

Trovagene Announces Activation of Second Clinical Trial Site in Phase 1b/2 Acute Myeloid Leukemia (AML) Trial for PCM-075

Activation of second trial site for Phase 1b/2 clinical trial of PCM-075, in combination with standard-of care, to evaluate dose and scheduling, and preliminary anti-leukemic activity

Dec 21, 2017

SAN DIEGO, Dec. 21, 2017 /PRNewswire/ -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, today announced the activation of the second clinical trial site for its Phase 1b/2 multicenter trial of PCM-075 in patients with AML, with Virginia Piper Cancer Institute and Principal Investigator, Dr. Michaela Tsai.

The primary objectives of this Phase 1b/2 trial in AML are to evaluate the safety of PCM-075 in combination with either low-dose cytarabine or decitabine in subjects and to identify the maximum tolerated dose (MTD) in Phase 1b to administer to further evaluate the safety and preliminary efficacy in Phase 2. This trial is being led by Hematologist Jorge Eduardo Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center.

"PCM-075 is the first highly PLK1-selective competitive inhibitor administered orally to enter clinical trials with potential activity in both hematologic and solid tumor cancers," said Bill Welch, Chief Executive Officer of Trovagene. "We are excited to have Virginia Piper Cancer Institute as one of our key trial sites and ready to screen and enroll subjects in our PCM-075 AML trial."

"As the only accredited cancer research program in the Twin Cities, we are pleased to be able to offer this promising new drug candidate to our AML patients through our participation in this important clinical trial," said Dr. Michaela Tsai, medical oncologist in Minneapolis, Minnesota affiliated with Abbott Northwestern Hospital and North Memorial Medical Center. "Through this Phase 1b/2 clinical trial, we look forward to gaining insight into the safety, tolerability and initial efficacy of PCM-075."

About PCM-075

PCM-075 is a highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1) enzyme, which is over-expressed in multiple hematologic and solid tumor cancers. Studies have shown that inhibition of polo-like-kinases can lead to tumor cell death, including a Phase 2 study in Acute Myeloid Leukemia (AML) where response rates up to 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine-LDAC) versus treatment with LDAC



alone with a 13.3% response rate. A Phase 1 open-label, dose escalation safety study of PCM-075 has been completed in patients with advanced metastatic solid tumor cancers, and published in *Investigational New Drugs*. Trovogene is initiating a Phase 1b/2 clinical trial with PCM-075 in AML that was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clinicaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03303339. PCM-075 has been granted Orphan Drug Designation by the FDA for the treatment of patients with AML.

PCM-075 only targets PLK1 isoform (not PLK2 or PLK3), is oral, has a 24-hour drug half-life with reversible on-target hematologic toxicities. Trovogene believes that targeting only PLK1 with reversible on-target activity and an improved dose/scheduling protocol can significantly improve on the long-term outcome observed in previous studies with a PLK inhibitor in AML.

PCM-075 has demonstrated synergy in preclinical studies with over 10 chemotherapeutic and target agents used in hematologic and solid tumor cancers, including FLT3 and HDAC inhibitors, taxanes, and cytotoxins. Trovogene believes the combination of its targeted PLK-1 inhibitor, PCM-075, with other compounds has the potential for improved clinical efficacy in Acute Myeloid Leukemia (AML), Castration-Resistant Prostate Cancer (CRPC), Non-Hodgkin Lymphoma (NHL), Triple Negative Breast Cancer (TNBC) and Adrenocortical Carcinoma (ACC).

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) is a hematologic malignancy in which myeloid lineage cells of the bone marrow cease to differentiate appropriately, resulting in a marked increase in the number of circulating immature blast cells. As a consequence, the counts of mature red blood cells, platelets, and normal white blood cells decline, causing fatigue, shortness of breath, bleeding, and increased susceptibility to infection. The Surveillance, Epidemiology and End Results (SEER) program estimates the annual incidence rate of AML in the United States (US) to be approximately 21,000 cases in 2017. Rates of new AML cases have been rising an average of 3.1% each year over the last 10 years. The median age of AML diagnosis is 68 years of age, and approximately 45% of new diagnoses are among patients age 70 years or older

About Trovogene, Inc.

Trovogene is a precision medicine biotechnology company developing oncology therapeutics for improved cancer care by leveraging its proprietary Precision Cancer Monitoring® (PCM) technology in tumor genomics. Trovogene 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. Trovogene 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 <https://www.trovogene.com>.

About Virginia Piper Cancer Institute

Patients and their families are the heart and soul of the Virginia Piper Cancer Institute®. We believe that every patient deserves the best technology, from a compassionate staff, in an environment that is focused on their needs. Our team of expert health care professionals combines current technology and treatment methods with clinical research, genetic counseling and alternative therapies. We are an Academic Comprehensive Cancer Program as accredited by [Commission on Cancer of the American College of Surgeons](http://www.facs.org). We are one of a select group of 22 U.S.-accredited cancer programs, and the only in the Twin Cities, to receive the [2016 Outstanding Achievement Award by the Commission on Cancer](http://www.facs.org) of the American College of Surgeons. The award recognizes cancer programs that achieve excellence in compliance to the Commission on Cancer standards and provide the highest quality care to cancer patients.

Offering patients choices in their cancer care that fit their lives is the most important service we can provide. Clinical research is a key part of the cancer care offered at the Virginia Piper Cancer Institute. Doctors and research staff create and participate in advanced cancer research studies to bring new treatments to patients. They work with the entire care team to ensure our research efforts are supported in all areas.

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 Trovogene's expectations, strategy, plans or intentions. These forward-looking statements are based on Trovogene'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 Trovogene'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 Trovogene'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 Trovogene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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