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): **January 13, 2019**

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)

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:

o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 7.01 Regulation FD Disclosure

Trovagene, Inc. (the “Company”) intends to conduct meetings with third parties in which its corporate slide presentation (“Company Presentation”) will be presented. The Company Presentation is attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

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 exhibit 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*.

99.1	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: January 13, 2020

TROVAGENE, INC.

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

Trovagene Oncology

Investor Presentation
January 2020

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Forward-Looking Statements

Certain statements in this presentation 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 actua 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. While the list of factors presented in the 10-K 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.

Company At-A-Glance

Clinical-stage oncology therapeutics company, developing **onvansertib,** an oral and highly-selective Polo-like Kinase 1 (PLK1) inhibitor

- Selectively targets PLK1, a proven therapeutic target; overexpressed in most cancers
- Stops division of cancer cells while limiting impact to normal cells
- Proven safety and preliminary efficacy in 3 clinical programs (mCRC, mCRPC, AML)
- Presentation of efficacy data from all 3 Phase 2 clinical trials in 2020

San Diego, CA

Nasdaq: TROV

Clinical Development Plan: Comple
Phase 2 clinical trials of onvansertib i
combination with standard-of-care
therapies, in colorectal cancer, prosta
cancer and acute myeloid leukemia, a
advance to registrational trials

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Investment Highlights

Ovansertib

1st-in-class, 3rd-generation, safe and well-tolerated, oral PLK1 inhibitor that selectively targets the PLK1 enzyme and blocks cancer cell division

Clinical Efficacy Demonstrated

3 ongoing clinical trials with demonstrated efficacy in patients who have developed resistance to standard-of-care or who have relapsed disease

Predictive Biomarkers

Assessment of response to treatment derived from a simple blood test

Validating Combination Clinical Trials

- metastatic colorectal cancer (mCRC): onvansertib + FOLFIRI® /Avastin®
- metastatic castrate-resistant prostate cancer (mCRPC): onvansertib + Zytiga®
- acute myeloid leukemia (AML): onvansertib + decitabine

Established Manufacturing and Drug Supply

FDA approved, GMP facility for production of raw material and finished drug

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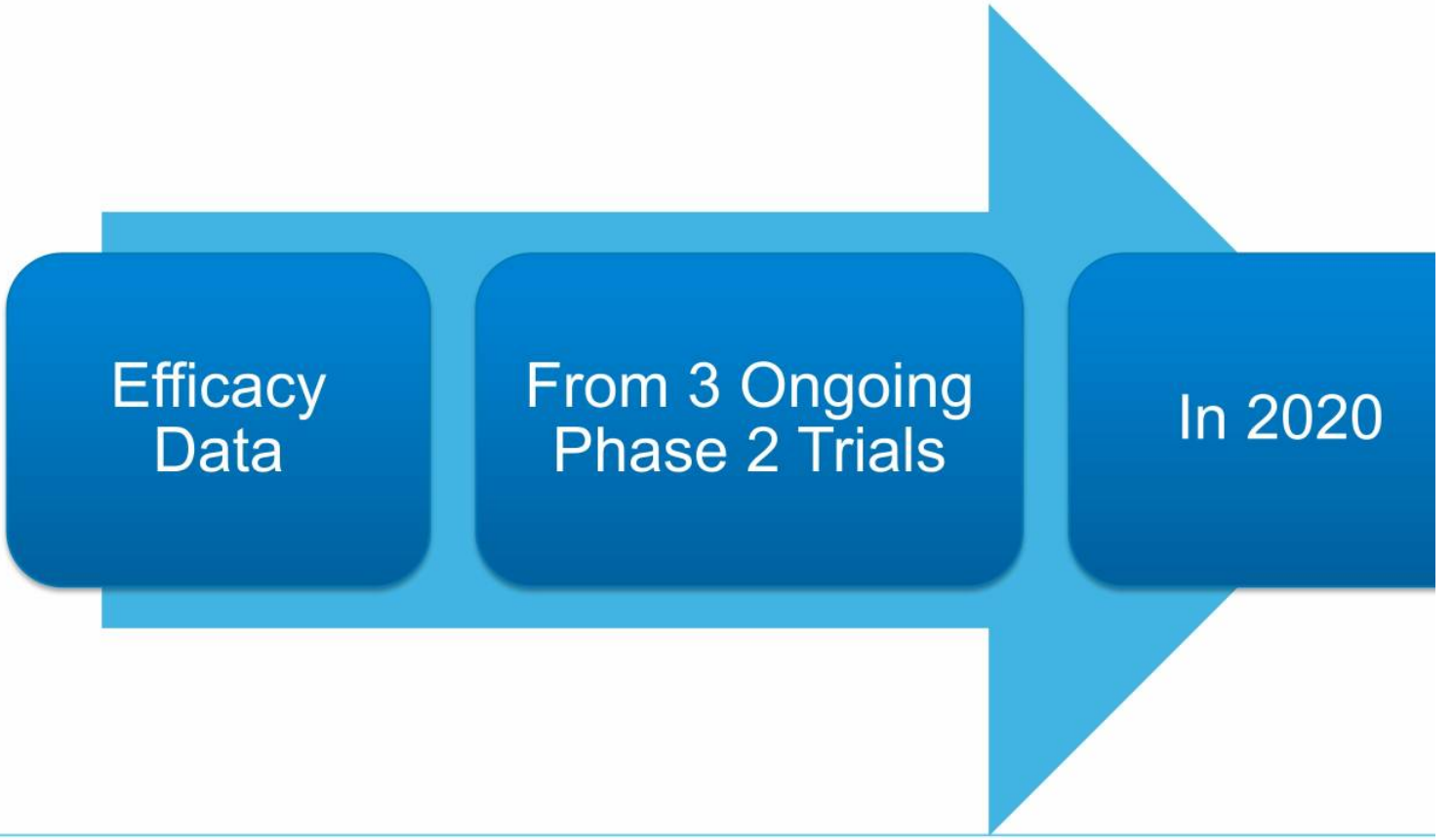
Significant Value Creation in 2020



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2020 Key Inflection Points

1H2020 Key Inflection Points	Event	Timing
Colorectal Cancer: Phase 1b Safety and Efficacy Data	Gastrointestinal Cancers Symposium	January 25th
Prostate Cancer: Phase 2 Efficacy Data	Genitourinary Cancers Symposium	February 13th
Acute Myeloid Leukemia: Biomarker Data		April 24th – 29th
Prostate Cancer: Phase 2 and Correlative Biomarker Data		April 24th – 29th
Acute Myeloid Leukemia: Phase 2 Efficacy Data	EHA	June 11th – 14th
2H2020 Key Inflection Points	**Event**	**Timing**
Prostate Cancer: Phase 2 Efficacy Data	ESMO	Sept. 18th – 22nd
Colorectal Cancer: Phase 2 Efficacy Data	ESMO	Sept. 18th – 22nd
Acute Myeloid Leukemia: Phase 2 Efficacy Data	ESMO	Sept. 18th – 22nd
Prostate Cancer: Phase 2 Efficacy Data	EMUC20	Nov. 12th – 15th
Colorectal Cancer: Phase 2 Efficacy Data	ESMO ASIA 2020	Nov. 20th – 22nd
Acute Myeloid Leukemia: Phase 2 Efficacy Data	Hematology 2020	Dec. 5th – 8th

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Onvansertib is a Platform for Value Creation

- **Clinical Programs Based on Scientific Rationale:** supported by preclinical and synergy data, and integration of biomarkers to rapidly assess response to treatment
- **Addressing Significant Medical Needs:**
  - overcome resistance to standard-of care drugs
  - extend duration of response and progression-free survival

	Indication	Preclinical	Phase 1/1b	Phase 2/2b	Next Milestone
Onvansertib ***Solid Tumors*** ***(2 INDs in Place)***	**mCRC**	*Onvansertib + FOLFIRI® /Avastin® in KRAS-mutated colorectal cancer*			**Q1 2020 ASCO-GI**
	mCRPC	*Onvansertib + Zytiga® /prednisone in metastatic castrate-resistant prostate cancer*			**Q1 2020 ASCO-GU**
Onvansertib ***Hematologic*** ***(1 IND in Place)***	**AML**	*Onvansertib + decitabine in relapsed or refractory acute myeloid leukemia cancer*			**Q2 2020 AACR, EHA**

IND = Investigational New Drug; mCRPC = metastatic castrate-resistant prostate cancer; mCRC = metastatic colorectal cancer; TNBC = triple-negative breast cancer; AML = acute myeloid leukemia

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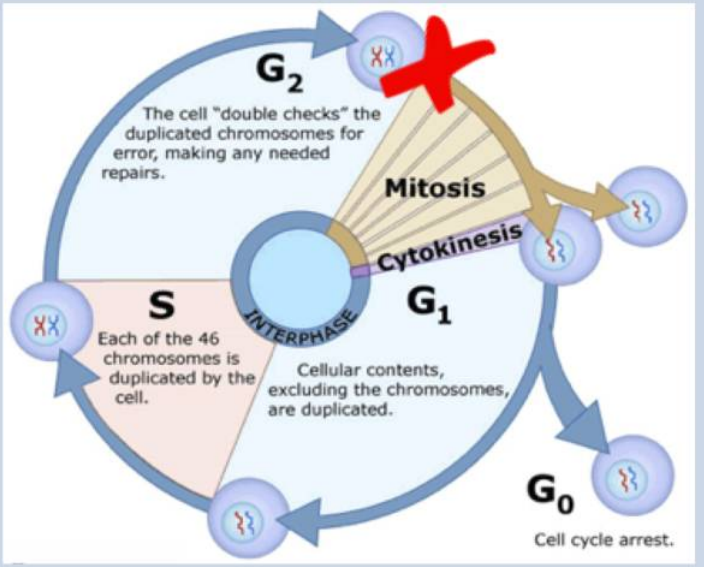
Onvansertib Mechanism of Action

Inhibition of PLK1 causes arrest of cell division and subsequent cell death[1]



[1]Zitouni et al., Nat Rev Mol Cell Biol. 2014 Jul;15(7):433-52

Synergistic in combination with chemotherapies and targeted therapeu

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Optimal Attributes for a Safe and Effective Drug

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Indication:
metastatic KRAS-Mutated Colorectal Cancer (mCRC)

USC Norris Comprehensive Cancer Center
Keck Medicine of USC

MAYO CLINIC
Cancer Center

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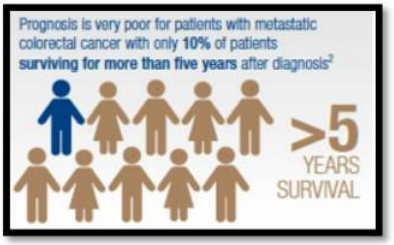
Improving Response and Progression-Free Surviva

Metastatic Colorectal Cancer (mCRC)



- Only a 5% response rate to standard-of-care FOLFOX/FOLFIRI[1]
- Onvansertib + FOLFIRI® significantly reduces tumor growth[3]
- Biomarkers drive therapy decisions[2]
- KRAS mutation is a biomarker for clinical response to onvansertib
- KRAS mutation in 50% of mCRC[2]

Establishing a Successful Path Forward:

- Positive results from Phase 1b/2 trial may provide an opportunity for Phase 2b registrational trial and Fast Track Designation
- Biomarker increases likelihood of success by enabling rapid, quantitative assessment of KRA mutation and patient response to treatment

[1]King et al, Frontline Strategies for Metastatic CRC, 2016, Amer J Hem/Onc; Loree&Kopetz; [2]Van Custem E, Borràs JM, Castells A et al. Improving outcomes in colorectal cancer. Where do we go from here J Cancer. 2013 Jul; 49(11): 2476–85;, Recent Developments in treatment of mCRC, 2017, Ther Adv Med Onc; [3]Investigator Brochure, Data-on-file, Trovagene

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Rationale for Onvansertib + FOLFIRI® /Avastin® in KRAS-Mutated Metastatic CRC

Onvansertib Targets KRAS Mutations Through Downstream Effects on Tumor Cell Division

Cracking KRAS

► Synthetic Lethality

- CRC tumor cells harboring KRAS mutation are r vulnerable to cell death with PLK1 inhibition
- Tumor cell viability is more sensitive to onvanse KRAS-mutated vs KRAS wild-type isogenic cell

► Synergy

- Onvansertib + irinotecan (the "IRI" in FOLFIRI) a synergistic in CRC cell lines
- Combination demonstrated significantly greater tumor growth inhibition than either drug alone

► Proof-of-Concept Clinical Response

- Phase 1 trial in solid tumors: 3 of 5 patients with stable disease had KRAS mutation; 2 in CRC ar in pancreatic cancer

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Demonstrating Clinical Benefit in KRAS-Mutated CRC as New Second-Line Treatment

Trial Design: Phase 1b/2, multi-center, open label trial in mCRC

Onvansertib + FOLFIRI®/ Avastin® (bevacizumab) ▶ Phase 1b (n=18) Phase 2 (n=26) ▶ Onvansertib administered orally, days 1-5 every 14-days (2 courses of treatment in every 28-day cycle)

Efficacy Endpoints:

Primary: overall response in patients who receive ≥1 cycle (2 courses) of treatment

Correlative Biomarker: decreases in KRAS mutation burden and response to treatment

Current Standard-of-Care FOLFIRI®/Avastin® Clinical Response: overall response is ~5%; median progression-free survival (PFS) is ~6 months[1]

Onvansertib: Achieving Clinical Success

- 5 of 26 (~20%) patients achieve clinical response confirmed by radiographic scan
- Patient median progression-free survival (PFS) of >6 months

[1]King et al, Frontline Strategies for Metastatic CRC

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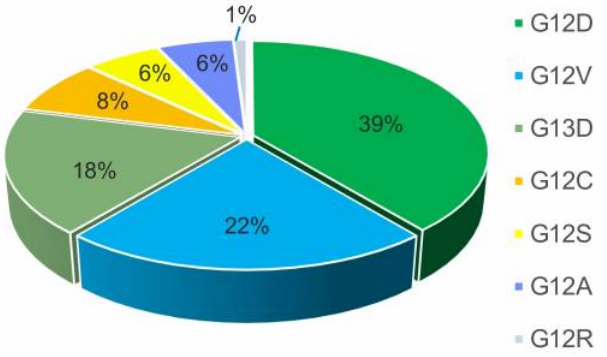
Clinical Data Shows Onvansertib Effectively Targets KRAS Mutations in CRC

Colorectal Cancer



- To-date, KRAS mutation decreased in all 6 patients completing their 1st cycle of onvansertib treatment
- Mutations identified in these patients account for nea 100% of those associated with CRC
  - G12D (39%), G12V (22%), G13D (18%), G12C (8%), G1
- Other drugs in development target only G12C which accounts for <10% of the KRAS mutations in CRC

[1]Jones et al. Specific Mutations in KRAS Codon 12 Are Associated with Worse Overall Survival in Patients with Advanced and Recurrent Colorectal Cancer; BJC Feb. 2017

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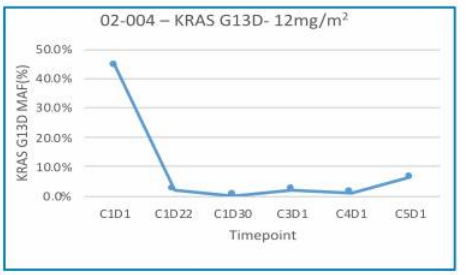
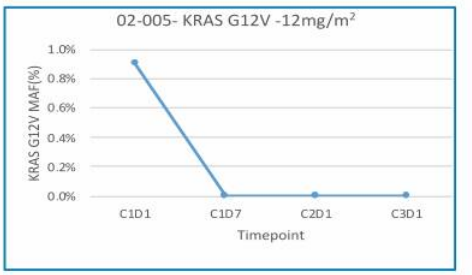
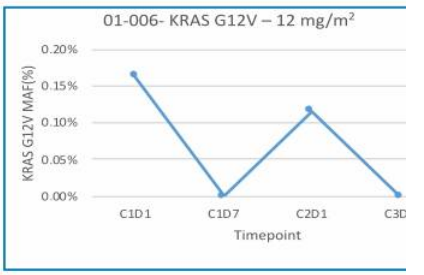
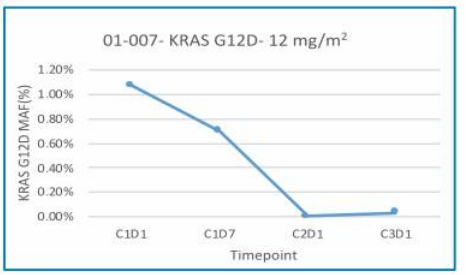
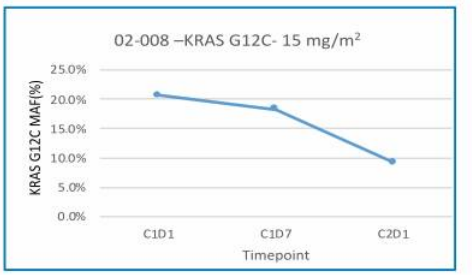
Decreases in Plasma KRAS Mutation Shown in All Patients Treated with Onvansertib

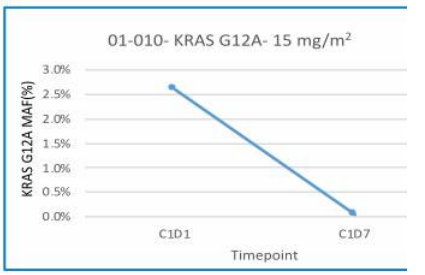












- Changes in plasma KRAS mutation level is an early marker for therapeutic response
- Significant decrease in KRAS mutation levels within the 1st treatment cycle are highly predictive of tu regression as measured by radiographic scans
- Decreases in plasma KRAS-mutated circulating tumor DNA, to a non-detectable level, observed in 5 patients within the first cycle of treatment, and highly predictive of tumor regression by radiographic s

Tie et al., 2015, Annals of Oncology 26: 1715–1722

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Indication:
metastatic Castrate-Resistant Prostate Cancer (mCRPC)

Beth Israel Deaconess Medical Center

DANA-FARBER CANCER INSTITUTE

MASSACHUSETTS GENERAL HOSPITAL CANCER CENTER

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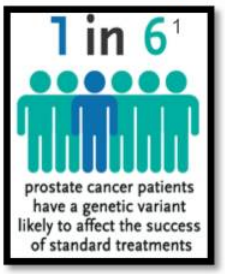
Overcoming Resistance and Extending Efficacy

Metastatic Castrate-Resistant Prostate Cancer (mCRPC)



- Resistance develops to standard-of-care therapy, Zytiga® and Xtandi®, within 9-15 months[3]
- Onvansertib + Zytiga® are synergistic in combination
- Combination significantly increase arrest of cell division
- Up to 40% AR-V7 resistance; very aggressive mutation and no effective treatment options[2]

Establishing a Successful Path Forwar

- Positive results from Phase 2 trial may provide an opportunity for a Phase 2b registrational trial
- Proactively assessing AR-V7 enables correlation of status (+/-) with response to onvansertib treatment
- Effective treatment of AR-V7+ patients coul lead to Breakthrough Designation

[1]Nicolosi P, Ledet E, Yang S et al. Prevalence of germline variants in prostate cancer and implications for current genetic testing guidelines. JAMA Oncol. Published online February 7, 2019; [2]Armstrong et al. JCO 37: 1120- [6]Zhang et al., 2015, Cell Cycle 14:13, 2142—2148; [3]GAntonarakis, Emmannel – Current Understanding of Resistance to Abiraterone and Enzalutamide in Advanced Prostate Cancer; Clinical A in Hematology & Oncology – May 2016 – Volume 14, Issue 5; [4]https://www.grandviewresearch.com/industry-analysis/prostate-cancer-therapeutics-market

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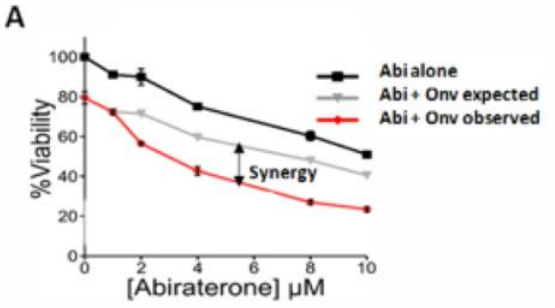
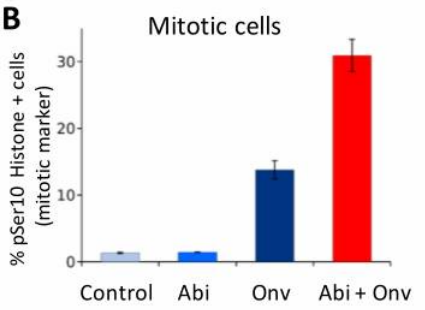
Rationale for Onvansertib + Zytiga® in Metatstatic Castrate-Resistant Prostate Cancer (mCRPC)

Onvansertib + Zytiga® (abiraterone) demonstrates synergy in mCRPC model (C4-2)[1]



Onvansertib + Zytiga® (abiraterone) significantly increases mitotic arrest[1]



[1]Patterson & Yaffe, 2019, MIT

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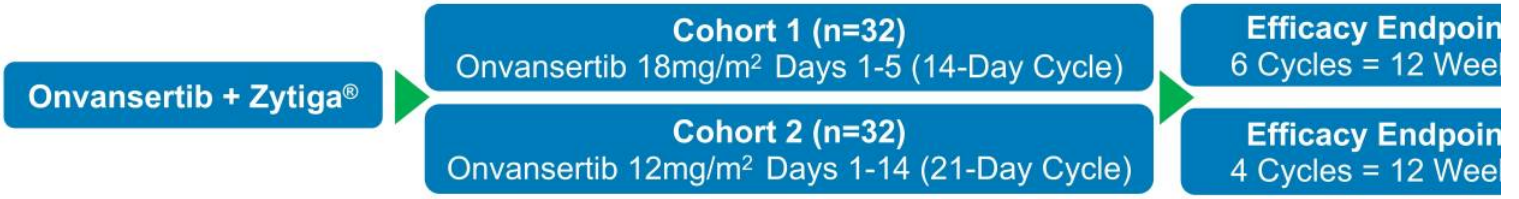
Overcoming Resistance and Extending Efficacy

Trial Design: Phase 2 multi-center, open label trial in mCRPC



Efficacy Endpoint – Internationally Recognized Prostate Cancer Working Group (PCWG)

Primary: disease control evaluated as PSA decline or stabilization (PSA rise <25% over baseline)

Correlative Biomarker: androgen receptor variant 7 (AR-V7) status and correlation with patient response

Current Standard-of-Care Zytiga® Clinical Response: median radiographic progression-free survival (RPFS) is ~7 months[1]

Onvansertib: Achieving Clinical Success

- 6 of 32 (~20%) patients achieve primary efficacy endpoint of disease control at 12 wee (PSA stabilization or decrease); confirmed by radiographic scan
- Patients achieve median RPFS of ≥7 months

Note: radiographic assessment by RECIST v1.1 [CR = disappearance of all target lesions, PR = ≥30% decrease, PD = ≥20% increase, SD = does not meet criteria for PR nor PD]

[1]Hussain et al., ESMO 2019

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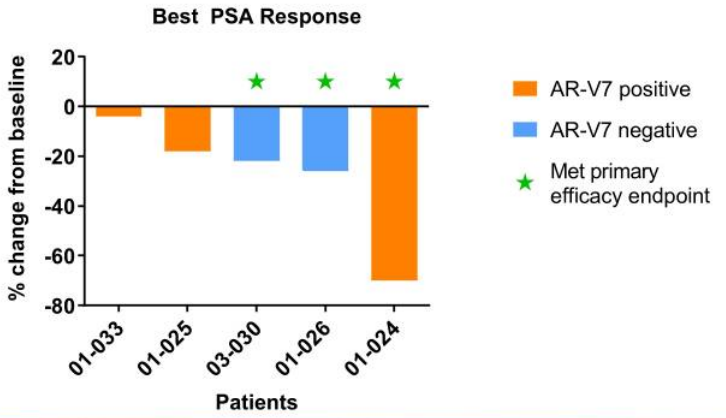
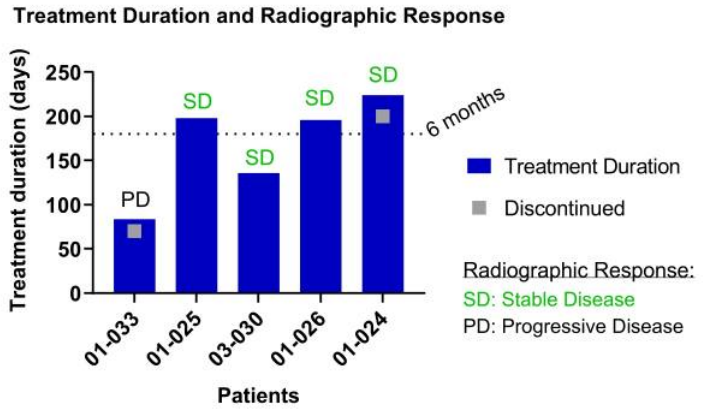
Efficacy Demonstrated by PSA Disease Control and Confirmed by Radiographic Scan



- Threshold for demonstrating onvansertib efficacy:
  - ≥20% of patients achieve primary efficacy endpoint of PSA stabilization
- To date, 3 of 5 patients in this cohort have met the efficacy endpoint



- Threshold for demonstrating onvanser efficacy:
  - Median of ≥6 months for radiograp progression-free survival (RPFS)
- To date, 3 of 5 patients have exceede months of RPFS

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Indication:
Acute Myeloid Leukemia (AML)

Yale Cancer Center
Seattle Cancer Care Alliance
UCLA Jonsson Comprehensive Cancer Center
Roswell Park
UT Southwestern Harold C. Simmons Comprehensive Cancer Center
Virginia Cancer Specialists
Allina Health Virginia Piper Cancer Institute
The University of Kansas Cancer Center

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Addressing the Need for New Treatment Options

Relapsed Acute Myeloid Leukemia (AML)

- 5-year survival rate of only 25%[1]
- Standard-of-care is venetoclax + azacytidine or decitabine; resistance develops in ~11 months[2]
- Onvansertib induces cell death in AML model resistant to Venclexta® [3]

Establishing a Successful Path Forward:

- Positive results from Phase 2 trial and Orphan Drug Designation may provide an opportunity for a Phase 2b registrational tri
- Opportunity to treat patients who relapse following first-line venetoclax
- Biomarker identifies patients most likely to respond, increasing likelihood of success

[1]National Cancer Institute SEER 2016; [2]DiNardo et al, Blood, 2019 [2]Valsasina et al., Mol Cancer Ther; 11(4) April 2012; [3]Trovagene, data on file

Providing a New, Safe and Effective Treatment

Trial Design: Phase 2 multi-center, open label trial in AML

Onvansertib +Decitabine ▶ Relapsed or Refractory Patients (n=32) ▶ Onvansertib 60mg/m^2 Days 1-5 (21-28 Day Cycle)

Efficacy Endpoint

Primary: safety and preliminary efficacy

Correlative Biomarker: Assess PLK1 inhibition (target engagement) by measuring changes in the PLK1 substrate pTCTP; evaluate predictive biomarkers associated with response to treatment

Current Standard-of-Care Clinical Response: Hypomethylating agents (decitabine and azacytidine) is 16.3% and IDH Inhibitors, ivosidenib (Agios), is 30.4%; enasidenib (Celgene) is 26.6%[2]

Onvansertib: Achieving Clinical Success

- 10 of 32 (~30%) achieve complete response (CR + CRi)
- Median overall survival of >2 months for relapsed/refractory AML patients

[1]Stahl et al., Blood Adv. 2018 Apr 24;2(8):923-932; [2]DiNardo et al, N Engl J Med. 2018 Jun 21;378(25):2386-2398; [3]Stein et al., Blood. 2017 Aug 10;130(6):722-731

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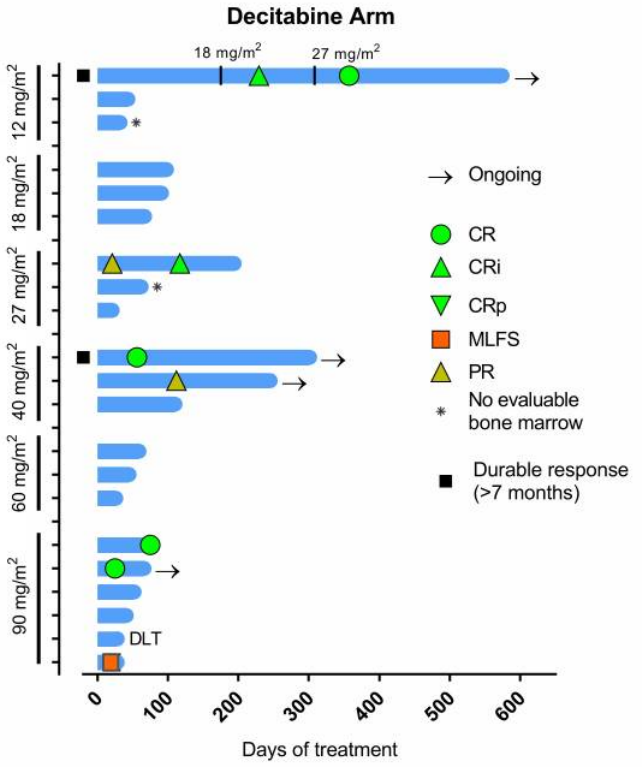
Phase 1b Completed Trial Efficacy Summary

Patients Treated with ≥ 1 Cycle (n=36)



- At the 4 higher dose levels (27 to 90 mg/m²), CR/CRi was observed in:
  - 5 of 16 (31%) patients in the decitabine Arm
- Median time to achieve CR/CRi was 4 cycles (range 1-7)
- Durable responses for >7 months

[1]Jones et al. Specific Mutations in KRAS Codon 12 Are Associated with Worse Overall Survival in Patients with Advanced and Recurrent Colorectal Cancer; BJC Feb. 2017

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Corporate

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Strong Patent Portfolio

- **Core Technology: 3 Issued Patents to 2030 in US, Europe and Asia with extension to 2035 i**
  - Compound (onvansertib): US 8614220
  - Salt forms of onvansertib: US 8648078
  - Combinations with anti-neoplastic compounds: US 8927530
- **Evergreening: Combination Therapy**
  - Exclusive license from MIT for 2 US issued patents with broad method claims for combination PLK inhibitor + anti-androgen compounds to treat any cancer
    - US 9566280, US 10155006; Expiration 2035
- **Evergreening: Biomarkers**
  - Method for assessing PLK1 target phosphorylation status for identifying patients to be treated Plk1 Inhibitors
    - PCT US1948044, Expiration 2039
  - Method for treating patient with a PLK inhibitor when there is a PSA rise
    - Provisional, Expiration 2040

Business Development Strategy

Objective: Joint Development and Commercialization Partnerships

- Financial and clinical support for company-sponsored and/or investigator sponsored (IST) studies
- Maintain rights in North America in part or in whole
- Co-develop and/or out-license specific indications in Japan and Europe
- Optimize development timelines while efficiently managing resources, internal and outsourced

Current Co-Research Collaboration

- Co-research agreement with Nektar Therapeutics to evaluate onvansertib in combination with NKTR-102 in colorectal canc

Partnering Strategy

- Successful partnership with US pharma/biotec for co-development
- Successful partnership with Japan Pharma for co-development and/or out-licensing

Financials

2019 Raised Capital & Clinical Research Commitment

- $14.5 million

Quarter Ending Cash and Cash Equivalents

- Q4’18 = $11.5M
- Q1’19 = $11.3M
- Q2’19 = $10.8M
- Q3’19 = $ 9.0M

Estimated Quarterly Cash Burn

- ~$4.0M

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2020 Key Inflection Points

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Acute Myeloid Leukemia: Phase 2 Efficacy Data	EHA EUROPEAN HEMATOLOGY ASSOCIATION	June 11th – 14th
2H2020 Key Inflection Points	**Event**	**Timing**
Prostate Cancer: Phase 2 Efficacy Data	ESMO	Sept. 18th – 22nd
Colorectal Cancer: Phase 2 Efficacy Data	ESMO	Sept. 18th – 22nd
Acute Myeloid Leukemia: Phase 2 Efficacy Data	ESMO	Sept. 18th – 22nd
Prostate Cancer: Phase 2 Efficacy Data	EMUC20	Nov. 12th – 15th
Colorectal Cancer: Phase 2 Efficacy Data	ESMO ASIA 2020	Nov. 20th – 22nd
Acute Myeloid Leukemia: Phase 2 Efficacy Data	Hematology 2020	Dec. 5th – 8th

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Thank You

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For additional information please contact: ir@trovagene.com