# TRACON PHARMACEUTICALS Investor Presentation

August 2018



NASDAQ: TCON

## **Forward-Looking Statements**

This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forwardlooking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success of development activities and business strategies, plans and objectives of management for future operations, and future results of anticipated product development efforts, including potential benefits derived therefrom. These statements involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with conducting clinical trials, whether any of our product candidates will be shown to be safe and effective, our ability to finance continued operations, our reliance on third parties for various aspects of our business, competition in our target markets, our ability to protect our intellectual property, our ability to execute our business development strategy and in-license rights to additional pipeline assets, and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including under the heading "Risk Factors". In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this presentation represent our estimates and assumptions only as of the date of this presentation and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this presentation.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our drug candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.



# Innovative Product Development Platform Leads to Expected Multiple Layers of Potential Value for Shareholders



MULTIPLE LAYERS OF POTENTIAL VALUE FOR SHAREHOLDERS



# **Investment Highlights Deep Pipeline and a Partnering Platform**

- Late Stage Pipeline with Multiple Near Term Readouts
- Significant
   Commercial
   Opportunities
   Supported by
   Strategic
   Partnerships

Oncology
Phase 3

TAPPAS trial under SPA in orphan indication; and multiple Phase 2 trials

Ophthalmology
Phase 2

AVANTE randomized wet AMD trial Global rights to licensed to Santen

Immuno
Oncology
Phase 1

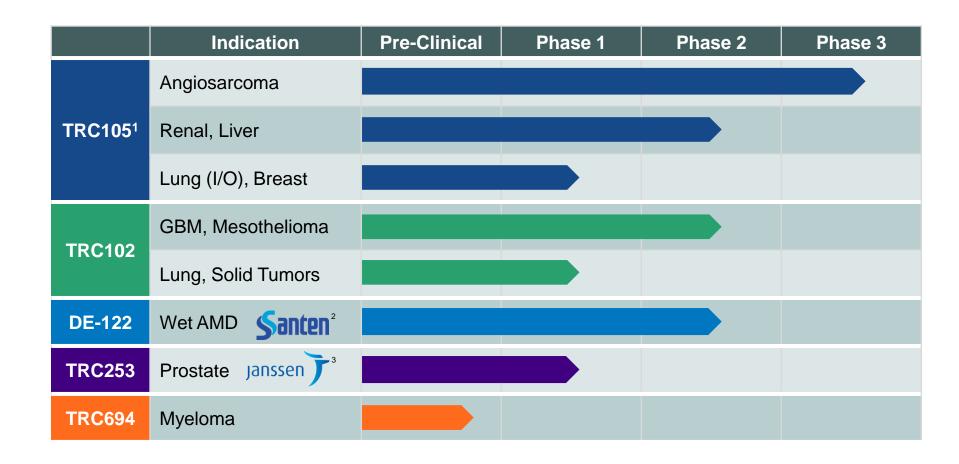
Lung cancer trial combined with Opdivo

- Opportunity to enhance efficacy of VEGF inhibitors and checkpoint inhibitors with new companion therapeutic
- All U.S. oncology commercial rights reserved
- Ambrx corporate partnership, developing lead program in China
- National Cancer Institute funding multiple trials

- Product Development Platform
- Risk and cost sharing drug development solution
- Built to deliver clinical results rapidly in US/EU
- Basis for in-license of prostate cancer/myeloma assets from Janssen without license payment
- Opportunity for U.S. commercialization
- Leverage to expand pipeline and build value



# **Broad Pipeline with Multiple Expected Near-term Readouts**



<sup>&</sup>lt;sup>1</sup> Ambrx has product rights to TRC105 (except ophthalmology) in China, Hong Kong, Macau and Taiwan

<sup>&</sup>lt;sup>2</sup> Partnered with Santen Pharmaceutical Co., Ltd. (Santen)

<sup>&</sup>lt;sup>3</sup> Janssen Pharmaceutica N.V. (Janssen) has a buyback option

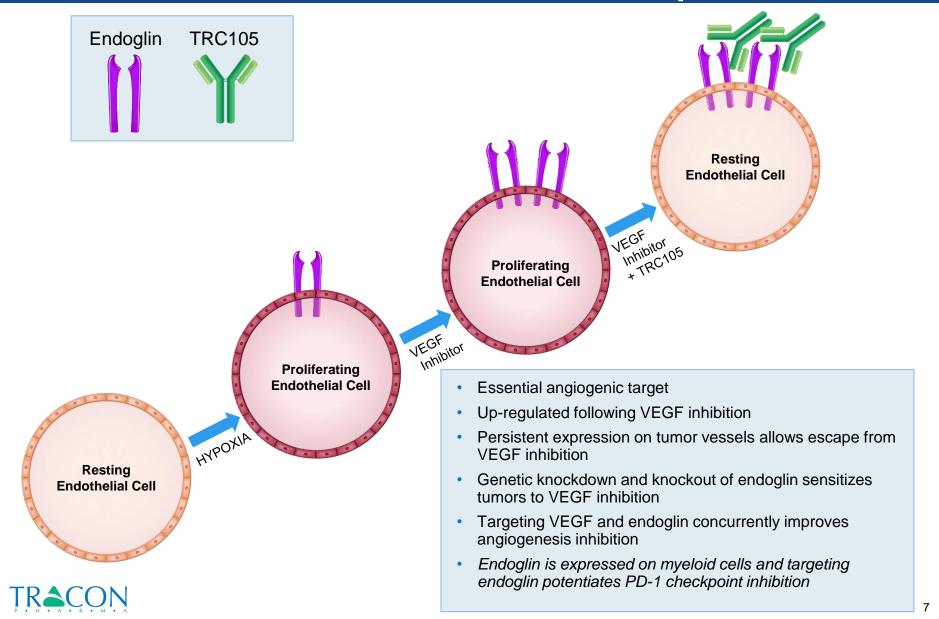
## **TRC105: Lead Program Expected Value Inflection Points**

Companion Therapy	2018	2019
Votrient	Phase 3 Angiosarcoma	*
Inlyta	Phase 2B RCC	
Nexavar	Phase 1B/2 HCC	
Opdivo	Phase 1B	

 $\stackrel{\wedge}{\bowtie}$  = interim inflection points



# Targeting Endoglin Interrupts a VEGF Escape Mechanism and Potentiates PD-1 Checkpoint Inhibition



# **Enhancing VEGF Inhibition Represents a Substantial Potential Commercial Opportunity for TRC105**

Indication	Approved VEGF Inhibitors	2017 VEGF Inhibitor Revenue <sup>1</sup>
2 <sup>nd</sup> Line Renal Cell Carcinoma	Inlyta (axitinib)	\$339 M
1 <sup>st</sup> Line Hepatocellular Carcinoma	Nexavar (sorafenib)	\$940 M <sup>2</sup>
2 <sup>nd</sup> Line Soft Tissue Sarcoma	Votrient (pazopanib)	\$808 M <sup>3</sup>
Colorectal Cancer, Lung Cancer	Avastin (bevacizumab) Cyramza (ramucirumab) Zaltrap (ziv-aflibercept) Stivarga (regorafenib)	\$6.8 B \$758 M \$85 M \$355 M
Wet AMD	Eylea (aflibercept) Lucentis (ranibizumab)	\$6.3 B \$3.3 B

Opportunity to build upon multiple VEGF inhibitor products by improving efficacy via inhibition of angiogenesis



<sup>1</sup> GlobalData.

<sup>2</sup> Nexavar is approved in HCC, RCC and thyroid cancer. The majority of Nexavar's sales are in HCC.

<sup>3</sup> Votrient is approved in both RCC and advanced STS with the majority of sales in RCC.

# TRC105: Lead Asset Oncology Development Strategy

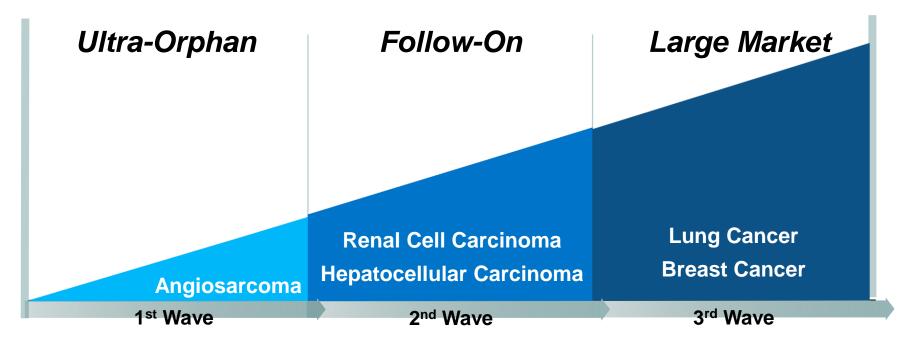
# TRC105 Development in Combination with Blockbuster Therapeutics in Early Line Treatment

#### **VEGF** Inhibitors

- Votrient in Angiosarcoma
- Inlyta in Renal Cell Carcinoma
- Nexavar in Hepatocellular Carcinoma

#### **Checkpoint Inhibitors**

Opdivo in Lung Cancer





## **Lead Indication: Angiosarcoma**

- Ultra Orphan indication: ~ 600 cases annually in the US and 1,200 in Europe; greater incidence in Asia<sup>1</sup>
- High Unmet Need: 5-year survival rate < 12% compared to 5-year survival rate of ~ 56% for all soft tissue sarcoma<sup>2</sup>
  - Treatment with chemotherapy (taxanes or doxorubicin) in the front line setting is associated with PFS of ~ 5 months and OS < 1 year<sup>3</sup>
  - Treatment with VEGF inhibitors in the second line setting is associated with PFS of 1.8 - 3.8 months and OS < 1 year</li>
- Two subtypes: About 50% of patients present with a primary cutaneous lesion
- Market potential: Estimated at \$100M+ in US/EU<sup>4</sup>

<sup>&</sup>lt;sup>4</sup>TRACON estimate



<sup>&</sup>lt;sup>1</sup>Suveillance, Epidemiology, and End Results Program, NCI, www.seer.cancer.gov; RARECARE database, <u>www.rarecare.eu</u> <sup>2</sup>www.cancerresearchuk.org

<sup>&</sup>lt;sup>3</sup>Penel et al, JCO 2008; Italiano et al, Cancer 2012

# High Unmet Need in Initial Pivotal Indication VEGF Inhibitors Have Limited Activity in Angiosarcoma

VEGF Inhibitor	Study	Patient Population	Activity
Votrient <sup>®1</sup>	Retrospective analysis (CTOS 2016)	Angiosarcoma (n = 40)	<ul> <li>ORR = 20% (No CRs)</li> <li>PFS = 3.0 months</li> <li>OS = 9.9 months</li> </ul>
Votrient	Retrospective analysis (ASCO 2014)	Soft tissue sarcoma including 6 angiosarcoma patients	• No CR's
Nexavar <sup>®</sup>	Single agent study (Maki 2009)	Angiosarcoma (n = 37)	• ORR = 14% (1/37 CR) • PFS = 3.8 months
Nexavar	Single agent study (French sarcoma group)	Angiosarcoma (n = 41)	Cutaneous angiosarcoma  • ORR = 15% (2/26 CR)  • PFS = 1.8 months  Visceral angiosarcoma  • ORR = 13% (No CRs)  • PFS = 3.8 months
Avastin®	Single agent study (Agulnik 2013)	Angiosarcoma (n = 23)	• ORR = 9% (No CRs) • PFS = 3.0 months

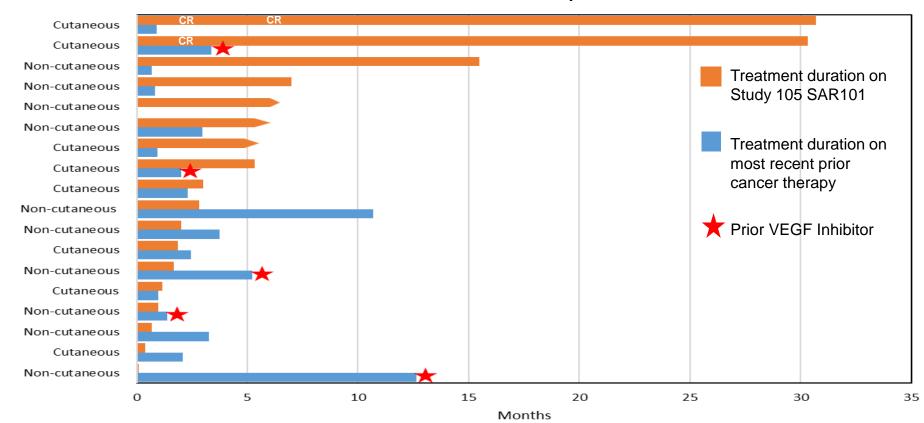


<sup>&</sup>lt;sup>1</sup> Votrient is the only VEGF inhibitor approved for the treatment of soft tissue sarcoma based on the superior PFS versus placebo (4.6 versus 1.6 months) in the Phase 3 PALETTE study.

## TRC105 + Votrient is Active in Angiosarcoma

- PFS in 13 VEGF inhibitor-naïve patients of 7.8 months vs. 3 month PFS expected with Votrient
- Most VEGF inhibitor patients had superior time on treatment with TRC105 + Votrient compared to prior chemotherapy.
- US and EU regulators allowed enrollment of treatment naive angiosarcoma patients into the Phase 3 TAPPAS trial

## Study Duration of 9 Angiosarcoma Patients Treated with TRC105 + Pazopanib in the Original Phase 1b/2 Trial and 9 Patients in the Expansion Cohort





## TRC105 + Votrient Phase 1b/2 Observations



Data as of November 2017



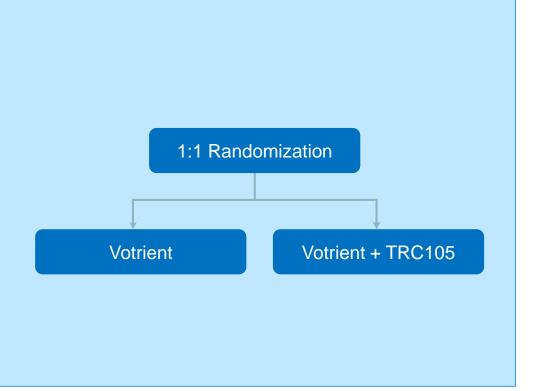




## Phase 3 TAPPAS Randomized Trial in Angiosarcoma

**TAPPAS**: TRC105 And Pazopanib versus Pazopanib alone in patients with advanced Angiosarcoma

- Primary Endpoint: PFS
- Independent blinded central review
- Key Secondary Endpoints: ORR, OS
- Key eligibility
  - Age ≥ 12
  - Unresectable angiosarcoma
  - Measurable disease by RECIST 1.1
  - No prior treatment with VEGF inhibitor
  - No more than 2 prior lines of treatment
  - ECOG PS 0-1
- Strata
  - Cutaneous vs Non-cutaneous
  - Prior chemotherapy: 0 vs 1 or 2
- N = 124 200 (TBD: adaptive design)

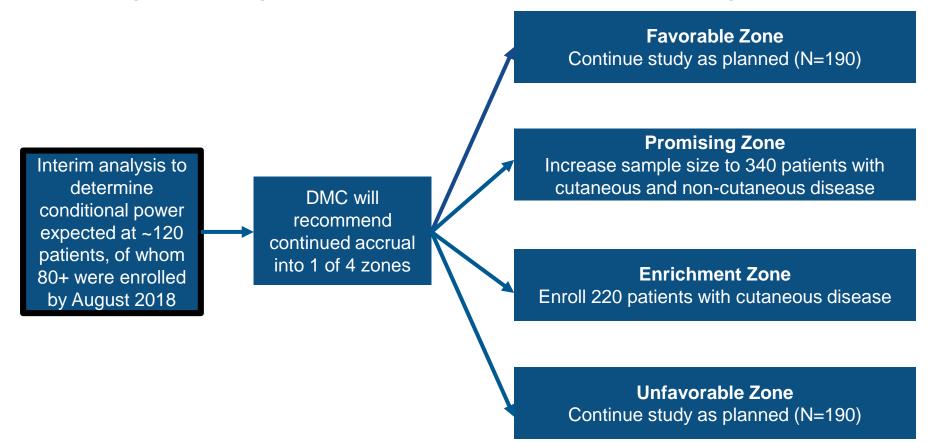




## Phase 3 TAPPAS Trial in Angiosarcoma

Adaptive design recognized as Most Innovative Clinical Trial of 2017.

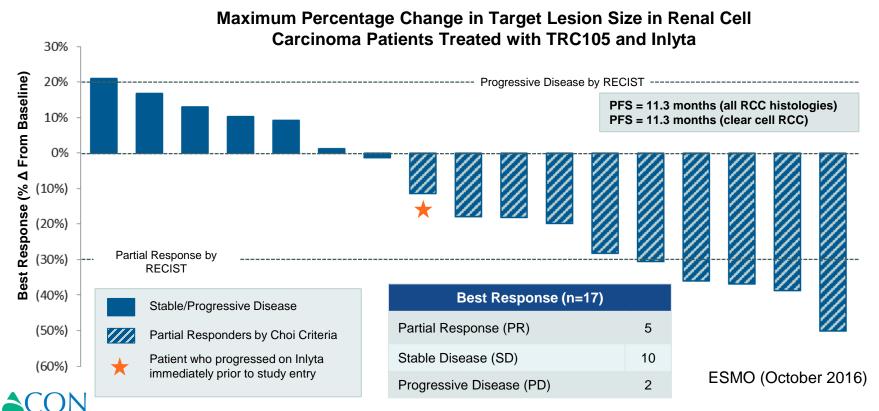
Allows for sample size re-estimation or enrichment of cutaneous disease at the time of the interim analysis expected in 1Q 2019. Accruing at higher rate than expected and protocol amended Q3 2018 to increase sample size.





# TRC105 Second Indication: TRC105 + Inlyta<sup>®</sup> in Renal Cell Carcinoma

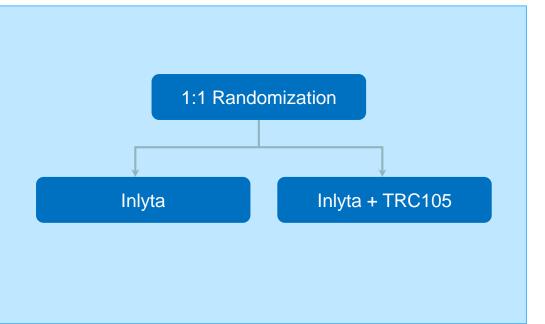
- 18 patients treated in a Phase 1b clinical trial who failed at least one VEGF inhibitor
- Partial response rate by RECIST of 29% (4 of which were in the fourth line setting)
  - Exceeded partial response rate of Inlyta following VEGFR TKI treatment in the Inlyta Phase 3 AXIS trial of 11%
- Median PFS in clear cell RCC of 11.3 months
  - Exceeded PFS of Inlyta following VEGFR TKI treatment in the Inlyta Phase 3 AXIS trial of 4.8 months
- Exploratory analysis indicated two biomarkers (baseline TGF-β R3 and osteopontin) correlated with activity
- In press at The Oncologist



# Phase 2 TRAXAR Trial in Renal Cell Carcinoma Fully enrolled with data expected Q4 2018

TRAXAR: Axitinib and TRC105 versus Axitinib Alone in Patients with Advanced or Metastatic Renal Cell Carcinoma

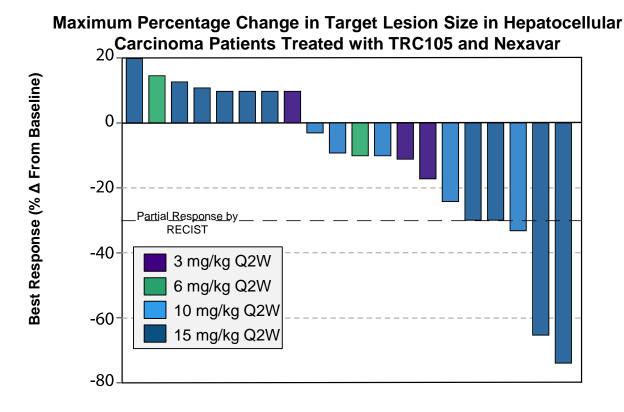
- Primary Endpoint: PFS by RECIST 1.1
- N = 150, Event driven trial
- Independent blinded central review
- Key eligibility
  - Advanced or metastatic clear cell RCC
  - Measurable disease by RECIST 1.1
  - Progression following 1 prior VEGF inhibitor
  - 1 prior mTOR inhibitor allowed
  - 1 prior immunotherapy allowed





# TRC105 Third Indication: TRC105 + Nexavar in Hepatocellular Carcinoma

- NCI Phase 1/2 study published in Clinical Cancer Research partial response rate by RECIST of 25% across 4 dose levels; all responses occurred at two highest dose levels (10 or 15 mg/kg) of TRC105
  - Exceeded partial response rate of Nexavar in Phase 3 pivotal studies of 2 3%
  - Median OS of 15.5 months exceeded median OS of Nexavar in its pivotal Phase 3 of 10.7 months



- Multicenter Phase 2 trial in up to 33 patients is enrolling to confirm response rate
  - Interim data presented at GI ASCO (January 2018): partial responses in 2 of first 8 evaluable patients
  - Full data expected at GI ASCO January 2019
- Late stage development in HCC in greater China to be led by corporate partner Ambrx



# TRC105 Large Indication: TRC105 + Opdivo® in Lung Cancer

- Endoglin is a TGF-β co-receptor expressed on fibroblasts and myeloid derived suppressor cells (MDSCs), cell types not addressed by checkpoint inhibition
  - TGF-β signaling implicated as a primary means of tumor immune evasion that complements checkpoint inhibition and tumor mutational burden
- TRC105 potentiated the activity of PD-1 inhibition in syngeneic mouse tumor models
  - Oral presentations from Leiden University researchers announced at International Microenvironment Cancer Society meeting in June 2018
- TRC105 is being studied with Opdivo in non-small cell lung cancer in a Phase 1 trial with cohorts of PD-1 naïve and resistant patients
  - Correlation between response and MDSC tumor content will be assessed

### **Santen License for DE-122**

Companion Therapy	2018	2019
Lucentis	Phase 2 AVANTE Trial in V	Vet AMD

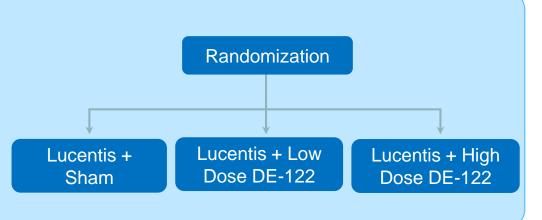
- Global ophthalmology company with \$1.8 billion in annual revenue leads global development and commercialization for DE-122 (ophthalmic formulation of TRC105) in wet AMD and other eye diseases
- Deal terms
  - \$20M received
  - Santen pays all development costs and commercializes
  - Up to \$145M in additional milestones
  - Royalties in the high single digits to low teens
- Failed Phase 2 and 3 studies from Ophthotech and Regeneron place DE-122 in lead for VEGF inhibitor companion drug to build on \$9B market in wet AMD. High unmet need.
- Regulatory path is well defined.



## Santen Development of DE-122 in wet AMD

- Phase 1/2 PAVE trial results presented February 10, 2018 at the Angiogenesis, Exudation and Degeneration meeting at Bascom Palmer Eye Institute
  - 8 out of 12 subjects demonstrated bioactivity: improved macular edema or visual acuity
  - Safe with no serious adverse events
- Phase 2 AVANTE randomized trial is enrolling data expected mid 2019

- Primary Endpoint: Best Corrected Visual Acuity following six monthly intravitreal injections
- Double masked
- N = 51





## **TRC102: Expected Value Inflection Points**

Companion Therapy	2018	2019
Alimta	Phase 2 Mesothelioma	
Temodar	Phase 2 GBM	
Temodar	Phase 1B/2 Multiple Solid Tumors	

- Small molecule designed to reverse resistance to chemotherapy and complement PARP inhibitors
- Inhibits base excision repair, a dominant pathway of DNA repair that allows for resistance to alkylating chemotherapy (e.g., Temodar®) and antimetabolite chemotherapy (e.g., Alimta®)
- Current clinical development funded by National Cancer Institute



## TRC102: Reversing Resistance to Chemotherapy

Combination	Well Tolerated	Signs of Activity in Phase 1b/2	Ongoing Development
TRC102 + Alimta (Published in Investigational New Drugs, 2012)		Stable disease in patients with squamous cell lung cancer, a tumor type where Alimta is inactive	Phase 2 trial with Alimta in mesothelioma
TRC102 + Fludara (Published in Oncotarget, 2017)		Partial response and stable disease in patients previously treated with Fludara	
TRC102 + Temodar (Presented at ASCO 2017)	<b>√</b>	Partial responses in patients with lung, KRAS+ colorectal and ovarian cancer; induced biomarkers of DNA damage Rad51, pNbs1, and/or γ-H2AX	Phase 2 expansion cohorts added in lung, colorectal, and ovarian cancer; Phase 2 trial with Temodar in glioblastoma

 Efforts are focused on identifying a biomarker (e.g., glycosylase expression) that will correlate with response to treatment with chemotherapy + TRC102



# Janssen In-Licenses: Expected Value Inflection Points

	2018	2019
TRC253	Phase 1/2 Prostate Cancer	
TRC694	Myeloma; Lymphoma	IND

- TRC253 is an antagonist of AR mutations that are resistance mechanisms for Xtandi® and Erleada®
  - Phase 1 trial completed July 2018; Phase 2 dose determined, dosing in Phase 2
- TRC694 is a selective inhibitor of NF-kB-inducing kinase (NIK)
- TRACON was chosen because of our innovative product development platform

#### **TRC253 Deal Terms**

- Janssen has rights to re-acquire TRC253 for \$45M, additional potential milestones of \$137.5M and low single digit royalty
- If Janssen passes, TRACON retains all rights and will owe development and regulatory milestones of up to \$45M and a low single digit royalty to Janssen

#### **TRC694 Deal Terms**

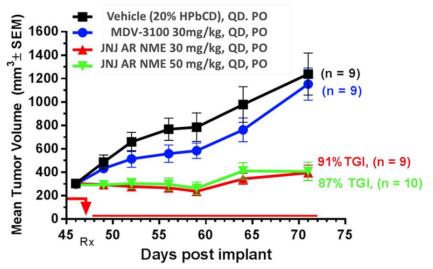
- Janssen has a right of first negotiation for TRC694 following Phase 1 POC
- TRACON owes development and regulatory milestones of up to \$60M and a low single digit royalty



## **TRC253:** Novel Androgen Receptor (AR) Mutant Inhibitor

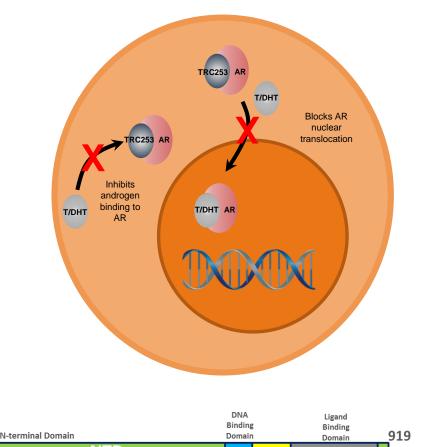
- Designed to treat AR resistant prostate cancer
  - Occurs in ~10% of mCRPC cases
- Active against wild-type AR and many clinically relevant ligand binding domain mutations
- Clear path to POC data in targeted population using a companion diagnostic
- Phase 1 trial completed and Phase 2 trial now enrolling

#### AR F877L-driven xenograft model



#### Hickson, I. AACR 2016 Annual Meeting. Joseph, JD, et al. Cancer Discovery 2013.

#### **Multiple Mechanisms of Action**

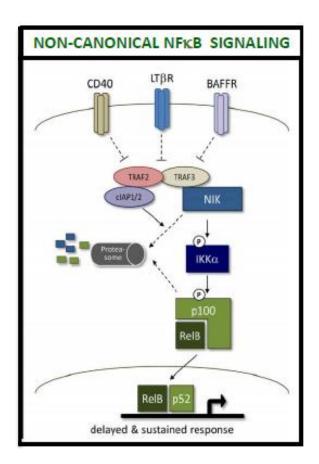


## TRC694: Novel NF-kB Inducing Kinase (NIK) Inhibitor

- NIK pathway is dysregulated in hematologic malignancies
  - Multiple myeloma (~12-20% of cases), mantle cell lymphoma (~17%), diffuse large B-cell lymphoma (~9-15%), CLL (~4% at diagnosis, higher later)
- Clear path to POC data in targeted population using a precision medicine approach→ IND expected in 2019

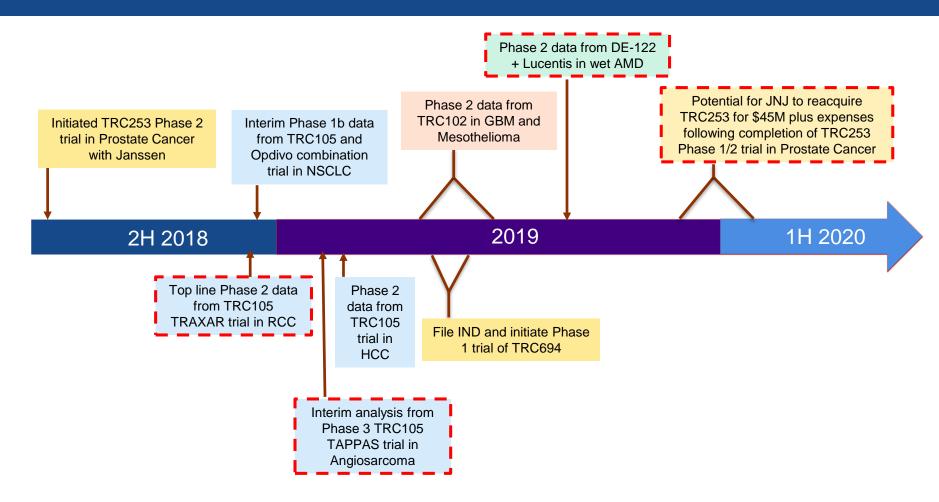
# NIK-translocated myeloma cell line (JJN3) xenograft model Vehicle TRC694 10 mg/kg TRC694 20 mg/kg TRC694 40 mg/kg TRC694 40 mg/kg TRC694 40 mg/kg Day Post Dose Initiation

# NIK is Critical for Non-Canonical NF<sub>K</sub>B Activation



Krappmann & Vincendeau, 2016

# Expected Milestones: Poised to Deliver on a Number of Clinical Programs in 2018 and 2019



Corporate Goal is to Collaborate on the Development of 2 Additional Assets

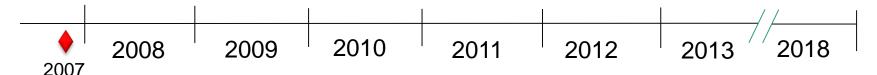


# TRACON: Transition from CRO-Dependent Development to In-House Product Development Platform

#### **CRO Outsourced:**

Pharmacovigilance, Statistics, Trial Master File, Contract Negotiations, Payments, Data Management, Programming

CRO Independent (5 completed trials, 9 ongoing)



Multiple INDs

- Clinical Development
- Pharmacovigilance
- Study Management
- Data Management
- Bioinformatics & IT

- Clinical Analytical
- Statistics (Consultant)
- Clinical Supplies
- CMC & Regulatory
- Monitoring (Contract)



# **Expand Pipeline through Innovative Product Development Platform Partnerships: Trust it to TRACON**

- Leverage a team of industry experts with previous leadership roles in project teams that contributed to multiple product approvals.
- In-house development platform built to deliver clinical results rapidly and reduce time to market, while using significantly less capital than competitors or CROs.
- Platform can be applied to develop first-in-class, best-in-class or fast-follower oncology and other physician specialist prescribed products.
- Rapid development and open communication results in an efficient and effective culture of collaboration.



# Expand Pipeline through Innovative Product Development Platform (cont.)

- Cost, risk and profit share of partnered assets produces goal alignment
- FDA NDA/BLA can be leveraged for regulatory filings in all major territories
- Commercial presence in U.S. expected in 2021 (through potential TRC105 approval) to preserve maximum value of product between corporate partners
- Collaboration with Janssen, including equity investment from JJDC, on TRC253/TRC694 validates TRACON's product development platform
- Industry recognition for innovative clinical trial design (Clinical Research Excellence Awards 2017)



## **Business Development Strategy**

- Leverage our innovative product development platform in new corporate partnerships to access promising specialty product assets
  - Transactions similar to the Janssen transaction where TRACON licenses asset(s) for no license fee and develops asset(s) to certain value inflection points in return for substantial economics and/or commercial rights
  - Solution for companies with little or no development infrastructure in the U.S.



## **TRACON's Vision as a Preferred Solution**

	TRACON	Bio/Pharma	CRO
Development speed	<b>✓</b>	X	X
Cultural fit		?	NA
Alignment			X
Cost effective		X	X
Cost share Risk share		<b>✓</b>	X
Maximum value retained		X	NA
Development and commercialization		<b>✓</b>	NA
Co-promote option		X	NA



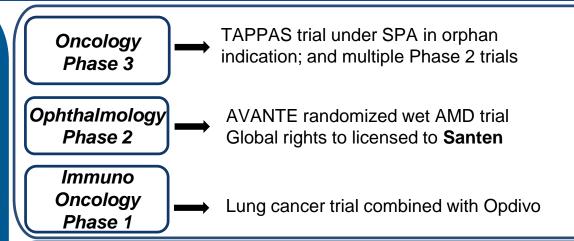
# Financial Overview (as of June 30, 2018)

Ticker	TCON (NASDAQ)	
Cash, Cash Equivalents and Short-term Investments	\$53.4 million	
Debt – Outstanding Principal	\$7.0 million	
Common Shares O/S	29.8 million	
Covering Analysts	Jim Birchenough (Wells Fargo) Bert Hazlett (BTIG) Chad Messer (Needham) Maury Raycroft (Jefferies)	



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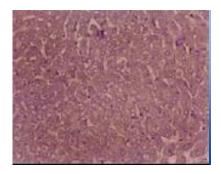


# Backup

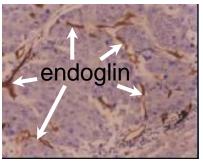


# TRC105 Target: Endoglin is an Essential Non-VEGF Angiogenic Target

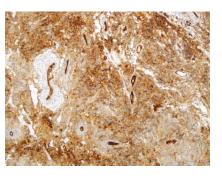
- Expressed on proliferating blood vessels in cancer and AMD
  - Essential for angiogenesis
  - Unfavorable prognostic marker
  - Up-regulated following VEGF inhibition
- Attenuated expression (Osler-Weber-Rendu syndrome) associated with improved cancer survival
- Genetic knockdown reverses resistance to VEGF inhibition
- Targeting VEGF and endoglin concurrently improves antitumor effects
- Targeting endoglin on myeloid derived suppressor cells (MDSCs) potentiates PD-1/PD-L1 inhibition in preclinical models



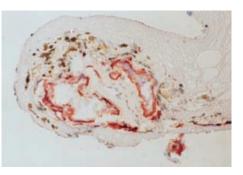
Normal Human Liver



**Human Liver Cancer** 



Angiosarcoma

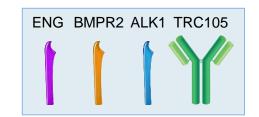


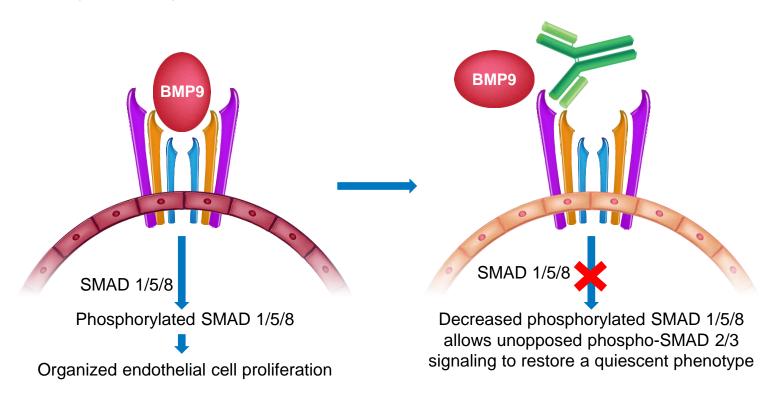
**Human AMD Membrane** 



## TRC105: Lead Endoglin Antibody

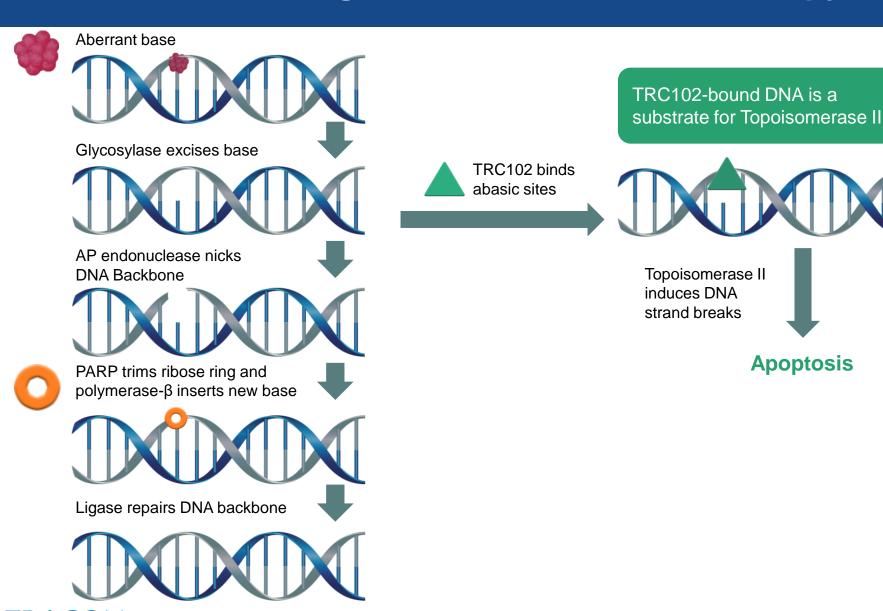
- TRC105 binds a precise endoglin epitope to inhibit BMP binding and angiogenesis
- TRC105 also potently mediates antibody-dependent cell mediated cytotoxicity (ADCC)







## **TRC102: Reversing Resistance to Chemotherapy**



## **Team of Industry Experts**

#### Charles Theuer MD PhD, President and CEO

- 23 years of experience in drug discovery and development
- Sutent, Rituxan, Zevalin







#### Mark Wiggins MBA, Chief Business Officer

- 30 years of drug development experience
- Commercialization of Rituxan and Zevalin







#### Bonne Adams MBA, SVP Clinical Operations

- 16 years of experience in drug discovery and development
- Sutent, Rituxan, Zevalin







#### Suzy Benedict, VP Regulatory Affairs

- 15 years of regulatory affairs experience
- Viracept, Macugen







#### Sharon Real PhD, SVP Product Development

- 23 years of experience in drug discovery and development
- Sutent, Macugen, Viracept, Targretin







#### Jennifer Ellis, VP Quality Assurance

- 25 years of drug development experience
- Sivextro, Inlyta, Viracept







## SAB and Board Bring Deep Industry Experience

#### **Scientific Advisory Board**

- Charles Sawyers, MD
   Memorial Sloan Kettering Cancer Center
- William Kaelin, MD
   Harvard Medical School
- Jeff Hager, PhD Former CSO, Aragon
- Stanton Gerson, MD
   Case Cancer Center
- Brian Daniels, MD
   5AM Ventures, former SVP, BMS

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- Paul Walker
   Partner, NEA
- Ted Wang, PhD
   CEO and CIO, Puissance Capital
- Stephen Worland, PhD CEO, Effector Therapeutics
- Charles Theuer, MD, PhD
   President and CEO

