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): October 24, 2018

Trovagene, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35558**	**27-2004382**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**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 7.01 Regulation FD Disclosure

On October 24, 2018, as previously announced, the Company held a conference call to review its Onvansertib clinical development program and provide a general business update. During the conference call a slide presentation (the "Investor Call Presentation") was presented. Additionally, during the call, Dr. Thomas Adams, the Company's interim Chief Executive Officer, stated that the Company's cash on hand should be sufficient for the Company's cash needs until July 2019. Currently, the Company is burning approximately $4.5 million per quarter and the Company expects the quarterly burn rate to increase to $5.0 million per quarter in 2020. The Company is not looking to raise funds at this time but in the future may look to raise an additional $10-$15 million to fund its cash needs to the first quarter of 2020.

A copy of the Investor Call Presentation is being furnished pursuant to Regulation FD as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information in the presentation shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Furthermore, the Presentation shall not be deemed to be incorporated by reference into the Company's filings under the Securities Act of 1933, as amended or under the Securities Act of 1934, as amended, except as set forth with respect thereto in any such filing.

Item 8.01 Other Events.

On October 24, 2018, Trovagene, Inc. (the "Company") issued a press release announcing that the U.S. Patent and Trademark Office (USPTO) has allowed claims that affirms the broadest coverage of NPM1 mutation testing; Patent Application 14/750331, entitled "*Nucleophosmin Protein (NPM) Mutants, Corresponding Gene Sequences and Uses Thereof*." A copy of the press release is furnished as Exhibit 99.2 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Investor Call Presentation dated October 24, 2018

99.2 Press Release of Trovagene, Inc. dated October 24, 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: October 24, 2018

TROVAGENE, INC.

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

Exhibit 99.1

Company Update

Wednesday, October 24th, 2018

trovagene
ONCOLOGY

Licensed Drug Candidate from NMS
Onvansertib – Polo-like Kinase 1 (PLK1) Inhibitor

NERVIANO MEDICAL SCIENCES

Oncology Drug Discovery

- Largest oncology research and development company in Italy
- Developed anthracycline class of drugs (doxorubicin)
- Leader in protein kinase drug development (Polo-like Kinase Inhibitors)
- Identification and validation of molecular targets focused on driver oncogenes
- Excellent track record licensing innovative drugs to pharma/biotech companies including: Genentech (Roche), Ignyta (Roche), Novartis

trovagene

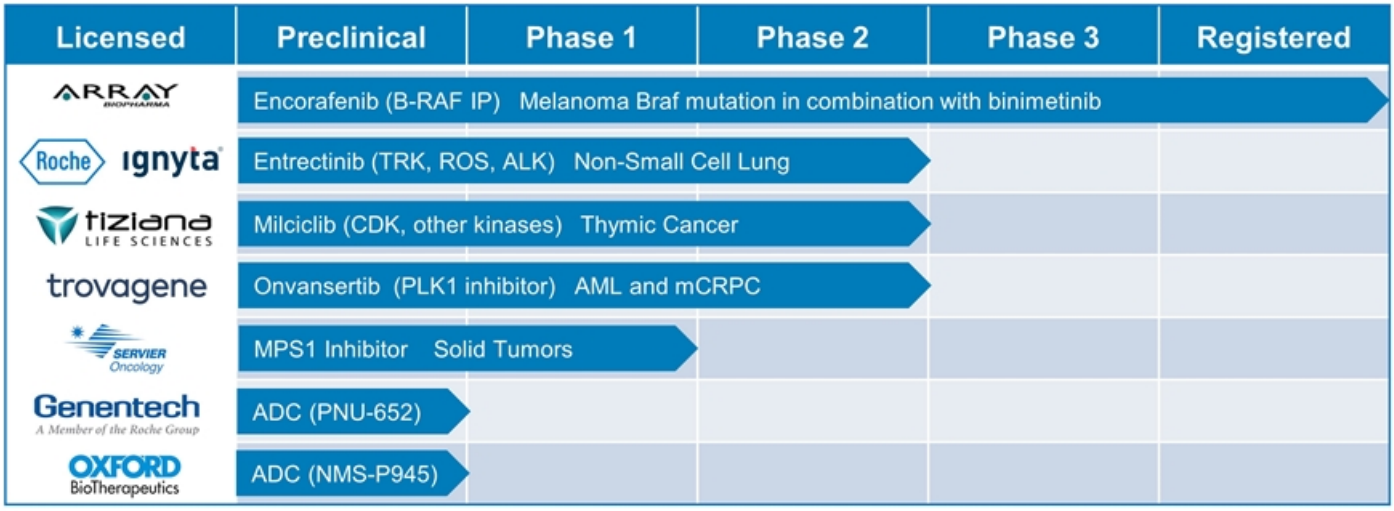
Developing Oncology Drugs That Target Mitosis

- Licensed global development and commercialization rights for Onvansertib
- Nerviano will continue manufacturing GMP API and finished drug
- Two active INDs in place with the FDA
- Financing in place to advance clinical programs

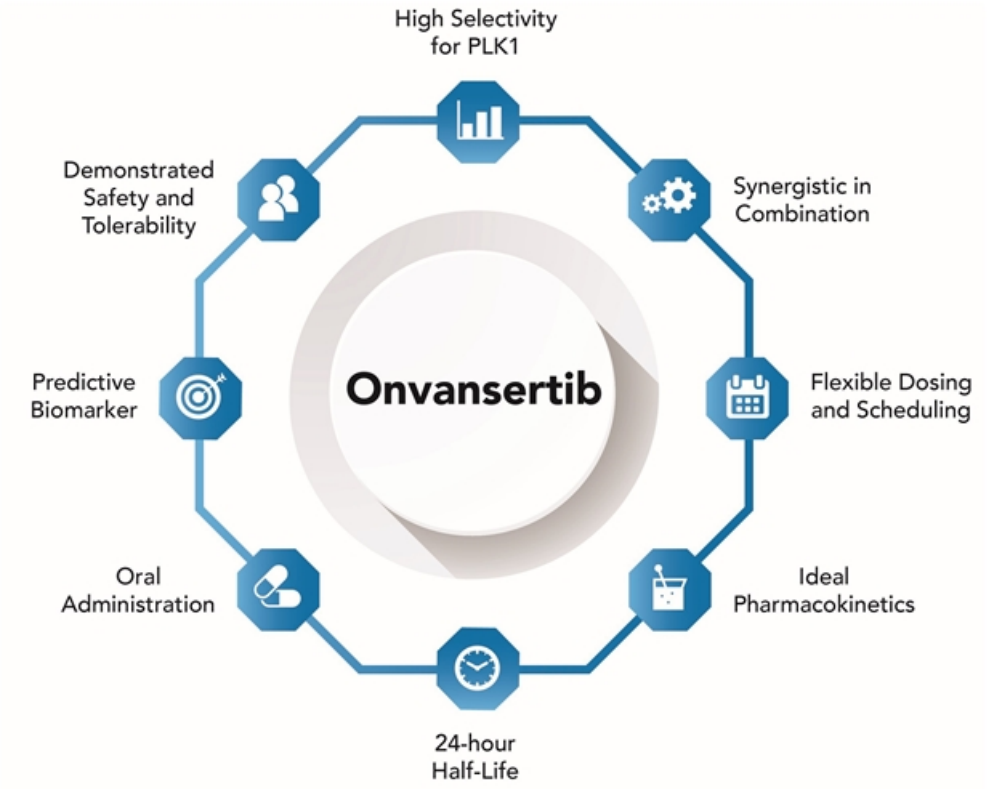
IND = Investigational New Drug

Nerviano Oncology Portfolio Success

- Excellent track record licensing innovative drugs to pharma/biotech companies that have subsequently received FDA breakthrough status and priority review designation



Onvansertib First-in-Class 3rd Generation PLK1 Best-in-Class Attributes

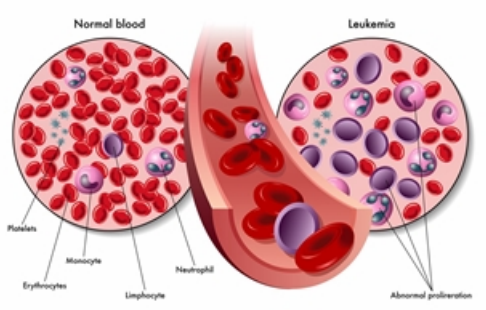


Strategy for Oncology Drug Development

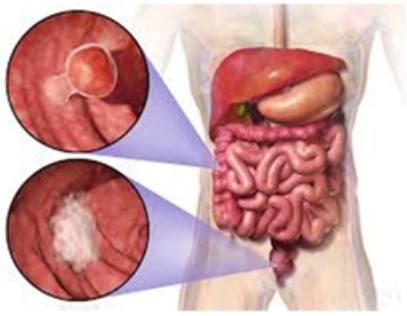
- Taking a precision cancer medicine approach to develop Onvansertib (PCM-075)
- Leveraging a proven cancer target, PLK1
- Incorporating predictive clinical biomarkers
- Combining Onvansertib with already approved drugs
  - Phase 1b/2 trial of Onvansertib + cytarabine or decitabine in Acute Myeloid Leukemia (AML)
  - Phase 2 trial of Onvansertib + abiraterone acetate (Zytiga®)/prednisone in metastatic Castration-Resistant Prostate Cancer (mCRPC)

Clinical Development Roadmap

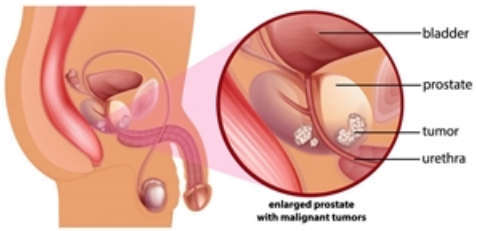
Acute Myeloid Leukemia



Colorectal Cancer



Prostate Cancer



Orphan Drug Designation (ODD) in AML

- In the U.S. and Europe
- Regulatory and Financial Incentives
- Market Exclusivity

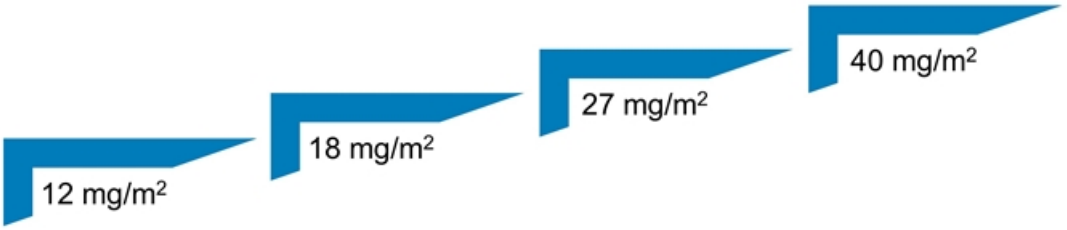
Japan Partnering Initiative

- Complementary therapeutic combination with already approved drug
- Enhance efficacy and market sustainability

Ongoing Phase 1b/2 Clinical Trial in AML

Onvansertib in Combination with Either Low-Dose Cytarabine or Decitabine in Patients with Acute Myeloid Leukemia (AML)

Phase 1b: Dose escalation to assess safety and identify recommended Phase 2 dose



- Administered orally, once daily on days 1-5 of each cycle (21-28 days)

Phase 2: Assess safety and preliminary antitumor activity

- **Efficacy Endpoints:** Rate of complete response (CR + CRi) defined as morphologic leukemia-free state (MLF)
- **Exploratory Endpoints:** Evaluation of pharmacodynamic and correlative biomarkers

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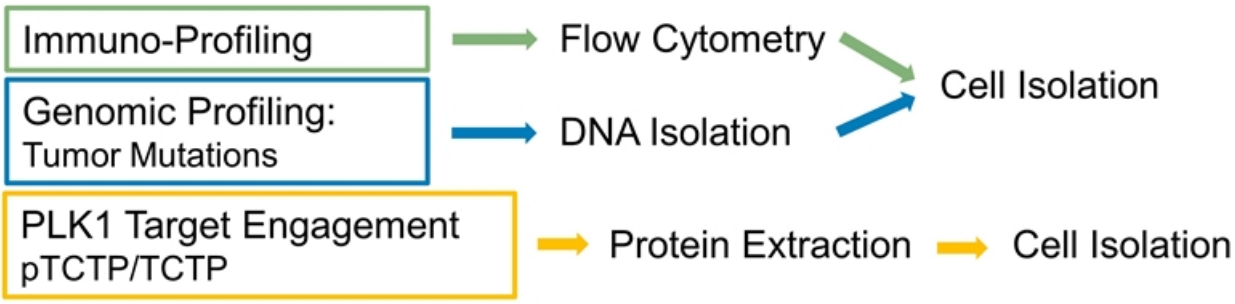
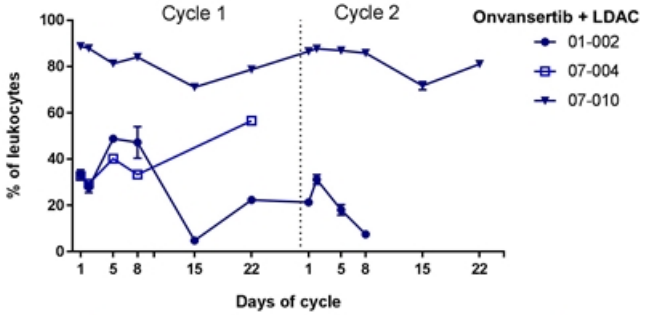
Biomarker Strategy in AML

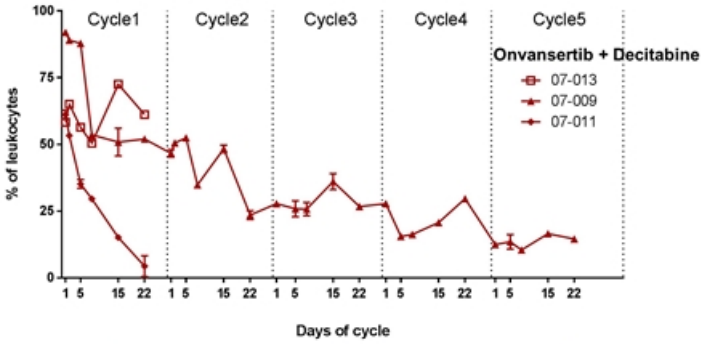
- Biomarkers will be measured and correlated with pharmacokinetic drug levels to assess:
  - Treatment effects by measuring % blast cells in blood and bone marrow
  - Inhibition of PLK1 by Onvansertib (Target Engagement)
  - Correlating underlying tumor genetics with treatment response



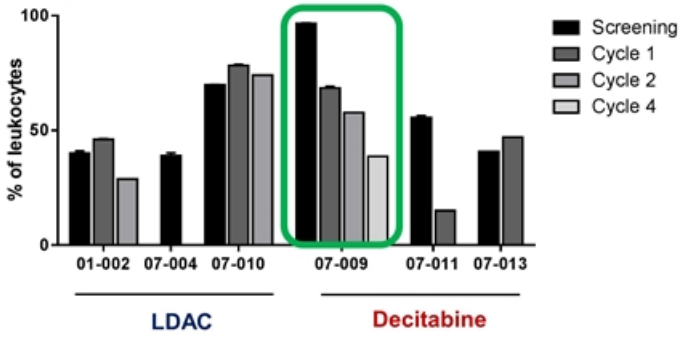
Onvansertib Phase 1b AML Trial

% of Leukemic Cells in Blood

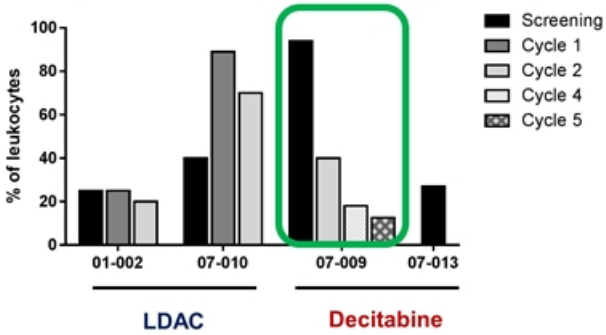




%Leukemic Cells in Bone Marrow (Trovagene analysis)

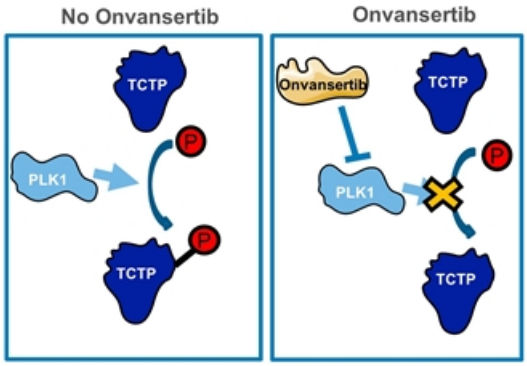


%Leukemic Cells in Bone Marrow (Clinical site analysis)



Target Engagement:
Monitoring PLK1 Inhibition Upon Treatment

The Translational Control Tumor Protein (TCTP) Identified as Specific Marker for PLK1 Activity In-Vivo[1]



- Onvansertib inhibits PLK1 kinase activity resulting in reduction in PLK1 substrates phosphorylation; Translational Control Tumor Protein (TCTP) is phosphorylated by PLK1
- PLK1 inhibition was assessed 3-hours following administration of Onvansertib at peak concentration (C_{max})

[1]Cusshi U. et al, Phosphorylation of TCTP as a Marker for Polo-like Kinase 1 Activity In Vivo – Anticancer Research December 2010 vol. 30 no. 12 pp. 4973-4985

Ongoing Phase 2 Clinical Trial in mCRPC

Onvansertib in Combination with Zytiga® and Prednisone in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Dosing Regimen	Duration	Evaluation
Onvansertib – 24 mg/m^2 Days 1-5 (21-Day Cycle) + Zytiga®/prednisone daily	4 Cycles = 12 Weeks	Disease Control based on PSA level

Efficacy Endpoints

Effect of Onvansertib in combination with Zytiga®/prednisone on disease control assessed by prostate-specific antigen (PSA) decline or stabilization pre- and post-treatment

Safety Endpoint

Safety of Onvansertib in combination with Zytiga®/prednisone

Exploratory Endpoint

Target inhibition of PLK1, evaluation of relevant biomarkers and correlation with patient response and genomic profile

PLK1 and Abiraterone Acetate (Zytiga®)
Metastatic Castration-Resistant Prostate Cancer (mCRPC)

- All metastatic prostate cancer patients become castration-resistant
- PLK1 dependent microtubule dynamics promotes androgen receptor (AR) signaling[1,2]
- PLK1 inhibition improves abiraterone efficacy[3]
- Inhibition of PLK1 represses androgen signaling pathway[4]
- PLK1 inhibitors may add important therapeutic benefit for the treatment of castration-resistant prostate cancer patients[5]

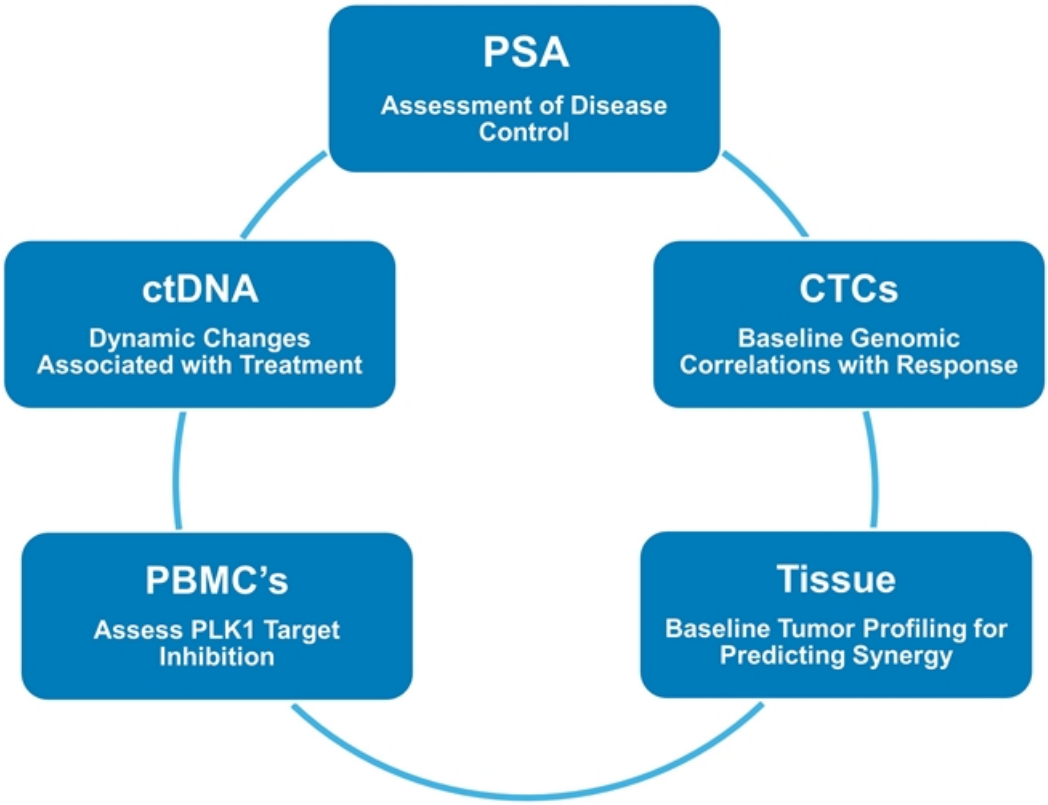
[1]Xianzeng, Hou, Zhiguo, Li – PLK1-Dependent Microtubule Dynamics Promotes Androgen Receptor Signaling in Prostate Cancer; Prostate. 2013 September; 73(12): 1352–1363. doi:10.1002/pros.22683; [2] Arpaporn, Deeraksa, Jing, Pan - Plk1 is upregulated in androgen-insensitive prostate cancer cells and its inhibition leads to necroptosis; Oncogene. 2013 June 13; 32(24): 2973–2983. doi:10.1038/onc.2012.309; [3]Clemens, Thoma – Prostate Cancer: PLK-1 Inhibition Improves Abiraterone Efficacy; Nature Reviews Urology volume11, page603 (2014); [4]Zhang Z1, Chen L – Inhibition of PLK1 Represses Androgen Signaling Pathway in Castration-Resistant Prostate Cancer; Cell Cycle. 2015;14(13):2142-8. doi: 10.1080/15384101.2015.1041689; [5]Klaus, Strebhardt - Drugging Plk1: An attractive approach to inhibit androgen receptor signaling; Cell Cycle. 2015 Jul 18; 14(14): 2193–2194

PSA: NCCN Recommended Biomarker
Trial Eligibility and Efficacy for mCRPC[1]

- PSA is a validated biomarker assessing disease stability or progression
- Prostate Cancer Clinical Trials Working Group (PCWG)[1] has set criteria for the use of blood PSA levels:
  - Trial eligibility (defining progression)
  - Initial assessment of efficacy

[1]PCWG2: Sher et al, JCO, 2008, PCWG3: Sher et al, JCO, 2016

Biomarker Strategy in mCRPC



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Colorectal Cancer: Unmet need in mCRC

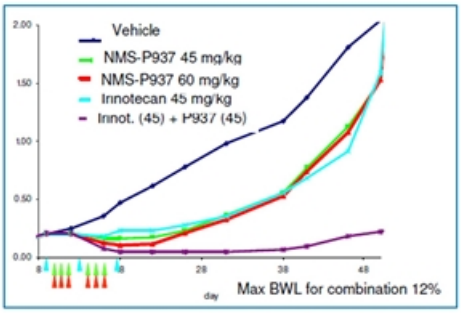
- 140K new cases of CRC in 2018 with 64.5% 5 year survival[1]
- ~51K deaths per year from mCRC[1]
- Tumor biomarkers drive therapy decisions for 1st line mCRC therapy[2]
  - ~50% mCRC is RAS wild-type: FOLFOX/FOLFIRI + AntiEGFR therapy
  - ~50% mCRC is RAS mutant (KRAS): FOLFOX/FOLFIRI/FOLFOXIRI
  - ~5% mCRC has microsatellite instability (MSI): candidate for immunoRx
- Large unmet need in RAS mutant CRC[2]
  - No targeted therapies are available for RAS mutant CRC
  - 2nd line therapies have ~5% response rate in metastatic CRC (mCRC)

[1]https://seer.cancer.gov/statfacts/html/colorect.html; [2]King et al, Frontline Strategies for Metastatic CRC, 2016, Amer J Hem/Onc; Loree&Kopetz, Recent Developments in treatment of mCRC, 2017, Ther Adv Med Onc;

Onvansertib in Pre-Clinical CRC Synergy with Irinotecan

- **In vitro:**
  - CRC cell lines are sensitive to Onvansertib:
    25/27 cell lines tested had an IC50<1uM and 10 had an IC50<0.1uM
  - Onvansertib is synergistic with paclitaxel, cisplatin, SN-38 and irinotecan
- **In-vivo:**
  - Onvansertib inhibits tumor growth of CRC xenograft models
    3 independent models were tested and Onvansertib induces a maximal tumor regression of 80% to 89% compare to vehicle
  - The combination of Onvansertib with Irinotecan significantly reduces tumor growth compared with vehicle or both single agent treatments

Note: P937 aka PCM-075 aka onvansertib



Value Creation Milestones

- In our Acute Myeloid Leukemia trial (AML):
  - We anticipate reaching our maximum tolerated dose and recommended Phase 2 dose within the next couple of months;
  - Enrolling patients in Phase 2 in the first half of 2019;
  - Providing efficacy and safety data readouts throughout the year; and
  - Developing our companion diagnostic
- In our metastatic Castration-Resistant Prostate Cancer (mCRPC) trial:
  - We expect to complete patient enrollment in the first half of 2019;
  - Present efficacy and safety data; and
  - Initiate plans for the follow-on randomized Phase 2b trial
- In metastatic Colorectal Cancer (mCRC):
  - Filing our IND and protocol for our Phase 2 trial in colorectal cancer by the end of this year; and
  - Initiating this trial in 2019
- On the collaboration and partnering front:
  - We are working to formalize a Japanese partnership; and
  - Explore opportunities to expand our clinical development program to sites in Europe

For additional information or questions please contact:
ir@trovagene.com

trovagene
ONCOLOGY

Trovagene Announces New Patent Claim Allowances Affirming Broad Patent Portfolio Coverage of NPM1 Mutations by U.S. Patent and Trademark Office

New patent claims strengthen patent estate revenue

Aligns with Onvansertib Clinical Development and Biomarker Strategy in AML

SAN DIEGO, CA – October 24, 2018 – Trovagene, 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 announced that the U.S. Patent and Trademark Office (USPTO) has allowed claims that affirms the broad coverage of NPM1 mutation testing; Patent Application 14/750331, entitled "*Nucleophosmin Protein (NPM) Mutants, Corresponding Gene Sequences and Uses Thereof*." This patent encompasses broad claims around the assessment of NPM1 mutational status in any cancer type, including acute myeloid leukemia (AML).

"We are pleased with the recent claim allowances by the USPTO, because this is not only aligned with our current biomarker play and clinical development of Onvansertib in AML, but also strengthens the revenue generating potential for Trovagene," said Thomas Adams, PhD, Executive Chairman of Trovagene. "Importantly, NPM1 testing is within the National Comprehensive Cancer Network (NCCN) guidelines to aid in treatment decisions and there is growing use of testing to monitor minimal residual disease (MRD) in AML."

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/m^2. Trovagene 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. Trovagene 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. Trovagene 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 Trovagene, Inc.

Trovagene 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. Trovagene 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. Trovagene plans to continue to vertically integrate its tumor genomics technology with the development of targeted 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. 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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vkelemen@trovagene.com