Trovanoge's PLK1 Inhibitor PCM-075 Demonstrates Synergy with a HDAC Inhibitor in Non-Hodgkin Lymphoma Cell Lines

Additionally, Trovagene announces PCM-075 synergy in combination with more than ten chemo and targeted therapeutics across a broad range of solid tumor and hematologic malignancies

SAN DIEGO, Aug. 21, 2017 /PRNewswire/ -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, today announced compelling results of preclinical research of PCM-075 with a Histone deacetylase (HDAC) inhibitor in Non-Hodgkin Lymphoma (NHL) cell lines. This synergy assessment study was conducted by Dr. Steven Grant, Associate Director for Translational Research and co-Leader, Developmental Therapeutics Program, Massey Cancer Center.

PCM-075, Trovagene's investigational Polo-like kinase 1 (PLK1) inhibitor, showed significant synergy in combination with a HDAC inhibitor of up to 80% in aggressive double-hit B-cell lymphoma (DLBCL) and mantle-cell lymphoma cell lines. DLBCL and mantle cell lymphomas within NHL represent challenging malignancies without a standard-of-care treatment and confer a poor prognosis for patients.

Additionally, PCM-075 synergy has been evaluated in combination with more than ten different chemotherapeutics, including cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, and targeted therapies, such as HDAC inhibitors, FLT3 inhibitors, and bortezomib. These therapeutics are used clinically for treatment of many solid and hematologic cancers, including Acute Myeloid Leukemia (AML), Acute Lymphocytic Leukemia (ALL), Non-Hodgkin Lymphoma (NHL), Multiple Myeloma, Adrenocortical Carcinoma (ACC), Triple-Negative Breast Cancer (TNBC), Small-Cell Lung Cancer (SCLC), and Ovarian Cancer.

"We are excited to see the synergistic benefits with PCM-075 in combination with a HDAC inhibitor in the most difficult cell lines in NHL," said Bill Welch, CEO of Trovagene. "This data complements our recent announcement of an in-vivo study demonstrating synergy of PCM-075 with a leading investigational FLT3 inhibitor, as well as PCM-075 synergy with many chemotherapeutics. We have an active Investigational New Drug (IND) in place with the FDA for each of solid tumors and hematologic malignancies, which could facilitate the development of PCM-075 across a number of cancer types."

The consistent and significant synergistic effects observed in preclinical research on tumor cell death indicates that PCM-075 could be effective in combination therapies to address a broad range of tumor types, as well as the emergence of drug-resistant tumors.

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 malignancies, as well as solid tumors such as adrenocortical, breast, prostate, ovarian, lung, gastric and colon cancers. PCM-075 is orally bioavailable and has been explored in an initial Phase 1, open-label, dose-escalation safety study in patients with advanced metastatic solid tumor cancers. Trovagene plans to initiate clinical trials of PCM-075 in AML, since it has significant advantages over prior PLK1 inhibitors evaluated in this indication, including a higher selectivity, greater potency, oral bioavailability and shorter half-life.

About Trovagene, Inc.

Trovagene 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. 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 https://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.

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