
**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): April 2, 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)

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 April 2, 2019, Trovogene, Inc.(the “Company”) issued a press release announcing the presentation of early data at the American Association for Cancer Research (AACR) 2019 Annual Meeting from its ongoing Phase 2 study evaluating Onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC). 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 April 2, 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: April 2, 2019

TROVAGENE, INC.

By: /s/ Thomas Adams

Thomas Adams
Chief Executive Officer



Early Data from Phase 2 Trial Indicates Activity of Onvansertib in Prostate Cancer Patients Showing Initial Resistance to Anti-Androgen Therapy

Early PSA response observed when onvansertib is added to abiraterone (Zytiga®) in 2 of 6 patients to-date; first patient achieves primary efficacy endpoint

PSA trajectory in patient achieving primary efficacy endpoint indicates alteration of the natural history of early abiraterone (Zytiga®) resistance

Patients with observed Responses to-date harbor highly aggressive androgen receptor variant (AR-V7) which is resistant to abiraterone (Zytiga®)

SAN DIEGO, CA – April 2, 2019 – Trovogene, Inc. (Nasdaq: TROV), a clinical-stage oncology therapeutics company, taking a precision medicine approach to develop drugs that target cell division (mitosis) for the treatment of leukemias, lymphomas and solid tumor cancers, today presented early data from its ongoing Phase 2 study evaluating Onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone in patients with metastatic Castration-Resistant Prostate Cancer (mCRPC).

The data, featured at the American Association for Cancer Research (AACR) shows clinical activity as measured by prostate specific antigen (PSA) response when onvansertib is added to Zytiga® in patients showing early signs of resistance to Zytiga®.

Presentation Highlights

Preliminary Efficacy:

- Early PSA response was observed with the addition of onvansertib to daily abiraterone in 2 of 6 patients, with 1 patient achieving the efficacy endpoint of disease control and a 30% decrease in tumor size by RECIST criteria (unconfirmed Partial Response to be confirmed with subsequent CT scan in May 2019)
- PSA trajectory in the patient achieving the primary efficacy endpoint changed from 100% increase (16.05ng/ml to 34.23 ng/ml) in the 60 days prior to study to 8.4% increase during 84 days on study, indicating alteration of the natural history of early abiraterone resistance
- Both patients that showed an early response (at C1D8) with decreases in PSA levels, also tested positive for AR-V7, a highly aggressive androgen receptor variant (AR-V7) which is resistant to Zytiga because it no longer needs androgen for tumor growth

Safety and Tolerability:

- The combination of onvansertib and Zytiga is safe and well tolerated as demonstrated in the safety lead-in segment of the trial
- No unexpected, off-target toxicities have been reported in patients treated to-date

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“We are encouraged by the signs of clinical activity observed to-date and intrigued by the potential to be able to effectively treat patients who are AR-V7 positive,” said Dr. Mark Erlander, Chief Scientific Officer of Trovogene. “There are limited options, other than intensive chemotherapy which has a poor prognosis, in patients who are showing initial signs of resistance to treatment with Zytiga® and those that harbor the highly aggressive androgen receptor variant (AR-V7). We believe the combination regimen may provide a much-needed new therapeutic option for these patients.”

Details of the poster presentation are provided below:

Title: *A Phase 2 Study of the Polo-like Kinase 1 (PLK1) Inhibitor Onvansertib in Combination with Abiraterone (Abi) and Prednisone in Patients with Metastatic Castration-Resistant Prostate Cancer*

Session Title: Phase I-III Trials in Progress: Part 2

Session Date and Time: Tuesday, April 2, 2019; 8:00 AM - 12:00 PM EST

Session Location: Georgia World Congress Center, Exhibit Hall B, Poster Section 17

About the Ongoing Onvansertib Phase 2 Trial in mCRPC

In this multi-center, open-label, Phase 2 trial, Onvansertib in combination with the standard dose of Zytiga® (abiraterone acetate) and prednisone, all administered orally, is being evaluated for safety and efficacy. The trial will enroll up to 45 patients with mCRPC showing early signs of disease progression demonstrated by two rising PSA values separated by at least one week, while on Zytiga®/prednisone therapy. The primary efficacy endpoint is the proportion of patients achieving disease control after 12 weeks of study treatment, as defined by lack of prostate specific antigen (PSA) progression in patients who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving abiraterone acetate and prednisone (NCT03414034). The trial is being conducted at Beth Israel Deaconess Medical Center (BIDMC), Dana Farber Cancer Institute (DFCI) and Massachusetts General Hospital (MGH).

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.

Onvansertib targets the PLK1 isoform, only (not PLK2 or PLK3), is orally administered, 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), Colorectal Cancer, Triple Negative Breast Cancer (TNBC), as well as other types of cancer.

About Trovogene, Inc.

Trovogene is a clinical-stage, oncology therapeutics company, taking 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. 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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