

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

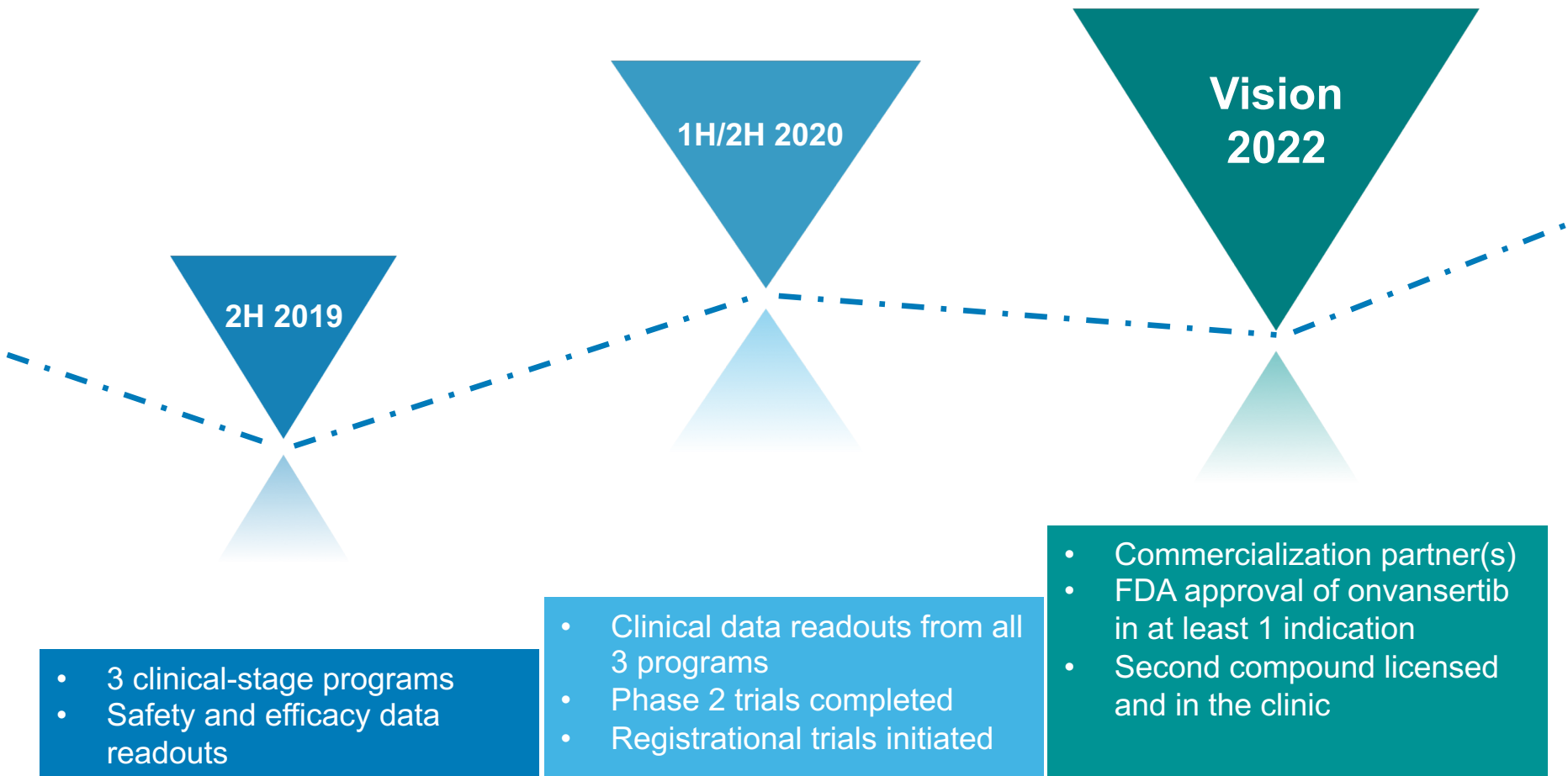


Vicki Kelemen
Vice President Clinical Development



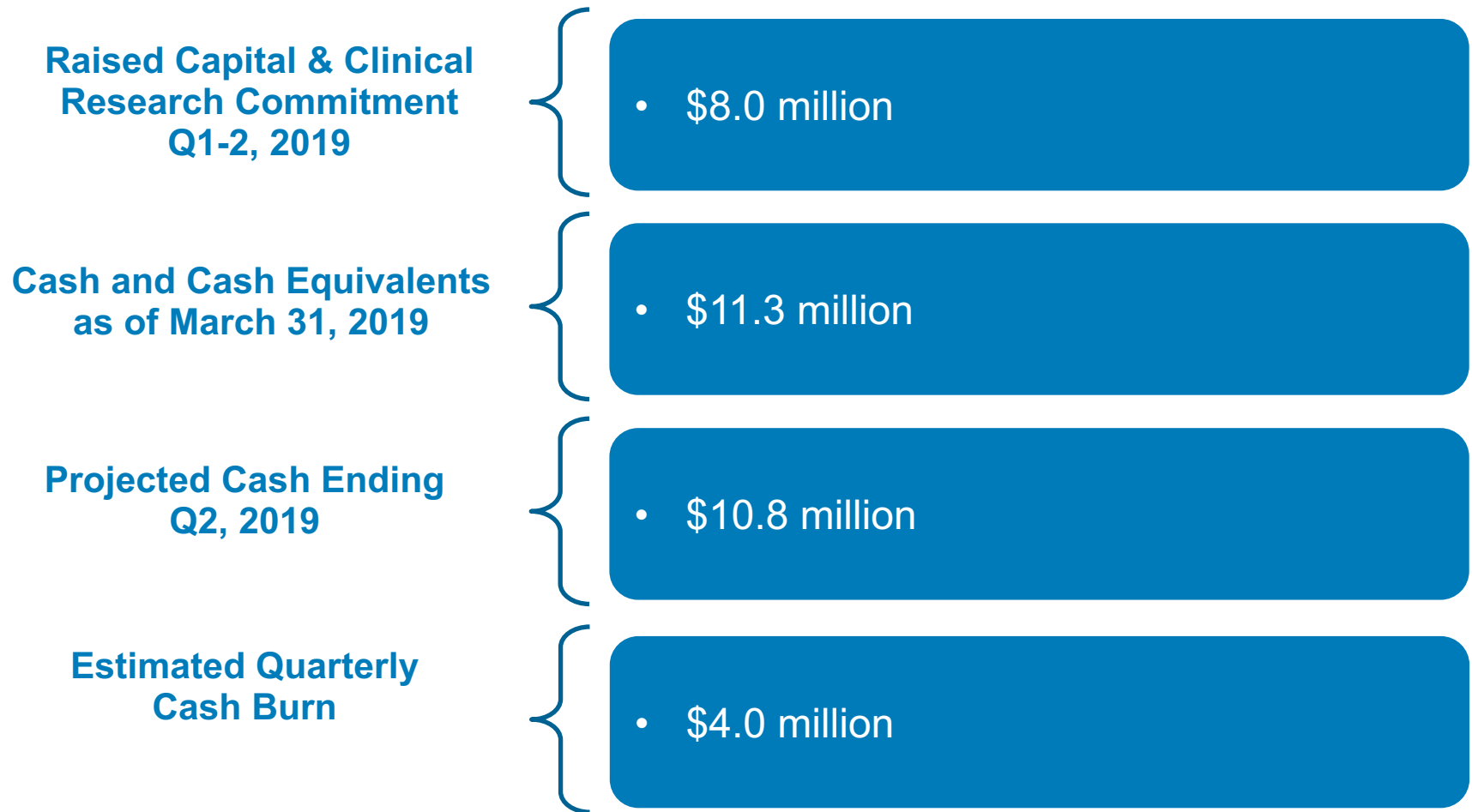
Our Vision

Rapidly Advancing Clinical Development Programs



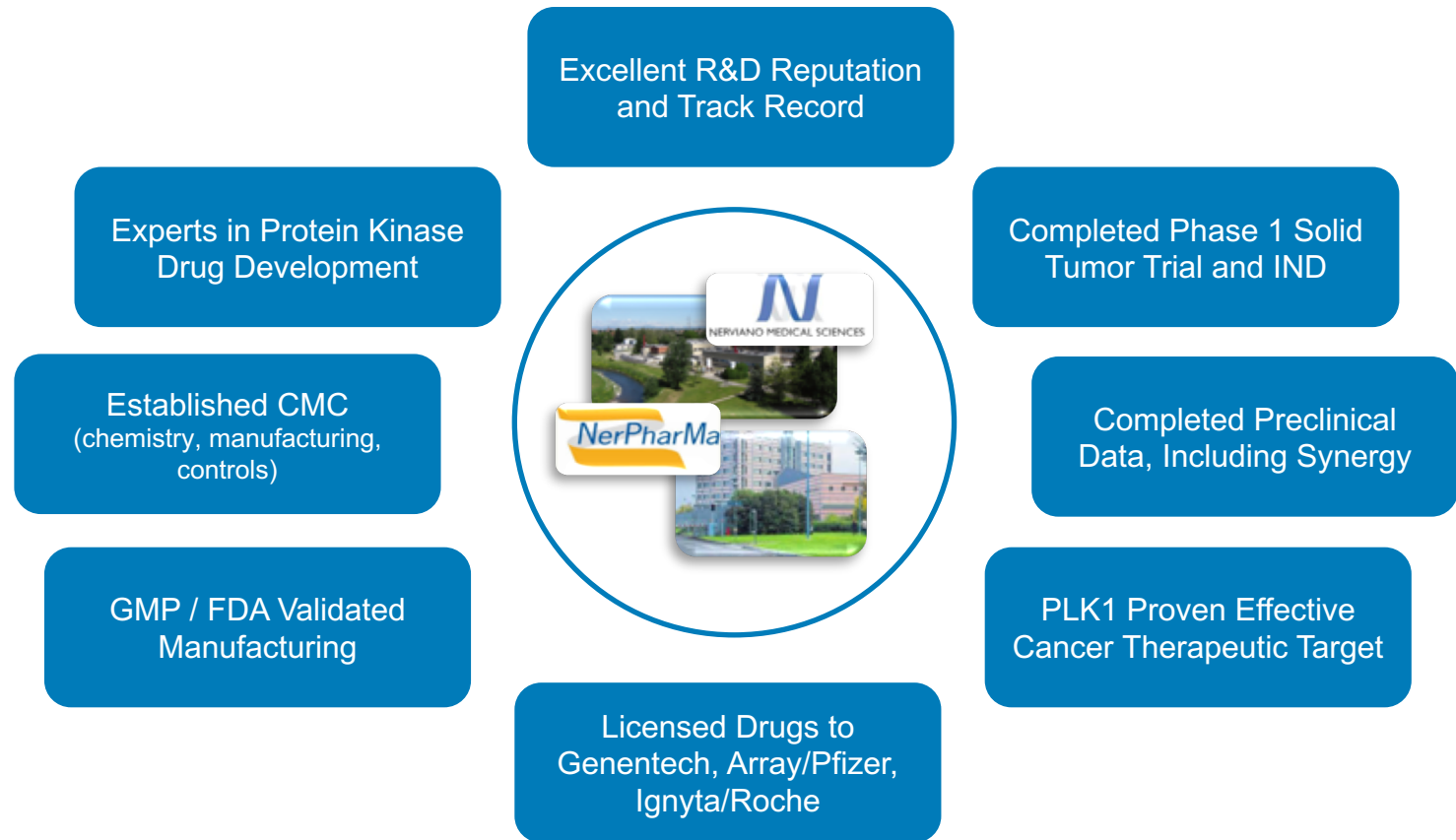
Demonstrated Operational Stability

Cost-Effective and Efficient Model

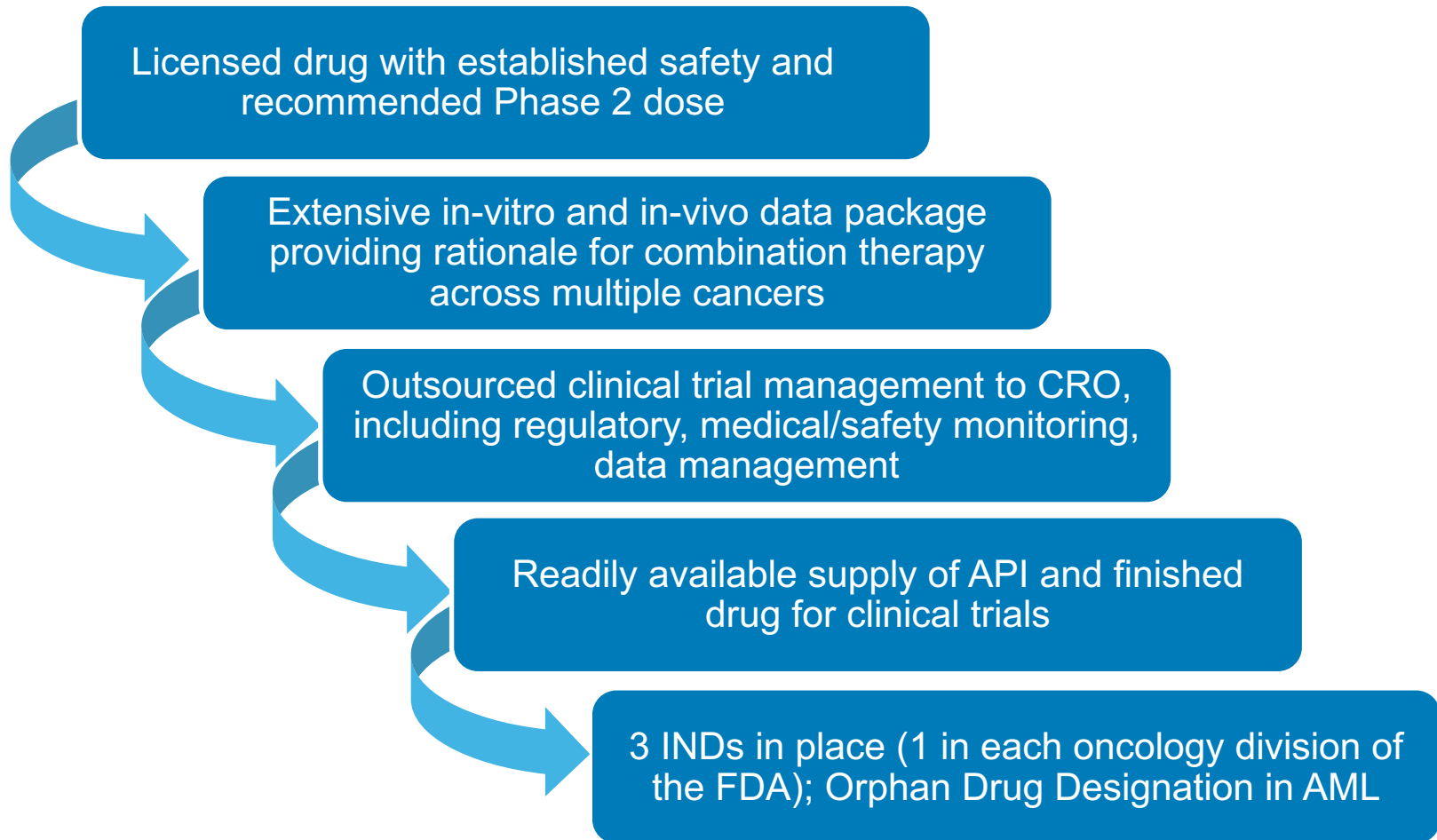


Exclusive Global Rights to Onvansertib Licensed from Nerviano Medical Sciences (NMS) in 2017

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

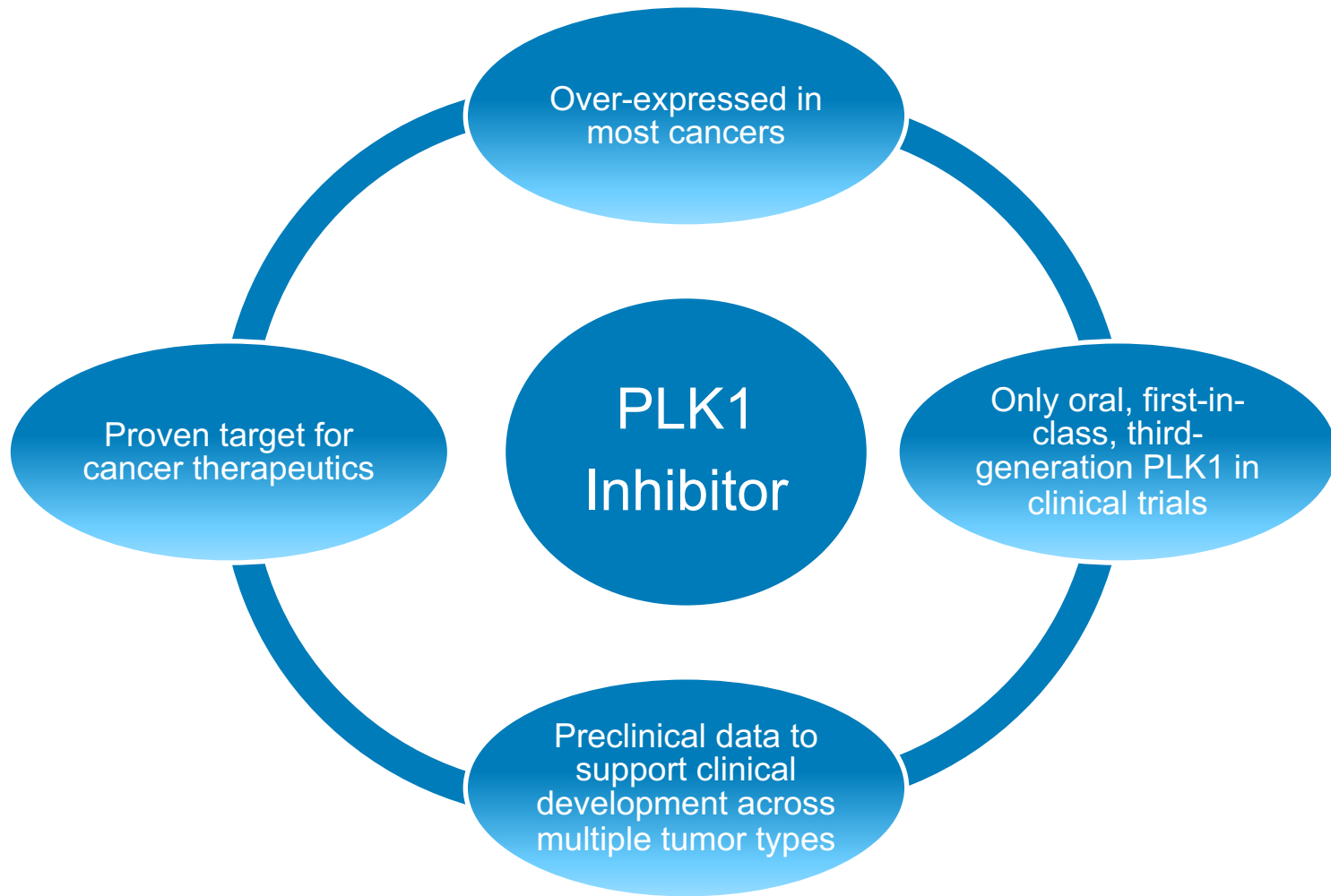


Optimized Operations and Clinical Development Leveraging Internal Expertise and External Resources



We Have the Perfect Target

Onvansertib – Polo Like Kinase 1 (PLK1) Inhibitor



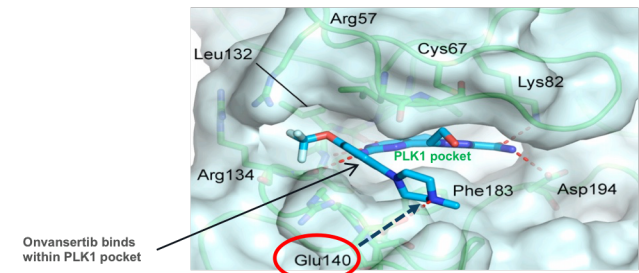
Onvansertib Targets the PLK1 Enzyme

A Proven Drug Target and Overexpressed in Most Cancers

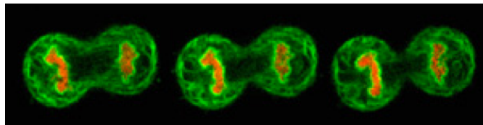
PLK Member	Onvansertib IC ₅₀ * (μM)
PLK1	0.002
PLK2	> 10
PLK3	> 10

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

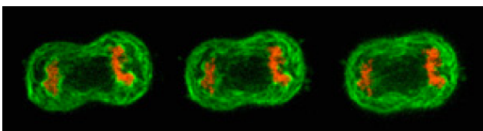
- ▶ Small molecule (MW 648.60 Daltons)
- ▶ Selectivity driven by stable interaction with carboxyl side chain of amino acid glutamate of PLK1 within PLK1's ATP binding pocket



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

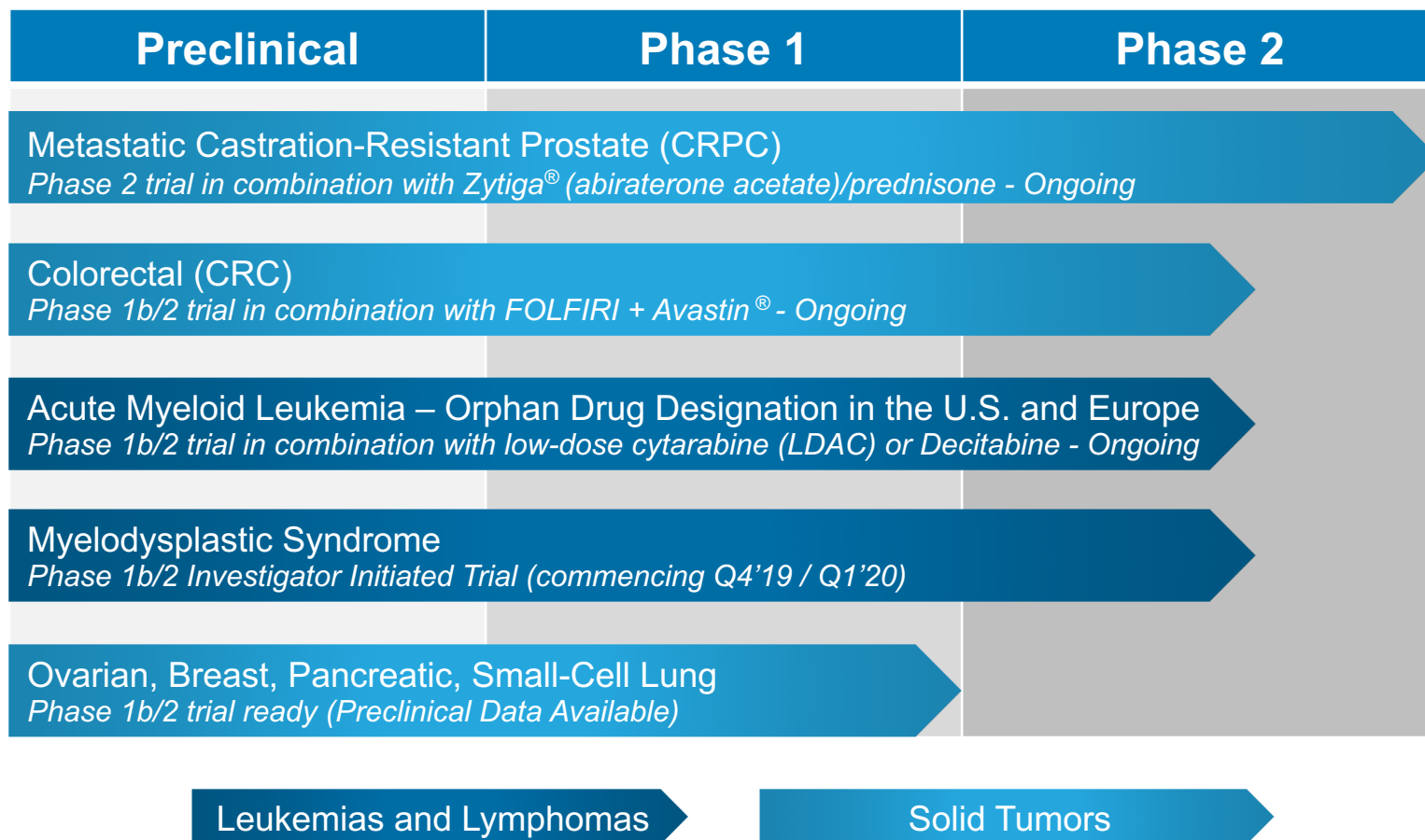
First-in-Class, Third-Generation PLK1 with Best-in-Class Attributes



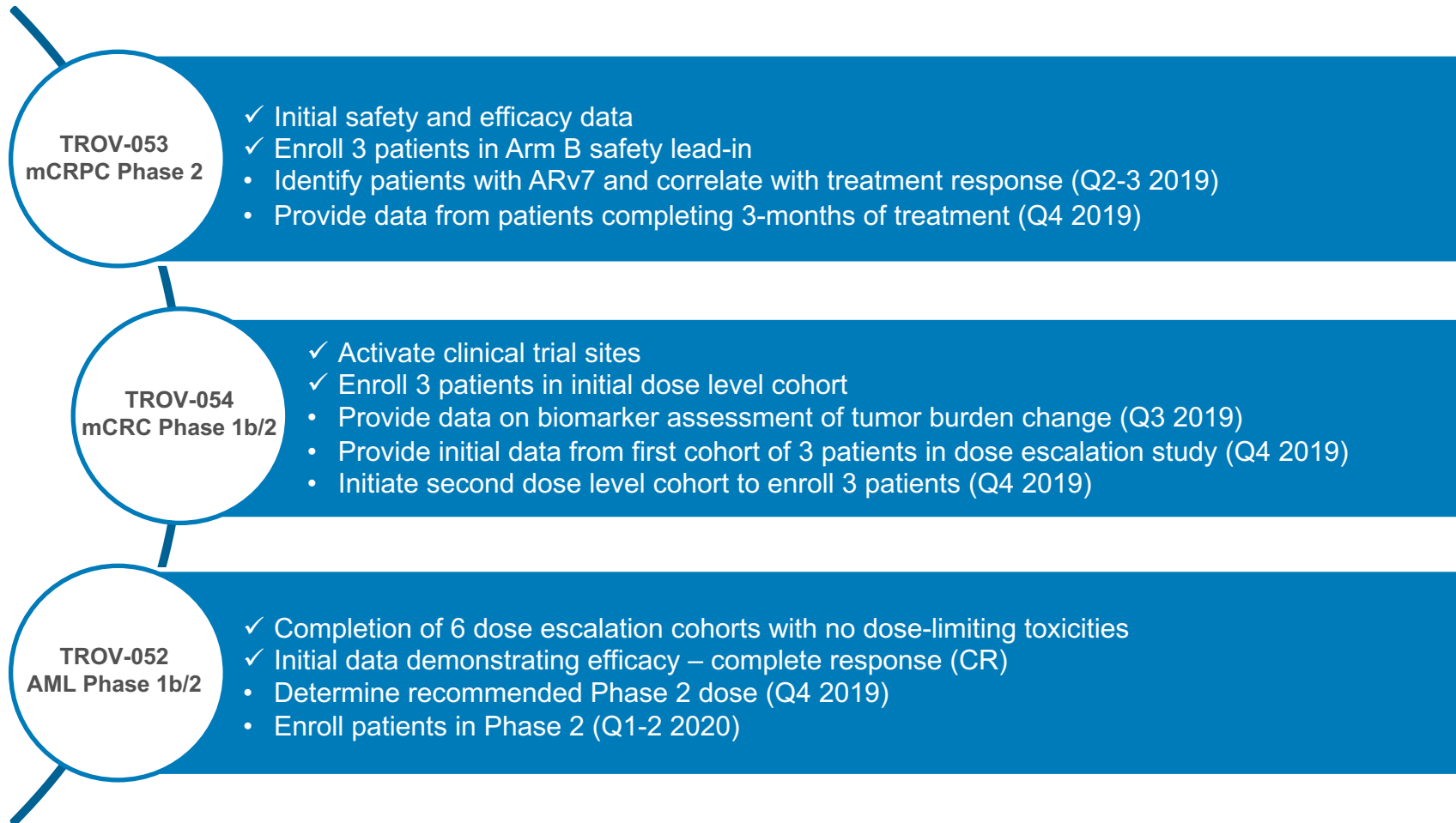
Diversified Pipeline with 3 Clinical-Stage Programs

Opportunities in Leukemias/Lymphomas and Solid Tumors

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



Encouraging Initial Data and Near-Term Readouts



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



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

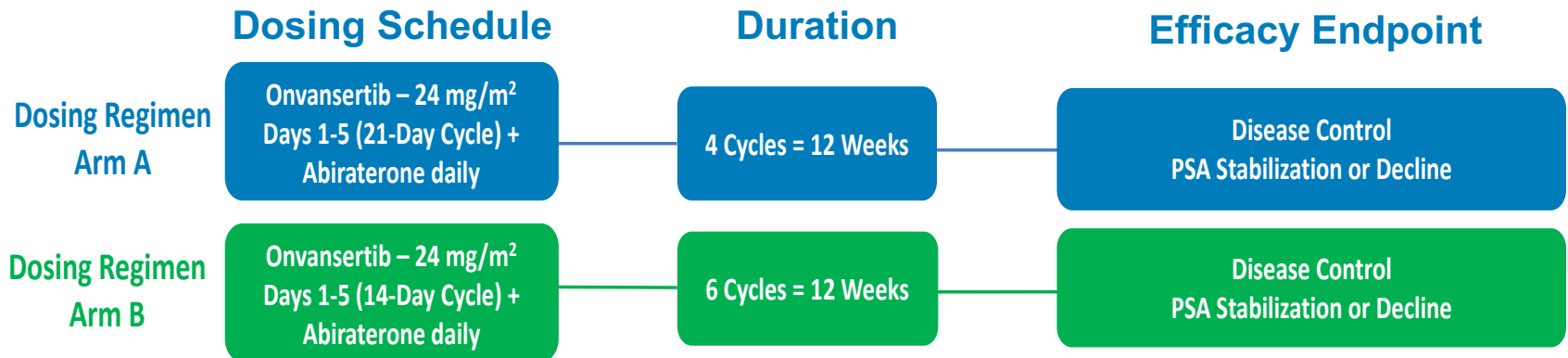
Inhibiting PLK1 blocks expression of ARv7; **stopping** this **resistance** pathway⁶

\$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; ³ National 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

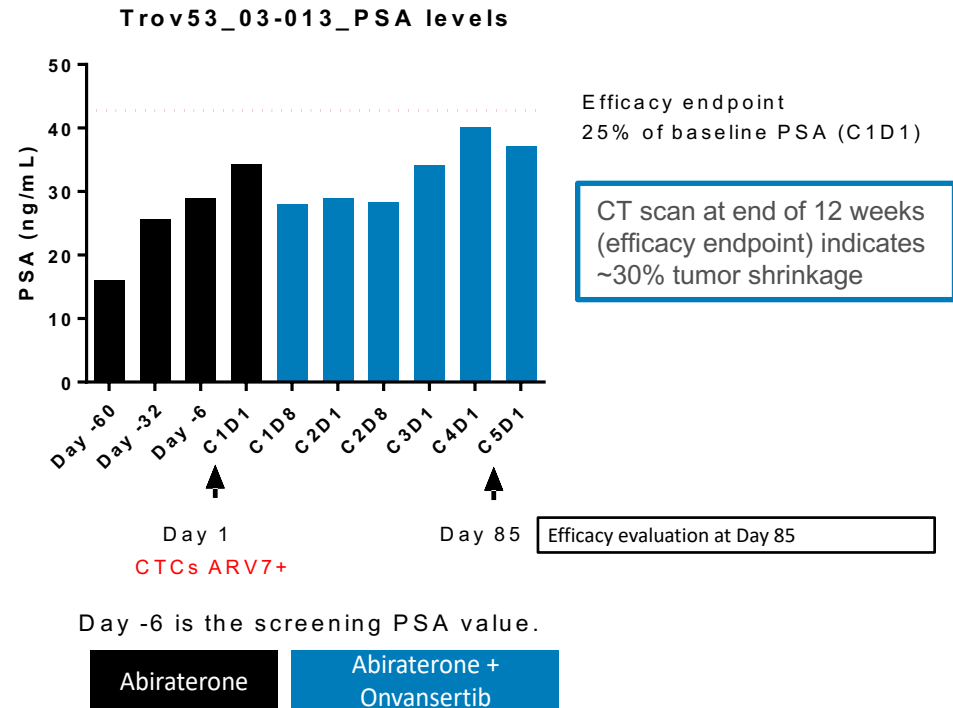
Disease Control Assessed by PSA Stabilization or Decline



- ▶ **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
Keck Medicine of **USC**

hoag
Hoag Family
Cancer Institute

 **MAYO CLINIC**
Cancer Center

 **trovagene**
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 growth**³

KRAS mutation is **biomarker** for onvansertib sensitivity

Research partnership with **Nektar Therapeutics**

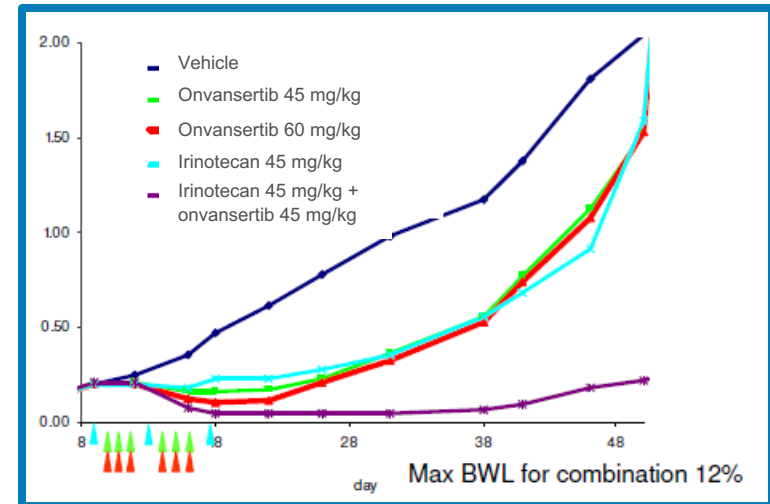
\$9.0 billion global market, expected to grow to \$11.0 billion by 2025⁴

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/gdhc141pidr--pharmapoint-colorectal-cancer-global-drug-forecast-and-market>

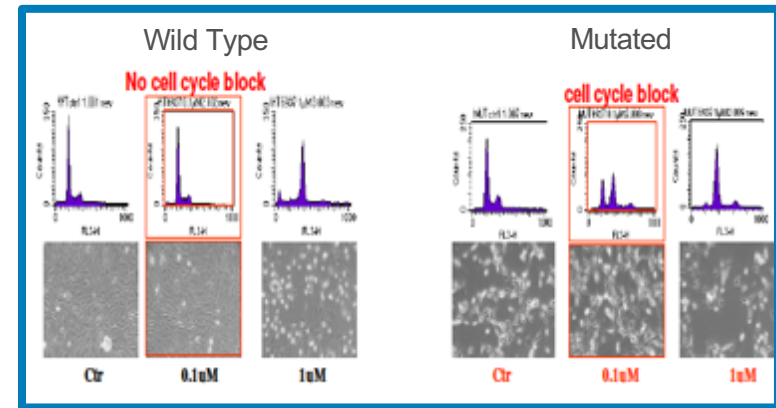
Synergy in Combination with Irinotecan

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

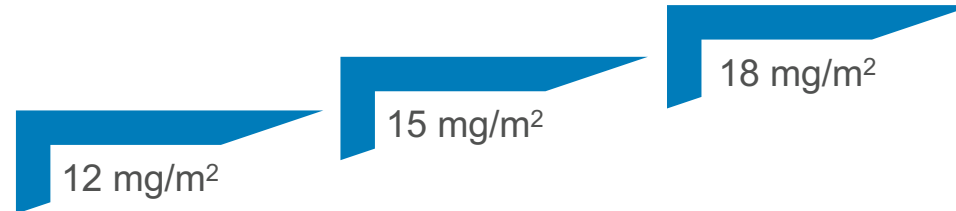


¹Investigator Brochure, Data-on-file, Trovogene

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)

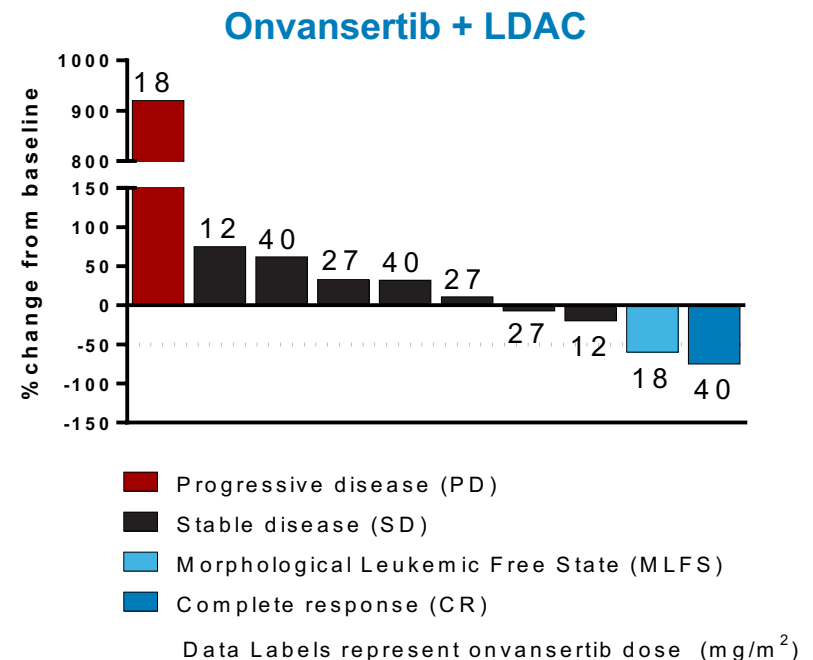
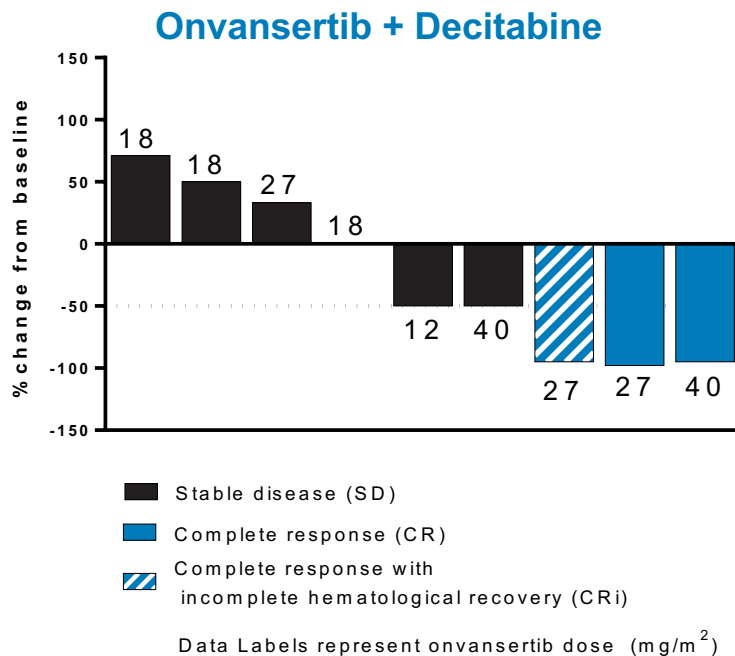
Phase 2: Assess safety and preliminary antitumor activity

- ▶ **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)

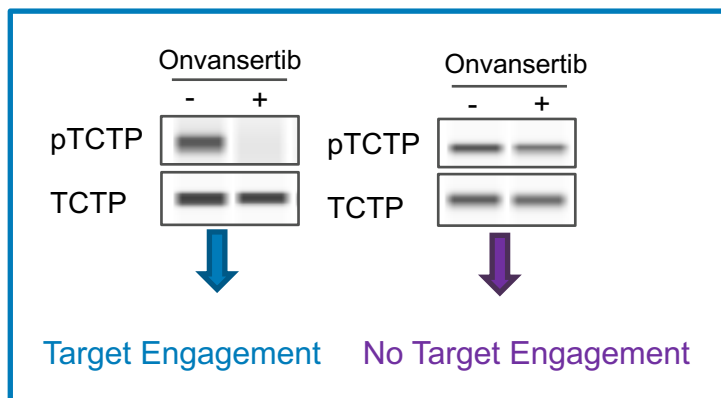


Biomarker Evaluates Inhibition of PLK1 Identifies Patients Most Likely to Respond to Treatment

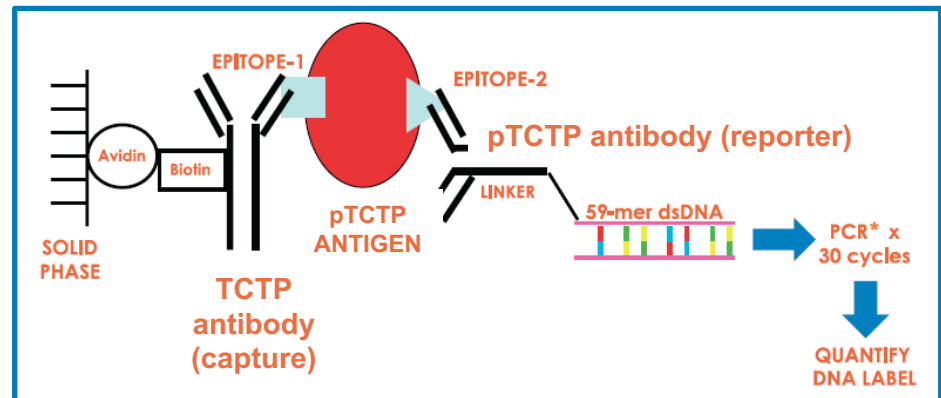
- ▶ Blood test examines the extent that onvansertib inhibits PLK1 enzymatic activity (target engagement) by assessing the phosphorylated status of TCTP within circulating leukemic blast cells



Current method: Western-Blot



Method in development: immuno-PCR based technology

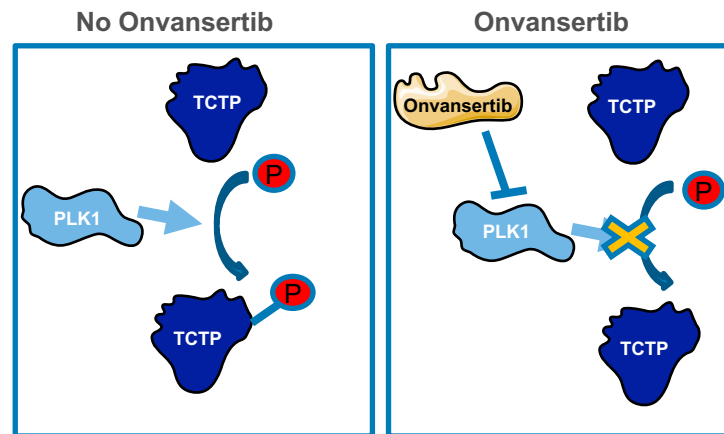


Biomarker to Assess Inhibition of PLK1

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**



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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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