Trovagene Investor Relations

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Trovagene Presents Data Showing Synergy of PCM-075 in Combination with Zytiga® in Castration-Resistant Prostate Cancer Model at 2018 Genitourinary Cancers Symposium

Targeted treatment with highly-selective Polo-like Kinase 1 inhibitor PCM-075 in combination with Zytiga® (abiraterone acetate) may represent a new treatment option in CRPC

Feb 9, 2018

SAN DIEGO, Feb. 9, 2018 /PRNewswire/ -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, developing targeted cancer therapeutics, today announced that preclinical data demonstrating the synergy of PCM-075, its highly-selective Polo-like kinase 1 (PLK1) Inhibitor, in combination with abiraterone acetate (Zytiga® – Johnson & Johnson), will be featured as a Poster Presentation at the *2018 Genitourinary Cancers Symposium* on February 9th, from 12:15 – 1:45 PM and 6:00 – 7:00 PM PST, in San Francisco, California.

The poster entitled, *Combination of Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 with Abiraterone in Prostate Cancer and Non-Androgen-Driven Cancer Models,* showcases data from Dr. Michael Yaffe's lab at the Koch Institute for Integrative Cancer Research at Massachusetts Institute of Technology and will be presented by Dr. Jesse Patterson.

The underlying mechanism of synergy was further examined by performing gene-expression comparison across more than 30 different synergistic and non-synergistic cell lines across multiple tumor types. From this analysis, multiple hypothesis-generating mechanisms were identified, one of which was the retinoic acid pathway, which when activated is predictive of synergy.

Polo-like Kinase 1 (PLK1) is known to be over-expressed in many hematologic and solid tumor cancers, including Castration-Resistant Prostate Cancer. PLK1 inhibition by PCM-075 induces cell-cycle arrest and apoptosis, or tumor cell death in numerous tumor cell lines, including prostate cancer cell lines. The presentation data indicates that PCM-075 in combination with anti-androgen, abiraterone acetate (Zytiga® - Johnson & Johnson), is synergistic in inducing cell death within prostate cancer cell lines.

"We are seeing significant synergy when PCM-075 is combined with chemotherapeutics and targeted therapies in xenograft models and believe that combination regimens that include PCM-075 may lead to improving patient outcomes in CRPC," said Mark Erlander, Chief Scientific Officer of Trovagene.

To further evaluate the potential of the combination of PCM-075 and Zytiga to improve treatment and extend patient response to Zytiga, Trovagene is initiating a Phase 2 clinical trial in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC). This clinical study is called UNITE, *"A Phase 2 Study to*

Understand the Novel Combination of PCM-075 and Abiraterone and the Opportunity to Improve Treatment and Extend Response in Patients with Metastatic Castration-Resistant Prostate Cancer." The Harvard Medical Cancer Centers will conduct this Phase 2 study that is expected to enroll approximately 25 patients with mCRPC who are showing early signs of disease progression while on abiraterone/prednisone therapy and will evaluate the proportion of patients achieving disease control after 12 weeks of study treatment. This study was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clnincaltrials.gov. The NCT number assigned to this trial by clinicaltrials.gov is NCT03414034.

Details of the poster presentation are provided below:

Title: Combination of Selective Polo-like Kinase 1 (PLK1) Inhibitor PCM-075 with Abiraterone in Prostate Cancer and Non-Androgen-Driven Cancer Models

Session Name: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers

Location: Poster Session B

Date and Time: Friday, February 9th – 12:15 – 1:45 pm and 6:00 – 7:00 pm PST

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 is initiating a Phase 2 trial of PCM-075 in combination with Zytiga® (abiraterone acetate) and prednisone in metastatic Castration-Resistant Prostate Cancer that was accepted by the National Library of Medicine (NLM) and is now publicly viewable on www.clnincaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03414034.

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 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 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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Symposium

http://trovagene.investorroom.com/2018-02-09-Trovagene-Presents-Data-Showing-Synergy-of-PCM-075-in-Combination-with-Zytiga-R-in-Castration-Resistant-Prostate-Cancer-Model-at-2018-Genitourinary-Cancers-Symposium