug and the first targeted therapy for chronic myelogenous leukemia (CML), while she was at Novartis Clinical Research. Dr. Silberman was Vice President, Global Head of Translational Medicine and Innovation at Quintiles Transnational, a premier clinical research organization. She was also the Vice President and Global Head of Oncology at Eisai Medical Research, and at present consults for a number of other oncology biotechnology companies. She is currently an attending physician in the Duke Hematology/Oncology Fellowship program at the VAMC in Durham, NC.

David Berz, MD, PhD, MPH
Dr. David Berz is triple Board Certified in Internal Medicine, Hematology and Oncology. Dr. Berz has many years of extensive experience in the field of oncology, including private practice and clinical research, and is currently a scientist at City of Hope. Dr. Berz specializes in thoracic/lung malignancies, melanoma, and cancer immune-therapy. He is a member of the Melanoma Research Society and the Multidisciplinary Malignant Melanoma Committee at City of Hope. Dr. Berz is also a member of the American Society of Clinical Oncology and the American Society of Hematology.

About Trovagene, Inc.

Trovagene is a biotechnology company developing oncology therapeutics for improved cancer care by leveraging its proprietary Precision Cancer Monitoring® (PCM) technology in tumor genomics. Trovagene has broad intellectual property and proprietary technology to measure circulating tumor

DNA (ctDNA) in urine and blood to identify and quantify clinically actionable markers for predicting response to cancer therapies. Trovagene offers its PCM technology at its CLIA/CAP – accredited laboratory and plans to continue to vertically integrate its PCM technology with precision cancer therapeutics. For more information, please visit www.trovagene.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Trovagene's expectations, strategy, plans or intentions. These forward-looking statements are based on Trovagene's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our need for additional financing; our ability to continue as a going concern; clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove to be commercially successful, or that Trovagene's strategy to design its liquid biopsy tests to report on clinically actionable cancer genes will ultimately be successful or result in better reimbursement outcomes. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any precision medicine therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Trovagene's Form 10-K for the year ended December 31, 2016, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Trovagene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Trovagene Contact
Vicki Kelemen
Sr. Director, Communications
858-952-7652
vkelemen@trovagene.com

SOURCE Trovagene, Inc.

---

http://trovagene.investorroom.com/2017-04-13-Trovagene-Announces-the-Addition-of-Dr-Sandra-Silberman-to-its-Clinical-Advisory-Board