Trovan Global Oncology Announces Presentations at the American Association for Cancer Research (AACR) Annual Meeting 2018

SAN DIEGO, April 12, 2018 /PRNewswire/ -- Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of hematologic and solid tumor cancers, today announced that three posters, focusing on preclinical and preliminary clinical biomarker data of PCM-075, its Polo-like Kinase 1 (PLK1) Inhibitor, will be presented at the American Association for Cancer Research (AACR) Annual Meeting to be held in Chicago, IL, April 14-18, 2018.

Trovagene will present data on its lead drug candidate, PCM-075, showing synergy of PCM-075 in combination with FLT3 inhibitors in models of Acute Myeloid Leukemia (AML); the identification and correlation of biomarkers and prediction of response to PCM-075, utilizing data from the Cancer Cell Line Encyclopedia (CCLE) database of the Broad Institute of MIT and Harvard; and initial pharmacodynamic and tumor biomarker analysis in its phase 1b/2 AML trial (NCT03303339).

Poster Presentation Details:

Poster Title: Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 is Highly Active Alone and Shows Synergy When Combined with FLT3 Inhibitors in Models of Acute Myeloid Leukemia (AML)
Poster Section and Number: Section 38 - #1885
Session Category: Experimental Agents and Combinations for Hematologic Malignancies 2
Session Date: Monday, April 16
Session Time: 8:00 am – 12:00 pm CDT

Poster Title: Computationally Predicted Sensitivity of Clinical Cohorts Identifies Drug Relationships and Biomarkers Associated with Response to PCM-075, a PLK1 Selective Inhibitor
Poster Section and Number: Section 36 - #2810
Session Category: Design, Structure/Activity, and Modeling
Session Date: Monday, April 16
Session Time: 1:00 pm – 5:00 pm CDT

Poster Title: Pharmacodynamic and Tumor Biomarker Analysis of a PLK1 Inhibitor, PCM-075, in a Phase 1b/2 Trial for Acute Myeloid Leukemia
Poster Section and Number: Section 38 - #4833
Session Category: DNA Damage and Cell Cycle Regulation Experimental Therapeutics
Session Date: Tuesday, April 17
Session Time: 1:00 pm – 5:00 pm CDT

About Trovagene, Inc.

Trovagene is a clinical-stage, oncology therapeutics company. The Company's primary focus is to develop targeted cancer therapeutics for improved patient care and to optimize drug development by leveraging its proprietary technology in tumor genomics. Trovagene has broad intellectual property and proprietary technology to analyze circulating tumor DNA (ctDNA) and clinically actionable biomarkers to identify patients most likely to respond to specific cancer therapies. The Company plans to continue to vertically integrate its tumor genomics technology with targeted cancer therapeutics. For more information, please visit https://www.trovagene.com.

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. Trovagene has an ongoing 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. Trovagene 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. Trovagene believes the combination of its targeted PLK1 inhibitor, PCM-075, with other compounds has the potential for improved clinical efficacy in Acute Myeloid Leukemia (AML), metastatic Castration-Resistant Prostate Cancer (mCRPC), Non-Hodgkin Lymphoma (NHL), Triple Negative Breast Cancer (TNBC) and Adrenocortical Carcinoma (ACC).

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, 2017, 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.

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