
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): September 5, 2018

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-35558
(Commission
File Number)

27-2004382
(IRS Employer
Identification No.)

**11055 Flintkote Avenue
San Diego, CA 92121**
(Address of principal executive offices)

Registrant's telephone number, including area code: (858) 952-7570

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On September 5, 2018, Trovogene, Inc. issued a press release announcing it has developed a method for predicting response to treatment by measuring the ability of Onvansertib, a first-in-class, 3rd generation, oral and highly-selective Polo-like Kinase 1 (PLK1), to inhibit PLK1 in patients with Acute Myeloid Leukemia (AML). A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release of Trovogene, Inc. dated September 5, 2018](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 5, 2018

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams

Interim Chief Executive Officer



Trovagene Announces Predictive Clinical Biomarker Approach to Identify Acute Myeloid Leukemia (AML) Patients Most Likely to Respond to Onvansertib

Target engagement and inhibition of PLK1 by Onvansertib predictive of treatment response

SAN DIEGO, CA – September 05, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, using a precision medicine approach to develop drugs for the treatment of leukemias, lymphomas and solid tumor cancers, today announced it has developed a method for predicting response to treatment by measuring the ability of Onvansertib, a first-in-class, 3rd generation, oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor, to inhibit PLK1 in patients with Acute Myeloid Leukemia (AML).

PLK1 uniquely phosphorylates translational control tumor protein (TCTP) to form pTCTP and inhibition of this enzymatic activity by Onvansertib appears to be predictive of patient response to treatment. In the ongoing Phase 1b/2 open label clinical trial in AML, PLK1 inhibition is being assessed 3-hours following administration, at the approximate peak concentration (C_{max}) of Onvansertib. In the first six patients treated, the greatest target engagement, or inhibition of PLK1, was observed in the three patients who showed a response to treatment.

“We are encouraged by these preliminary results and believe that a simple blood test obtained 3-hours post-dose could enrich for patients who are most likely respond to treatment with Onvansertib,” said Dr. Mark Erlander, Chief Scientific Officer of Trovagene. “We believe that integrating a predictive biomarker strategy into our Onvansertib clinical development program may enable us to tailor treatment to specific sub-groups of patients and have a positive clinical impact.”

Trovagene has filed a U.S. patent application with the United States Patent and Trademark Office (USPTO) to protect its method for evaluating responsiveness of a cancer to a Polo-like Kinase 1 (PLK1) inhibitor by determining the ability of the PLK1 inhibitor to inhibit phosphorylation of a unique target of PLK1 in cells of the cancer.

About the Onvansertib Phase 1b/2 Acute Myeloid Leukemia Trial

The Phase 1b/2 trial (NCT03303339) is a multi-center, open-label trial to evaluate the safety and efficacy of Onvansertib in combination with standard-of-care chemotherapy in AML patients who are ineligible for intensive induction therapy or whose disease is relapsed or refractory. In Phase 1b dose-escalation segment of the trial, the primary objective is to determine the maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D), using a traditional 3+3 design. In Phase 2 the MTD or RP2D will be administered to 32 patients to evaluate preliminary antitumor activity and to continue to evaluate the safety and tolerability of Onvansertib in combination with standard-of-care chemotherapy. This trial is being led by Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and Amer Zeidan, MBBS, MHS, assistant professor of Medicine at Yale School of Medicine, Hematology expert at Yale Cancer Center. The trial is being conducted at nine sites in the U.S.

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About Onvansertib

Onvansertib is a first-in-class, 3rd generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK 1) enzyme, which is over-expressed in multiple cancers, including leukemias, lymphomas and solid tumors. Separate studies with other PLK inhibitors 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 of up to 31% were observed when combined 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 Onvansertib has been completed in patients with advanced metastatic solid tumor cancers and published in *Investigational New Drugs*. The maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) in this trial was 24 mg/m². Trovogene has an ongoing Phase 1b/2 clinical trial with Onvansertib 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. Onvansertib has been granted Orphan Drug Designation by the FDA in the U.S. and by the EC in the European Union (EU) for the treatment of patients with AML. Trovogene is also enrolling a Phase 2 trial of Onvansertib in combination with Zytiga[®] (abiraterone acetate) and prednisone in metastatic Castration-Resistant Prostate Cancer (mCRPC) 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 NCT03414034.

Onvansertib targets the PLK1 isoform (not PLK2 or PLK3), is orally available, has a 24-hour drug half-life with only mild to moderate side effects reported. Trovogene believes that targeting only PLK1 and having a favorable safety and tolerability profile, along with an improved dose/scheduling regimen will significantly improve on the outcome observed in previous studies with a former panPLK inhibitor in AML.

Onvansertib has demonstrated synergy in preclinical studies with numerous chemotherapies and targeted therapeutics used to treat leukemias, lymphomas and solid tumor cancers, including FLT3 and HDAC inhibitors, taxanes, and cytotoxins. Trovogene believes the combination of its targeted PLK1 inhibitor, Onvansertib, with other compounds has the potential to improve clinical efficacy in Acute Myeloid Leukemia (AML), metastatic Castration-Resistant Prostate Cancer (mCRPC), Non-Hodgkin Lymphoma (NHL), Triple Negative Breast Cancer (TNBC), as well as other types of cancer.

About Trovogene, Inc.

Trovogene is a clinical-stage, oncology therapeutics company, using a precision medicine approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including leukemias, lymphomas and solid tumors. Trovogene has intellectual property and proprietary technology that enables the Company to analyze circulating tumor DNA (ctDNA) and clinically actionable markers to identify patients most likely to respond to specific cancer

therapies. Trovogene plans to continue to vertically integrate its tumor genomics technology with the development of targeted cancer therapeutics. For more information, please visit <https://www.trovogene.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 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, 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 Trovogene does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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