

**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): **July 15, 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:

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
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 7.01 Regulation FD Disclosure

On July 15, 2019, Trovagene, Inc. (the “Company”) issued a press release announcing release to shareholders and investors of its latest Company Presentation ahead of commencing a roadshow to investment institutions, analysts and shareholders in New York City. The press release and Company Presentation are attached to this Current Report on Form 8-K as Exhibits 99.1 and 99.2, respectively and each is incorporated into this Item 7.01 by reference.

All statements in this Item 7.01 and the press release and Company Presentation, may be deemed to be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance, and actual results or developments may differ materially from those in the forward-looking statements. See the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 and the Company’s other filings with the Securities and Exchange Commission for a discussion of other risks and uncertainties. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

In accordance with General Instruction B.2 of Form 8-K, the information furnished under this Item 7.01 of this Current Report on Form 8-K and the exhibits attached hereto are deemed to be “furnished” and shall not be deemed “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information and exhibit be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release
99.2	Company Presentation

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: July 15, 2019

TROVAGENE, INC.

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



Trovogene Commences Non-Deal Investor Roadshow

Management team to meet with investment institutions, analysts and shareholders in NYC to provide an overview of the Company and its advancing clinical development of onvansertib

SAN DIEGO, CA — July 15, 2019 — Trovogene, Inc. (Nasdaq: TROV), a clinical-stage, Precision Cancer Medicine™ company, developing targeted therapies to treat cancers with significant medical need for new treatment options, is pleased to release to shareholders and investors its latest Company Presentation ahead of commencing a roadshow to investment institutions, analysts and shareholders in New York City.

Trovogene's Chief Executive Officer and Chairman, Dr. Thomas Adams, and Chief Scientific Officer, Dr. Mark Erlander, will be meeting with investment fund managers to provide an overview of the Company, its three clinical trials of onvansertib, which are underway in metastatic Castration-Resistant Prostate Cancer (mCRPC), metastatic Colorectal Cancer (mCRC) and Acute Myeloid Leukemia (AML), and anticipated key near-term milestones."

"We are excited to have the opportunity to meet with key investment funds to share the highlights of our clinical development program and, what we believe, is a position of strength in the evolving cancer treatment landscape," said Tom Adams, CEO and Chairman of Trovogene. "We value our investors and shareholders and are pleased with our ability to maintain a consistent cash position that allows us to continue advancing development of onvansertib, through investments by Lincoln Park Capital, as well as support from PoC Capital to finance our colorectal cancer clinical trial."

A copy of the roadshow presentation is appended to this announcement.

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 (PLK 1) 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-

Trovogene Inc. | 11055 Flintkote Avenue | San Diego | CA 92121 | Tel.: USA [+1] 888-391-7992

Hodgkin lymphoma (NHL), colorectal cancer, triple-negative breast cancer (TNBC), as well as other types of cancer.

Trovagene has an ongoing Phase 2 clinical 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®. The trial was accepted by the NLM and is now publicly viewable on www.clinicaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is NCT03414034.

Trovagene has an ongoing Phase 1b/2 Study of onvansertib in Combination with FOLFIRI and Avastin® for second-line treatment in patients with mCRC with a KRAS Mutation. The trial was accepted by the NLM and is now publicly viewable on www.clinicaltrials.gov. The NCT number assigned by clinicaltrials.gov for this study is (NCT03829410). The trial is being conducted at three prestigious cancer centers: USC Norris Comprehensive Cancer Center, Hoag Cancer Center and The Mayo Clinic.

Trovagene has an ongoing Phase 1b/2 clinical trial of onvansertib in combination with low-dose cytarabine or decitabine in patients with relapsed or refractory 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 for the treatment of patients with AML.

Trovagene 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 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.trovageneoncology.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.

Trovogene Contact:

Vicki Kelemen
VP, Clinical Development and Investor Relations
858-952-7652
vkelemen@trovogene.com

Taking a Precision Cancer Medicine™ Approach to Develop Targeted Drugs for Cancer Indications with Significant Need for New Treatment Options

NASDAQ: TROV



Forward-Looking Statements

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Trovagene Oncology

Developing First-in-Class, Third-Generation, Oral PLK1 Inhibitor



Robust, diversified pipeline with single molecule, onvansertib, addressing multiple cancer indications, each with significant medical need for new treatment options



Preclinical data demonstrating efficacy of onvansertib in combination with standard-of-care drugs, expanding therapeutic and partnership opportunities



Encouraging initial efficacy data from ongoing clinical trials with additional data readouts in 2019-2020



Precision Cancer Medicine approach and integration of biomarkers to target treatment for patients most likely to respond



Experienced team with proven oncology drug development experience

Experienced Management Team

Drug Development Expertise + Biomarker Technology



Thomas Adams, PhD
Chief Executive Officer and Chairman



Mark Erlander, PhD
Chief Scientific Officer

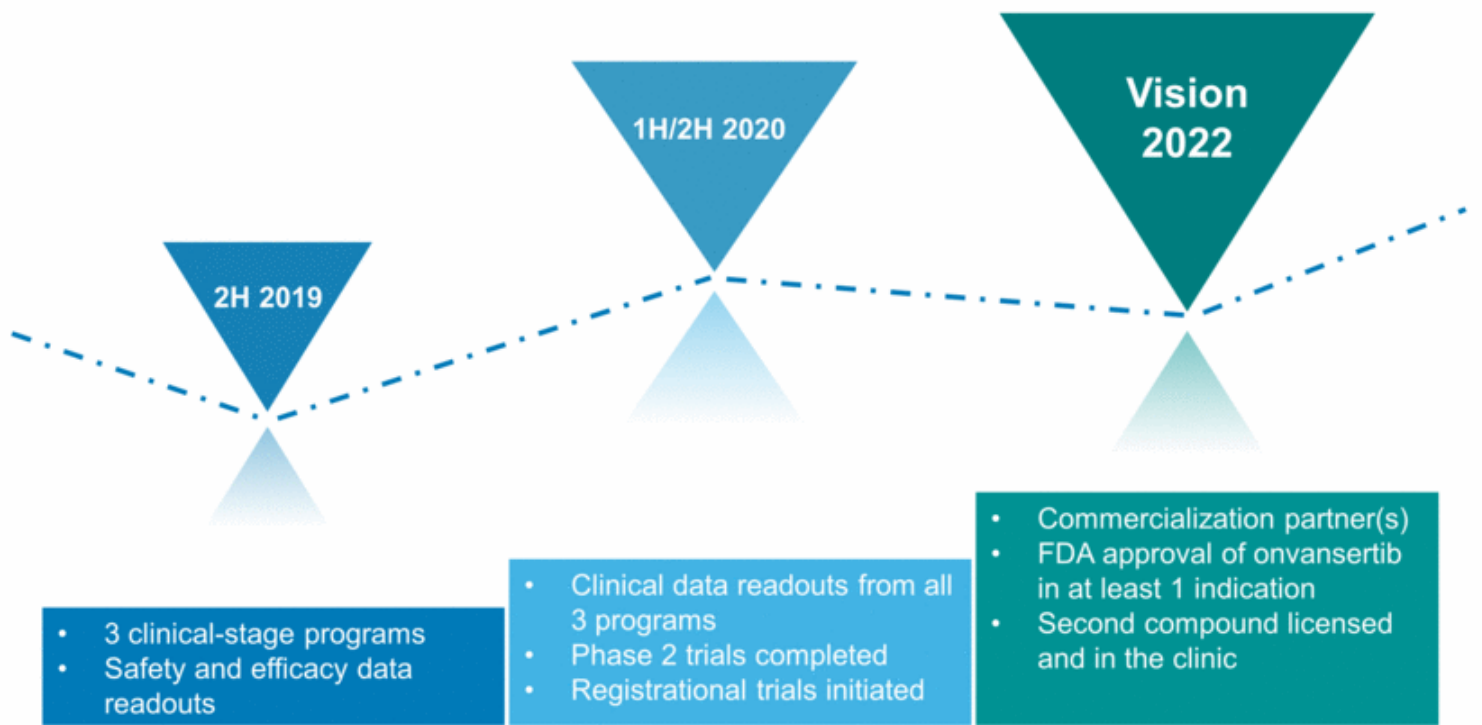


Vicki Kelemen
Vice President Clinical Development



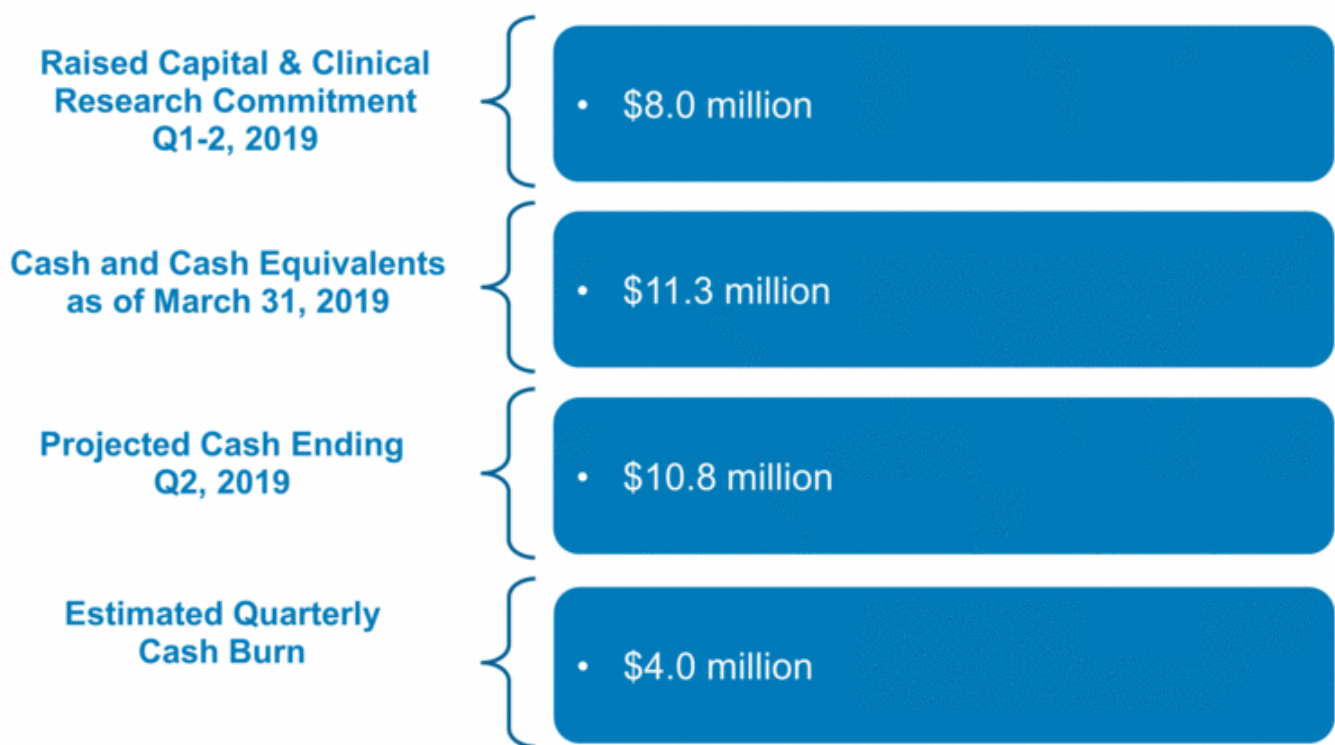
Our Vision

Rapidly Advancing Clinical Development Programs



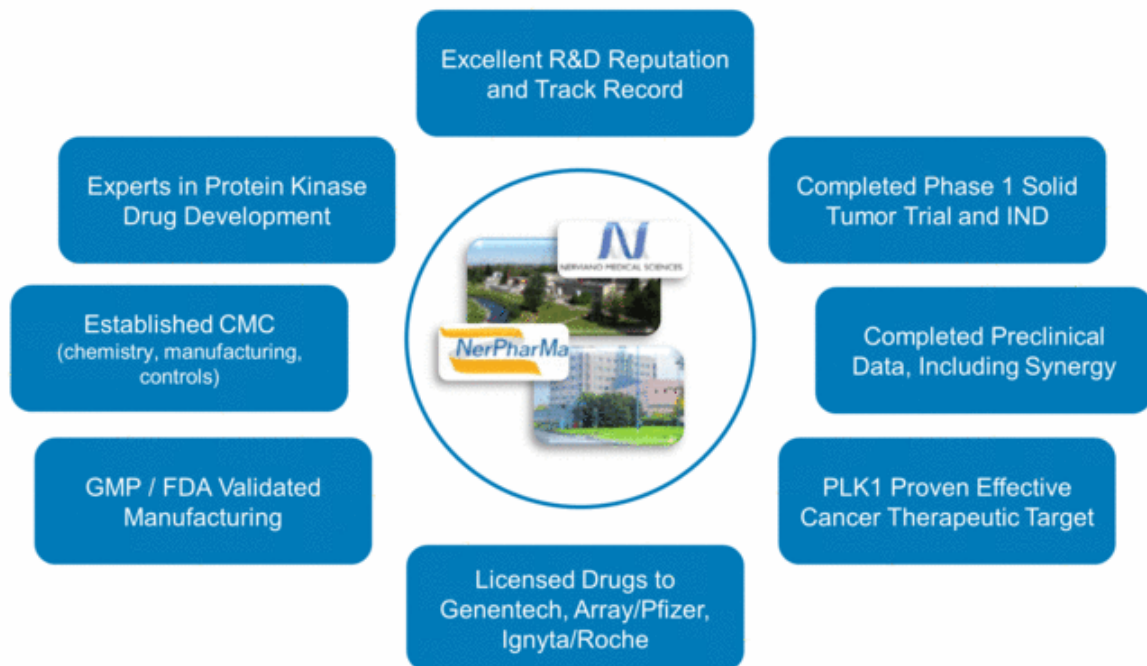
Demonstrated Operational Stability

Cost-Effective and Efficient Model

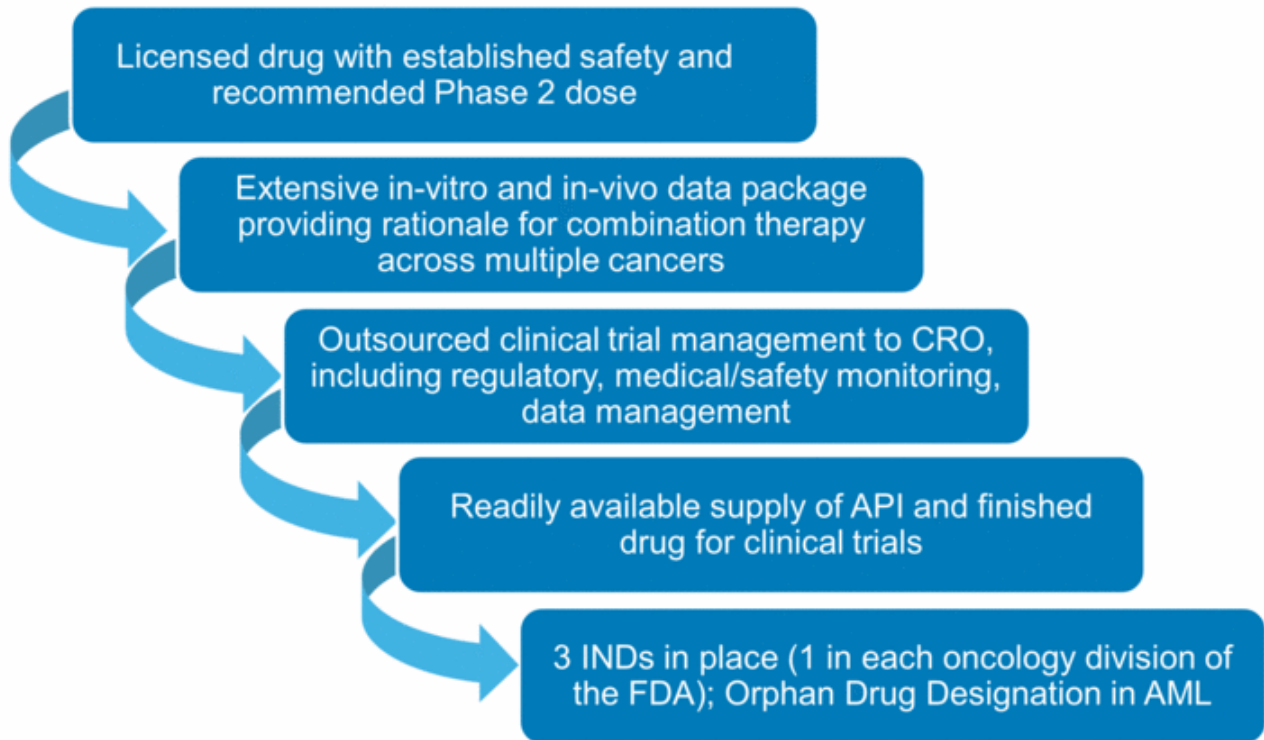


Exclusive Global Rights to Onvansertib Licensed from Nerviano Medical Sciences (NMS) in 2017

- ▶ Largest oncology research and development company in Italy; highly regarded throughout Europe and the U.S.

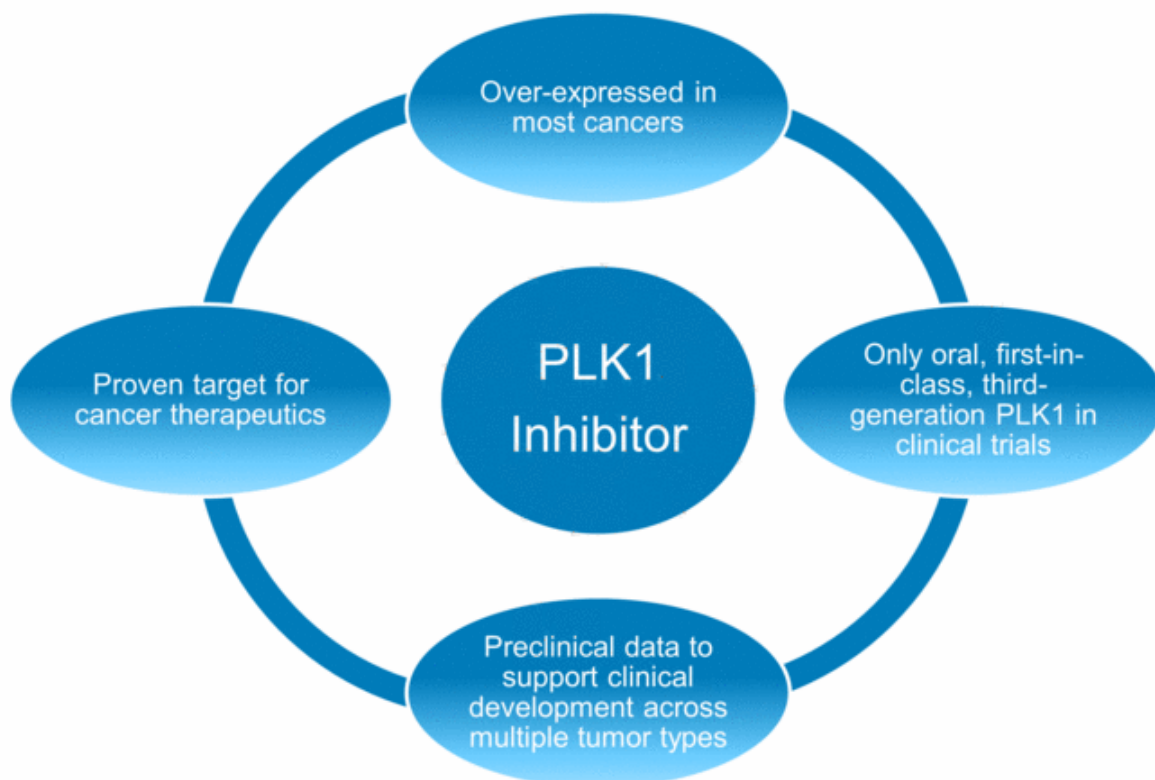


Optimized Operations and Clinical Development Leveraging Internal Expertise and External Resources



We Have the Perfect Target

Onvansertib – Polo Like Kinase 1 (PLK1) Inhibitor



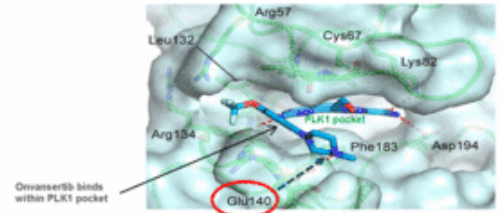
Onvansertib Targets the PLK1 Enzyme

A Proven Drug Target and Overexpressed in Most Cancers

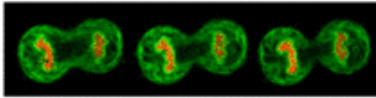
PLK Member	Onvansertib IC ₅₀ * (μM)
PLK1	0.002
PLK2	> 10
PLK3	> 10

- ▶ High selectivity for PLK1, only
- ▶ Tested against >260 kinases; PLK1 only active target (IC₅₀ of 2nM)

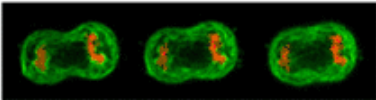
- ▶ Small molecule (MW 648.60 Daltons)
- ▶ Selectivity driven by stable interaction with carboxyl side chain of amino acid glutamate of PLK1 within PLK1's ATP binding pocket



Tumor Cell Division



Onvansertib Blocks Tumor Cell Division



- ▶ Onvansertib blocks cells from dividing by arresting them before they divide

Onvansertib

Benefiting from Class Experience

- ▶ 1st and 2nd generation PLK inhibitors demonstrated clinical activity, but were non-specific for PLK1 and had toxicity issues

Product Attributes	1 st and 2 nd Generation PLK Inhibitors	3 rd Generation Onvansertib
Selectivity for PLK1	<ul style="list-style-type: none"> • panPLK inhibition of PLK1,2,3* 	<ul style="list-style-type: none"> • Highly-selective <u>only</u> for PLK1
Antileukemic Activity	<ul style="list-style-type: none"> • Phase 2 & 3 trial results indicate activity • Improved response rates 	<ul style="list-style-type: none"> • Clinical response in patients • Biomarker strategy identifies patients most likely to respond
Administration	<ul style="list-style-type: none"> • Intravenous (IV) 	<ul style="list-style-type: none"> • Oral
Half-Life	<ul style="list-style-type: none"> • ~135 hours (5.5 days) 	<ul style="list-style-type: none"> • ~24 hours
Dosing and Schedule	<ul style="list-style-type: none"> • Fixed treatment schedule • Fixed dose for all patients 	<ul style="list-style-type: none"> • Treatment schedule flexibility • Dose determined based on BSA
Tolerability	<ul style="list-style-type: none"> • Insufficient time between treatment cycles negatively impacted tolerability/survival 	<ul style="list-style-type: none"> • Time allotted between cycles for patient recovery from on-target hematologic toxicities
Infection Prophylaxis	<ul style="list-style-type: none"> • Increased rate of fatal infections 	<ul style="list-style-type: none"> • Antibiotics to proactively mitigate infections

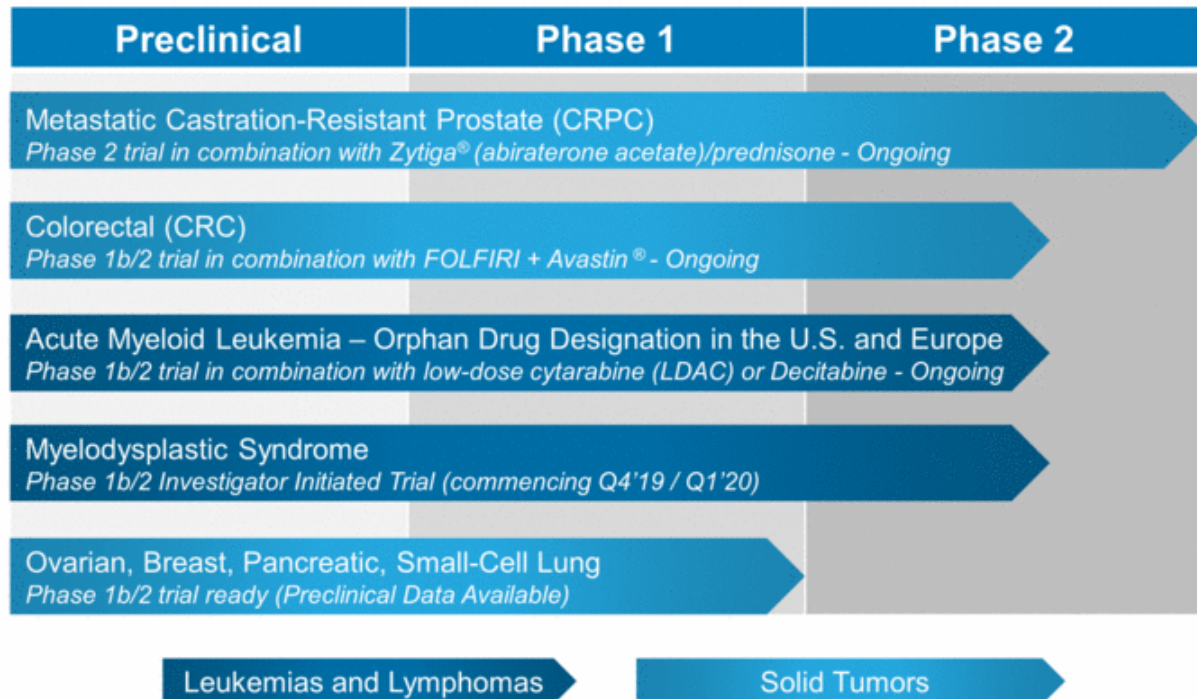
Onvansertib

First-in-Class, Third-Generation PLK1 with Best-in-Class Attributes



Diversified Pipeline with 3 Clinical-Stage Programs Opportunities in Leukemias/Lymphomas and Solid Tumors

▶ 3 Investigational New Drug (INDs) in place with the FDA



Encouraging Initial Data and Near-Term Readouts

TROV-053 mCRPC Phase 2

- ✓ Initial safety and efficacy data
- ✓ Enroll 3 patients in Arm B safety lead-in
- Identify patients with ARv7 and correlate with treatment response (Q2-3 2019)
- Provide data from patients completing 3-months of treatment (Q4 2019)

TROV-054 mCRC Phase 1b/2

- ✓ Activate clinical trial sites
- ✓ Enroll 3 patients in initial dose level cohort
- Provide data on biomarker assessment of tumor burden change (Q3 2019)
- Provide initial data from first cohort of 3 patients in dose escalation study (Q4 2019)
- Initiate second dose level cohort to enroll 3 patients (Q4 2019)

TROV-052 AML Phase 1b/2

- ✓ Completion of 6 dose escalation cohorts with no dose-limiting toxicities
- ✓ Initial data demonstrating efficacy – complete response (CR)
- Determine recommended Phase 2 dose (Q4 2019)
- Enroll patients in Phase 2 (Q1-2 2020)

mCRPC = metastatic castration-resistant prostate cancer; mCRC = metastatic colorectal cancer; AML = acute myeloid leukemia

Combination Therapy for Cancer Treatment

Two Drugs are Better Than One (1+1 = 5)

Onvansertib is uniquely synergistic (1 +1 = 5) with many FDA-approved drugs; it selectively targets the enzymatic activity of PLK1 that is fundamental for tumor growth

Increases efficacy of the therapeutic effect, particularly when the two drugs differ in their mechanism of action and both deliver anti-tumor activity

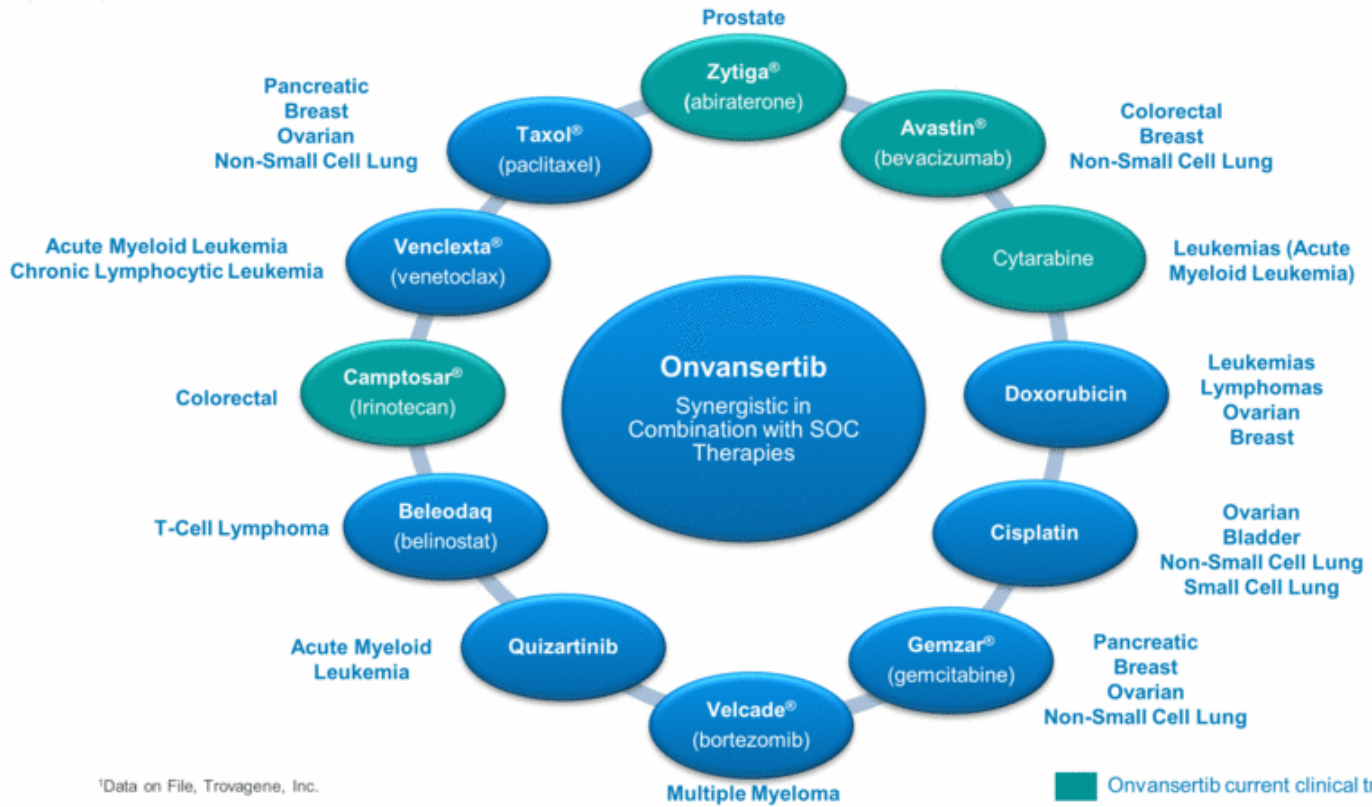
Combination Therapy
The Cornerstone of
Precision Cancer Medicine™

Decreases required dose of each drug and associated toxicity, potentially reducing side effects

Minimizes the development of drug resistance because the two drugs block different tumor-promoting pathways for cancer growth

Onvansertib

Synergy May Enhance Efficacy of Standard-of-Care Therapies¹



¹Data on File, Trovogene, Inc.

Phase 2 Trial: metastatic Castration-Resistant Prostate Cancer



Beth Israel Deaconess
Medical Center



DANA-FARBER
CANCER INSTITUTE



MASSACHUSETTS
GENERAL HOSPITAL
CANCER CENTER



Onvansertib Market Opportunity in mCRPC

Significant Disease Burden - Need for More Effective Treatment Options



Disease Burden

1 of 6 men will be **diagnosed** with **prostate cancer**²

25,000 men die from metastatic prostate cancer annually²

5-year survival rate is **37%**²



Treatment

Standard-of-care is **Zytiga® and Xtandi®**; **resistance** develops within **9-15 months**⁴

Tumors re-engineer androgen receptor (AR), variant 7 (ARv7); tumor growth without need for androgens⁴

Up to **40% ARv7 resistance**; **very aggressive** with **no viable treatment options**⁵



Opportunity

PLK1 inhibition improves Zytiga® efficacy, repressing androgen signaling pathway^{3,4}

PLK1 inhibition destabilizes AR and ARv7⁶

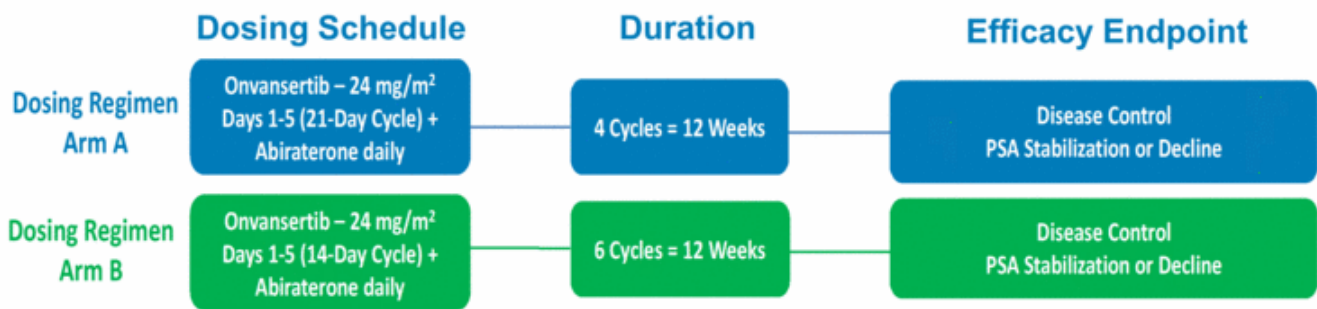
Inhibiting PLK1 blocks expression of ARv7; **stopping** this **resistance** pathway⁶

\$7.9 billion global market; **\$12.0 billion** by 2025⁷

¹2017 Annual Report on Prostate Disease – Harvard Health Publications; ²GlobalData. Prostate Cancer—Global Drug Forecast and Market Analysis to 2023. Apr, 2015; ³National Cancer Institute Metastatic cancer. Mar, 2013. Available at: <http://www.cancer.gov/about-cancer/what-is-cancer/metastatic-fact-sheet>; ⁴Antonarakis, Emmannel – Current Understanding of Resistance to Abiraterone and Enzalutamide in Advanced Prostate Cancer; Clinical Advances in Hematology & Oncology – May 2016 – Volume 14, Issue 5; ⁵Armstrong et al., 2019, JCO 37: 1120- ⁶Zhang et al., 2015, Cell Cycle 14:13, 2142–2148; ⁷<https://www.grandviewresearch.com/industry-analysis/prostate-cancer-therapeutics-market>

Phase 2 Clinical Trial in mCRPC

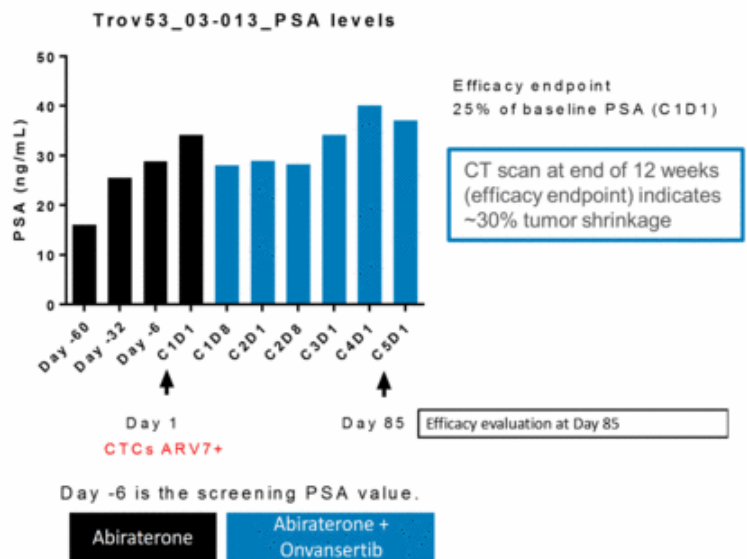
Disease Control Assessed by PSA Stabilization or Decline



- ▶ **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 and tolerability of onvansertib in combination with Zytiga[®]/prednisone
- ▶ **Exploratory Endpoints:** Target inhibition of PLK1, evaluation of relevant biomarkers and correlation with patient response and genomic profile

Early PSA Response Observed Addition of Onvansertib to Daily Zytiga®

- ▶ 6 patients have completed 4 cycles (3 months) of treatment with onvansertib + abiraterone
- ▶ 2 of 6 patients had observed declines in PSA levels after dosing with onvansertib
- ▶ To-date, 1 patient in Arm A has achieved the efficacy endpoint of disease stabilization based on PSA levels (primary endpoint)



- ▶ PSA trajectory in patient achieving primary efficacy endpoint changed from 100% increase (16.05 ng/ml to 34.23 ng/ml) in the 60 days prior to adding onvansertib to only an 8.4% increase during 84 days on treatment
- ▶ Tumor assessed at Cycle1 Day 1 as a variant known as **AR-V7**, considered an aggressive tumor that is resistant to anti-androgen therapy

Phase 1b/2 Trial: metastatic Colorectal Cancer

**USC Norris Comprehensive
Cancer Center**
Kek Medicine of USC

hoag
Hoag Family
Cancer Institute

 **MAYO CLINIC**
Cancer Center



 **trovogene**
ONCOLOGY

Onvansertib Market Opportunity in mCRC

Only 5% Response to Current Second-Line Therapies



Disease Burden

140,000 new cases of CRC
in 2018¹

65% 5-year survival¹

~51,000 deaths per year from
mCRC¹



Treatment

Tumor **biomarkers drive therapy decisions** for 1st-line mCRC therapy²

~50% mCRC has RAS (**KRAS**) mutation²

Standard-of-care is chemotherapy (**FOLFOX/FOLFIRI**)²

2nd-line therapies have **~5% response rate** in mCRC²



Opportunity

Onvansertib + irinotecan (FOLFIRI) significantly **reduces tumor growth³**

KRAS mutation is **biomarker** for onvansertib sensitivity

Research partnership with **Nektar Therapeutics**

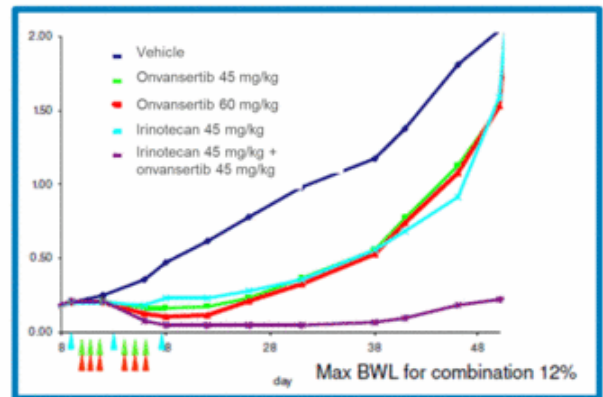
\$9.0 billion global market, expected to grow to **\$11.0 billion** by 2025⁴

¹<https://seer.cancer.gov/statfacts/html/colorect.html>; ²King 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; ³Investigator Brochure, Data-on-file, Trovogene; ⁴<https://www.globaldata.com/store/report/gdnc141pidr--pharmapoint-colorectal-cancer-global-drug-forecast-and-market>

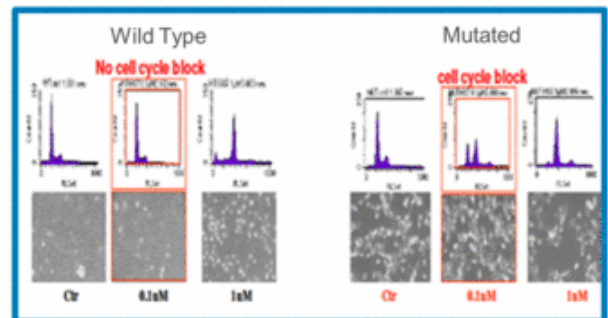
Synergy in Combination with Irinotecan

Preclinical Data Demonstrates Reduced Tumor Growth

- ▶ Combination of onvansertib with irinotecan (FOLFIRI) significantly reduces tumor growth compared to either drug alone
- ▶ In 3 independent models tested, onvansertib induced maximal tumor regression of ~84% compared to vehicle



- ▶ Kras mutation is a biomarker for onvansertib sensitivity
- ▶ KRAS mutated NIH3T3 cells showed higher sensitivity to onvansertib compared with KRAS wild-type cells¹

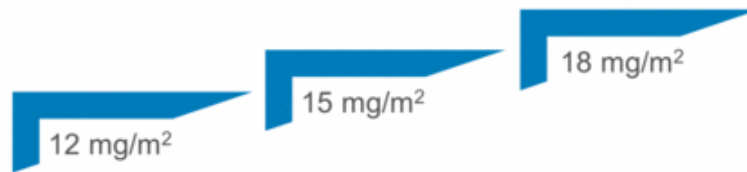


¹Investigator Brochure, Data-on-file, Trovogene

Phase 1b/2 Clinical Trial in mCRC

Objective Response Rate (ORR) in Second-Line Treatment

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



- ▶ Administered orally, once-daily on Days 1-5 every 14-days (2 courses per 28-day cycle)

Phase 2: Assess safety and preliminary antitumor activity

- ▶ **Efficacy Primary Endpoint:** Objective response rate (ORR) in patients who receive at least 1 cycle (2 courses) of onvansertib in combination with FOLFIRI and bevacizumab
- ▶ **Efficacy Secondary Endpoint:** Preliminary efficacy defined as complete response (CR) plus partial response (PR) plus stable disease (SD)

Phase 1b/2 Trial: Acute Myeloid Leukemia



Onvansertib Market Opportunity in AML

Providing a New Treatment for Relapsed/Refractory Patients



Disease Burden

20,000 new cases *annually*

5-year survival rate of only **25%**¹

Aggressive blood cancer that usually **occurs in the elderly**¹



Treatment

Today's standard-of-care for elderly AML patients is **Venclexta[®] plus azacytidine or decitabine**

Patients **develop resistance** to **Venclexta[®]** in **~11 months** with no viable treatment options²



Opportunity

Onvansertib + chemotherapy has **significant activity in AML** models³

Onvansertib induces cell death in AML model **insensitive to Venclexta[®]**⁴

Onvansertib + **decitabine** will be evaluated as treatment in **Venclexta[®] resistant patients**

\$1.0 billion global market by 2023⁵

¹National Cancer Institute SEER 2016; ²DiNardo et al, Blood, 2019 ³Valsasina et al., Mol Cancer Ther; 11(4) April 2012; ⁴Trovagene, data on file; ⁵<https://www.medgadget.com/2019/04/global-acute-myeloid-leukemia-treatment-market-is-expected-to-reach-usd-1-billion-with-cagr-of-5-3>

Phase 1b/2 Clinical Trial in AML

Onvansertib + Low-Dose Cytarabine or Decitabine

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



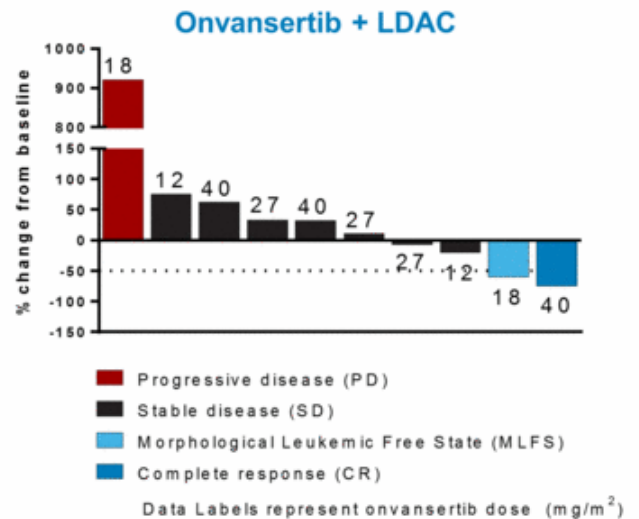
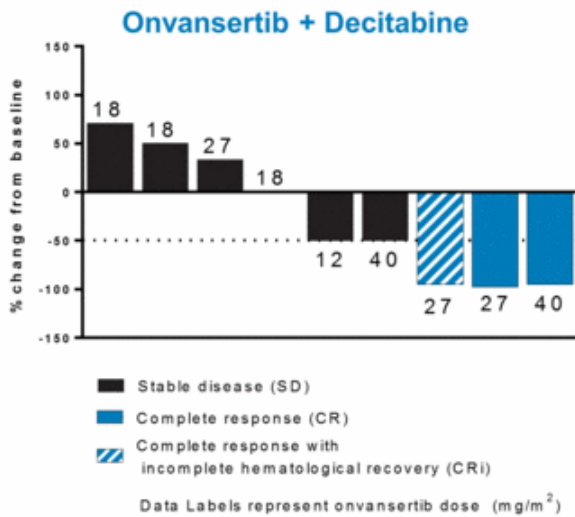
- ▶ Administered orally, once-daily on Days 1-5 of each cycle (21-28 days)

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

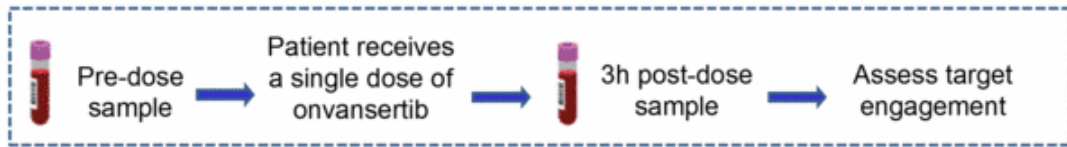
Patients Achieving Complete Response Onvansertib is Safe and Well Tolerated

- ▶ Of the 26 patients evaluable for safety, 19 had an evaluable bone marrow biopsy to assess efficacy
- ▶ Preliminary efficacy in the evaluable population includes 3 patients achieving complete response (CR) and 1 patient achieving complete response with incomplete hematologic recovery (CRi)

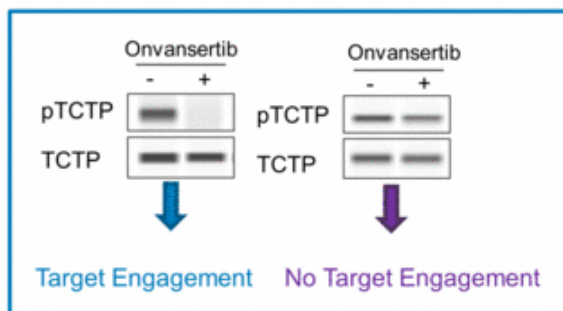


Biomarker Evaluates Inhibition of PLK1 Identifies Patients Most Likely to Respond to Treatment

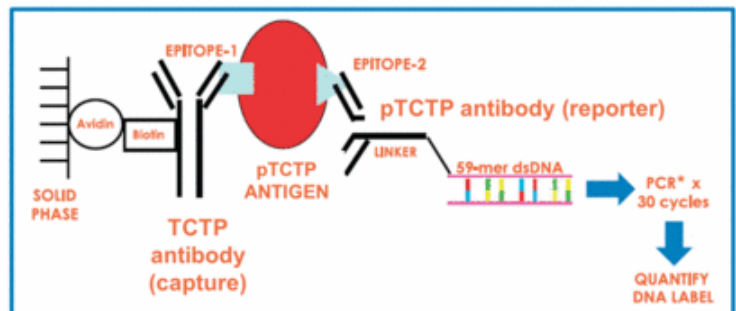
- ▶ Blood test examines the extent that onvansertib inhibits PLK1 enzymatic activity (target engagement) by assessing the phosphorylated status of TCTP within circulating leukemic blast cells



Current method: Western-Blot



Method in development: immuno-PCR based technology

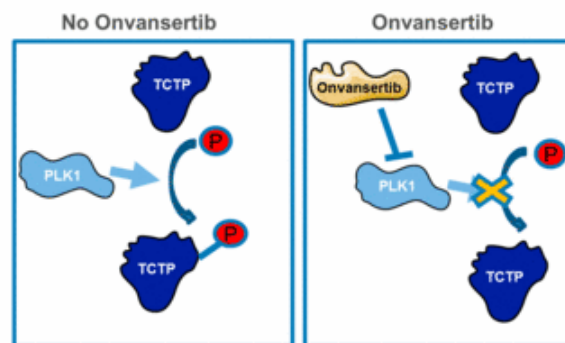


Biomarker to Assess Inhibition of PLK1

Correlation of Biomarker⁺ Patients with Treatment Response

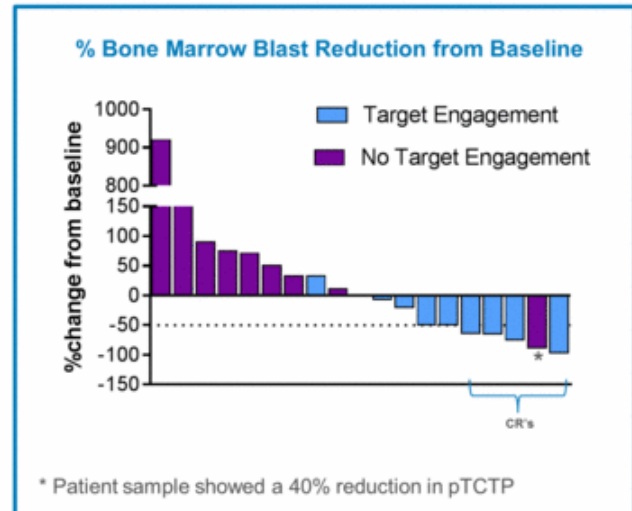
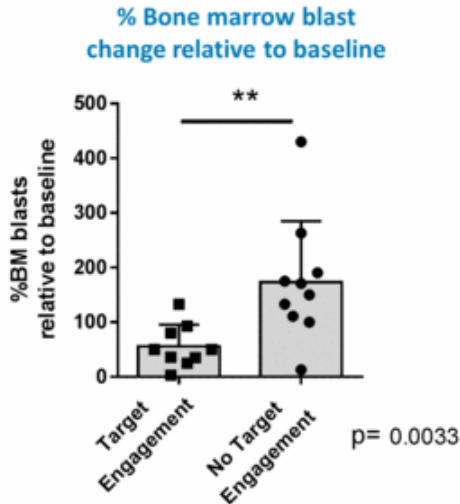
PLK1 inhibition can be monitored in patients through pTCTP status to determine target engagement of onvansertib with PLK1

- ▶ **pTCTP as a marker of PLK1 activity:**
 - PLK1 phosphorylates the translational control tumor protein (TCTP) on serine 46
 - pTCTP was identified as a specific marker for PLK1 activity in vivo in preclinical models
- ▶ **The comparative change in pTCTP status between pre-dose and 3 hours post-dose is being assessed**



Biomarker-Positive Patients Significantly Correlated with Treatment Response

- ▶ PLK1 inhibition by onvansertib (target engagement) is correlated with higher response to treatment
 - Patients with target-engagement had a significantly greater decrease in BM blasts compared to patients with no target-engagement
 - 6 out of the 9 patients with target-engagement had a decrease in BM blasts $\geq 50\%$
 - Among the 4 patients with objective responses, 3 had target engagement ($\geq 50\%$ decrease in pTCTP) and 1 had a 40% decrease in pTCTP



Trovagene Oncology

Developing First-in-Class, Third-Generation, Oral PLK1 Inhibitor



Robust, diversified pipeline with single molecule, onvansertib, addressing multiple cancer indications, each with significant medical need for new treatment options



Preclinical data demonstrating efficacy of onvansertib in combination with standard-of-care drugs, expanding therapeutic and partnership opportunities



Encouraging initial efficacy data from ongoing clinical trials with additional data readouts in 2019-2020



Precision Cancer Medicine approach and integration of biomarkers to target treatment for patients most likely to respond



Experienced team with proven oncology drug development experience



Thank You



For additional information please
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