
**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): **November 6, 2019**

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:

Trading Symbol(s)

Name of each exchange on which registered:

Common Stock

TROV

Nasdaq Capital Market

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 November 6, 2019, Trovogene, Inc. issued a press release announcing that data from its completed Phase 1b and ongoing Phase 2 study of onvansertib in patients with relapsed/refractory acute myeloid leukemia (AML) has been accepted for an oral presentation at the 61st American Society of Hematology (ASH) Annual Meeting to be held December 7 - 10, 2019 in Orlando, Florida. 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 November 6, 2019](#)

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: November 6, 2019

TROVAGENE, INC.

By: /s/ Thomas Adams
Thomas Adams
Chief Executive Officer

Trovogene Announces Data from Acute Myeloid Leukemia (AML) Phase 1b/2 Trial of Onvansertib Chosen for Oral Presentation at ASH 2019 Annual Meeting

- ***Results from completed Phase 1b and ongoing Phase 2 trial of onvansertib in relapsed/refractory AML to be presented in oral session***

SAN DIEGO (November 6, 2019) – Trovogene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis), for the treatment of various cancers including leukemia, prostate and colorectal, today announced that data from its completed Phase 1b and ongoing Phase 2 study of onvansertib in patients with relapsed/refractory acute myeloid leukemia (AML) has been accepted for an oral presentation at the 61st American Society of Hematology (ASH) Annual Meeting to be held December 7 - 10, 2019 in Orlando, Florida. In addition to the oral presentation, the abstract will also be published online in the November supplemental issue of the journal *Blood*.

“We believe that having our abstract selected for presentation in an oral session at ASH signifies the level of interest in onvansertib, a first-in-class, third-generation oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor,” said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovogene. “Our results to-date are very encouraging and we continue to rapidly advance our Phase 2 trial of onvansertib in combination with standard-of-care chemotherapy to bring a much-needed new treatment option to patients with relapsed/refractory AML, including patients who have developed resistance to first-line treatment with venetoclax.”

Oral Presentation Details

Title: *Safety, Efficacy and Biomarker Analysis of a Phase 1b/2 Study of Onvansertib (ONV), a Polo-like Kinase 1 (PLK1) Inhibitor, in Combination with Low-Dose Cytarabine (LDAC) or Decitabine (DEC) in Patients with Relapsed/Refractory Acute Myeloid Leukemia (R/R AML)* [Abstract 230]

Session Name: 616. Acute Myeloid Leukemia: Novel Therapy, Excluding Transplantation; Novel Targets and Combinations

Session Date: Saturday, December 7, 2019

Session Time: 2:00 PM - 3:30 PM EST

Presentation Time: 2:15 PM EST

Location: Orange County Convention Center, Chaplin Theater (W320)

About the Ongoing Phase 2 Clinical Trial of Onvansertib in AML

The Phase 2 AML trial (NCT03303339) of onvansertib in combination with decitabine will enroll 32 patients who are either treatment naïve and not candidates for induction therapy or who have relapsed disease after treatment with one prior regimen, including patients treated with venetoclax in combination with a hypomethylating agent. Patients will receive onvansertib, administered orally, on days 1 through 5 of each 21-28-day cycle in combination with decitabine.

The primary efficacy endpoint of objective response (CR + CRi) will be assessed in patients who complete at least 1 cycle of treatment.

About Onvansertib

Onvansertib is a first-in-class, third-generation, oral and highly-selective adenosine triphosphate (ATP) competitive inhibitor of the serine/threonine polo-like-kinase 1 (PLK1) enzyme, which is over-expressed in multiple cancers including leukemias, lymphomas and solid tumors. Onvansertib targets the PLK1 isoform only (not PLK2 or PLK3), is orally administered and has a 24-hour 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 irinotecan, FLT3 and HDAC inhibitors, taxanes and cytotoxins. Trovogene believes the combination of 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), colorectal cancer and triple-negative breast cancer (TNBC), as well as other types of cancer.

Trovogene has three ongoing clinical trials of onvansertib: A Phase 2 trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with mCRPC who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving Zytiga® (NCT03414034); a Phase 1b/2 Study of onvansertib in combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS mutation (NCT03829410); and a Phase 1b/2 (Phase 1b completed in 2019) clinical trial of onvansertib in combination with low-dose cytarabine or decitabine in patients with relapsed or refractory AML (NCT03303339). Onvansertib has been granted orphan drug designation by the FDA in the U.S. and by the EC in the European Union for the treatment of patients with AML.

Trovogene licensed onvansertib (also known as NMS-1286937 and PCM-075) from Nerviano Medical Sciences (NMS), the largest oncology-focused research and development company in Italy, and a leader in protein kinase drug development. NMS has an excellent track record of licensing innovative drugs to pharma/biotech companies, including Array (recently acquired by Pfizer), Ignyta (acquired by Roche) and Genentech.

About Trovogene, Inc.

Trovogene is a clinical-stage, Precision Cancer Medicine™ oncology therapeutics company developing drugs that target cell division (mitosis), for the treatment of various cancers 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.trovogeneoncology.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; 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. 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, 2018, 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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