Trovagene Investor Relations

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Trovagene Announces FDA Approval of IND for Phase 1b/2 Trial of PCM-075 in Patients with Acute Myeloid Leukemia

PCM-075, in combination with decitabine, in patients with Acute Myeloid Leukemia (AML) for exploration of the safety, tolerability, dose and scheduling, and antitumor activity

Jul 27, 2017

SAN DIEGO, July 27, 2017 /PRNewswire/ -- Trovagene, Inc. (NASDAQ: TROV), a precision medicine biotechnology company, announced today that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) Application for PCM-075, a Polo-like Kinase 1 (PLK1) inhibitor, and has provided authorization to proceed with the treatment of patients with AML. Trovagene submitted its IND for a Phase 1b/2 clinical trial of PCM-075 in patients with AML to the FDA on June 27, 2017.

The Phase 1b/2 clinical trial will be 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.

"The FDA's timely acceptance of our IND application and Phase 1b/2 protocol is an important milestone for Trovagene," said Bill Welch, Chief Executive Officer of Trovagene. "We have already received positive indications of interest from numerous key investigators and clinical institutions as we make preparations to initiate our trial in the U.S. Also, we are fortunate to have Dr. Cortes as the Principal Investigator on our trial given his vast experience in leukemia and his prior work with PLK1 inhibitors."

Clinical Study Details

The Phase 1b/2 is an open-label trial to evaluate the safety and anti-leukemic activity of PCM-075 in combination with decitabine in subjects with AML. The Phase 1b subjects will have relapsed, or have resistant disease to three or fewer prior therapeutic regimens. The Phase 2 subjects will have received no more than one prior regimen for the treatment of their AML, have either relapsed or refractory disease, and are judged not to be candidates for re-induction therapy. Newly diagnosed subjects will be included if they have not received prior therapy for their disease, and are ineligible for, or have refused, standard intensive induction therapy.

The Phase 1b is a dose escalation trial of PCM-075 in combination with decitabine to evaluate drug safety, tolerability, dose and scheduling, and determine a recommended clinical treatment dose for the Phase 2 continuation trial. The initial Phase 1b dose level of 12 mg/m2/day will be increased by 50% increments to reach the maximum clinical dose for AML patients. Pharmacokinetics of PCM-075 and correlative biomarker activity will be assessed prior to the initiation of Phase 2.

The Phase 2 continuation trial is open-label with administration of the recommended PCM-075 clinical dose in combination with decitabine. Doses of PCM-075 will be administered orally each day for five consecutive days in a 28-day cycle in both Phase 1b and Phase 2. Trovagene expects approximately 60 patients to be dosed with PCM-075 and evaluated in the Phase 1b/2 trial. PCM-075 will be supplied as hard gelatin capsules and will be manufactured by NerPharMa, a pharmaceutical manufacturing company and a subsidiary of Nerviano Medical Sciences.

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 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 several different hematologic malignancies, as well as solid tumors such as 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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