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

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): June 15, 2018**

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**Trovagene, Inc.**

(Exact name of registrant as specified in its charter)

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**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)

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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.

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**Item 8.01 Other Events.**

On June 15, 2018, Trovogene, Inc. issued a press release announcing the completion of the first dose cohort of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in combination with decitabine, in its Phase 1b/2 clinical trial 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 June 15, 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: June 15, 2018

TROVAGENE, INC.

By: /s/ William J. Welch  
William J. Welch  
President and Chief Executive Officer



## **Trovagene Announces Completion of First Dosing Cohort of Patients Treated with PCM-075 in Combination with Decitabine in Ongoing Phase 1b/2 AML Trial**

### ***Safety Review Committee (SRC) recommends proceeding to the second dosing cohort of PCM-075 in combination with decitabine in dose-escalation phase of trial***

SAN DIEGO, CA – June 15, 2018 – Trovagene, Inc. (NASDAQ: TROV), a clinical-stage oncology therapeutics company, developing targeted therapeutics for the treatment of hematologic and solid tumor cancers, today announced completion of the first dose cohort of PCM-075, a highly-selective Polo-like Kinase 1 (PLK1) Inhibitor, in combination with decitabine, in its Phase 1b/2 clinical trial in patients with Acute Myeloid Leukemia (AML).

Three patients were treated with PCM-075 at 12 mg/m<sup>2</sup>, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with decitabine. The combination of PCM-075 and decitabine was well tolerated in all patients. The independent Safety Review Committee (SRC) has recommended escalating to the second dose cohort of three patients at 18 mg/m<sup>2</sup> of PCM-075 (approximately a 50% increase) in combination with decitabine.

This is the second dose cohort to be completed in the Phase 1b/2 open-label AML study of PCM-075 in combination with standard-of-care chemotherapy. In May 2018, Trovagene announced the successful completion of the first dose cohort of three patients treated with PCM-075 at 12 mg/m<sup>2</sup>, administered orally, once daily, on days 1-5 of the treatment cycle, in combination with low-dose cytarabine (LDAC). Achieving this milestone enabled the initiation of recruitment and enrollment of the next three-patient cohort for dosing of PCM-075 at 18mg/m<sup>2</sup>, administered once daily, on days 1-5 of the treatment cycle, in combination with LDAC.

The PCM-075 dose level may be increased by 50% increments on either LDAC or decitabine in successive cohorts of three patients until a maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) is achieved. The MTD or RP2D will be used in the Phase 2 segment of the trial to evaluate antitumor activity and to continue to assess the safety and tolerability of PCM-075 in combination with standard-of-care chemotherapy.

“We are pleased that the combination of PCM-075 and decitabine was well tolerated and that the SRC recommended we advance to our second dose cohort,” said Bill Welch, Chief Executive Officer of Trovagene. “We are excited to be moving forward with the next dose level of PCM-075 (18 mg/m<sup>2</sup>) in combination with standard-of-care chemotherapy – cytarabine or decitabine – in our Phase 1b dose escalation trial, with each cohort enrolling three patients, respectively.”

### **About the PCM-075 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 PCM-075 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 PCM-075 in combination with standard-of-care chemotherapy. This trial is being led by Hematologist Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center. Eight of ten clinical sites are currently activated in the U.S. and recruiting patients.

### **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. 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 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*. The maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) in this trial was 24 mg/m<sup>2</sup>. Trovogene 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](http://www.clinicaltrials.gov). The NCT number assigned by [clinicaltrials.gov](http://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. Trovogene 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. Trovogene 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), as well as other hematologic and solid tumor cancers.

### **About Trovogene, Inc.**

Trovogene is a clinical-stage, oncology therapeutics company. The Company's primary focus is to develop oncology therapeutics for the treatment of hematologic and solid tumor cancers for improved cancer care, utilizing its technology in tumor genomics. 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 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.

### **Trovagene Contact:**

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