

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

July 23, 2018
Date of report (Date of earliest event reported)

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

Delaware
(State or other jurisdiction
of incorporation)

001-37990
(Commission
File Number)

27-4412575
(IRS Employer
Identification No.)

**47 Thorndike Street, Suite B1-1
Cambridge, MA**
(Address of principal executive offices)

02141
(Zip Code)

Registrant's telephone number, including area code **(617) 714-0360**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications 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 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 8.01. Other Events.

On July 23, 2018, Leap Therapeutics, Inc. (the "Company") updated the corporate slide presentation available on its website at <http://www.leaptx.com> (as updated from time to time, the "Corporate Presentation"). A copy of the Corporate Presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Corporate Presentation is current as of July 23, 2018, and the Company disclaims any obligation to update the Corporate Presentation after such date.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation of Leap Therapeutics, Inc. current as of July 23, 2018.

2

SIGNATURES

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.

Leap Therapeutics, Inc.

Dated: July 23, 2018

By: /s/ Douglas E. Onsi
Name: Douglas E. Onsi
Title: Chief Financial Officer, General Counsel, Treasurer and Secretary



Company Update
July 2018

Forward-Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We assume no obligation to update any forward-looking statements, except as required by applicable law.

All product trademarks listed are the properties of their owners.



Leap Therapeutics

- **Oncology drug development company**
- **Novel targets and compounds**
 - DKN-01 (anti-DKK1)
 - TRX518 (GITR agonist)
- **Clinical responses in multiple indications**
- **Strategic relationships established**
 - DKN-01 Collaborations with Merck and Roche
 - TRX518 Collaboration with Pfizer/EMD Serono
 - Strategic Investment from Eli Lilly
- **Important new clinical data throughout 2018 and 2019**
 - Combination data with PD-1/PD-L1 immunotherapies
 - Biomarker-defined populations
 - 7 studies across 5+ different tumor types

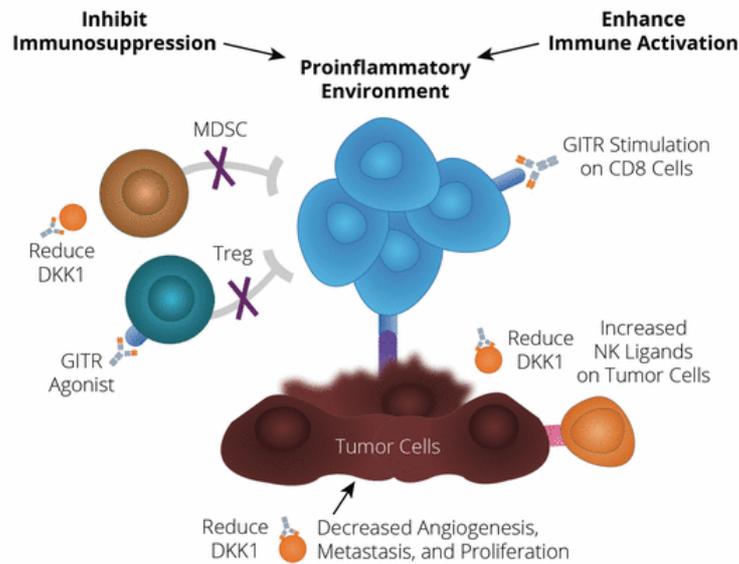
Copyright © 2018

Recent Highlights

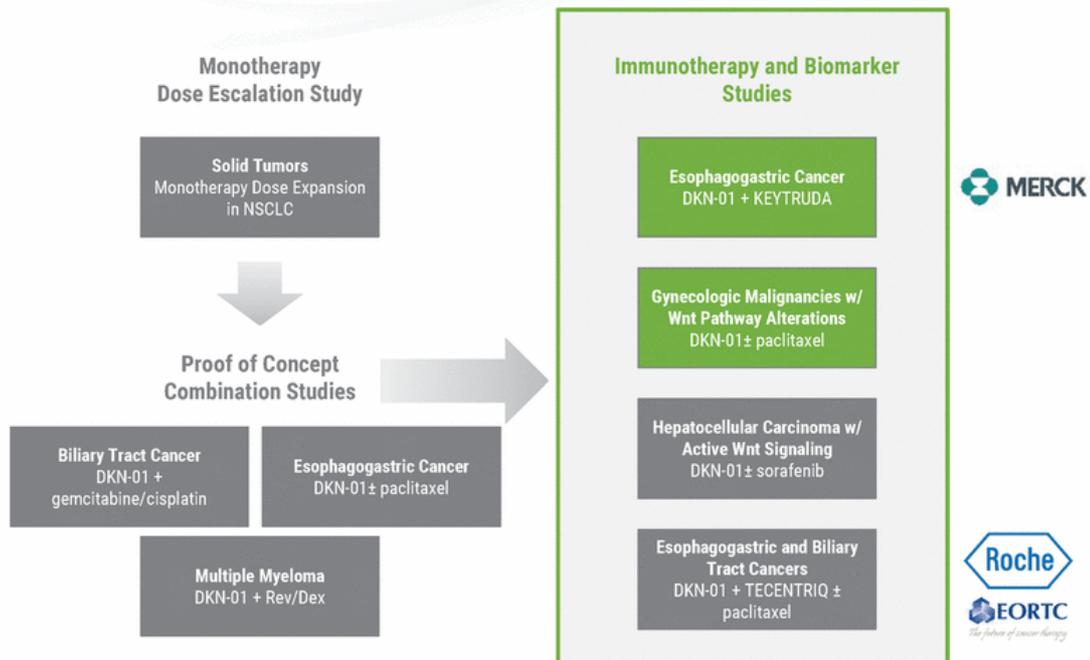
- **Collaboration with Pfizer/EMD Serono for combination study of TRX518 with BAVENCIO® and cyclophosphamide**
 - Study design based on preclinical data presented by MSKCC at AACR 2018
 - Bavencio's fully Fc functional antibody pairs with TRX518's structure
 - Expansion cohorts focused on breast, ovarian and prostate cancers
- **Clinical responses for DKN-01 in combination with KEYTRUDA® (collaboration with Merck) in Esophagogastric Cancer study**
 - 2 patients with Partial Responses (82% and 42% tumor reductions) in dose escalation cohort; both PD-L1 negative, microsatellite stable (MSS), KRAS mutant
 - Actively enrolling expansion cohorts; targeting full enrollment in Q1 2019
- **Enrollment continuing in DKN-01 study in Gynecological cancers and TRX518 combination studies with KEYTRUDA®, OPDIVO® and gemcitabine**

Copyright © 2018

DKK1 and GITR are Compelling Oncology Targets



Advancing DKN-01 Clinical Development



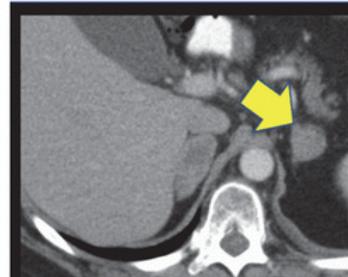
Active as a Single-Agent in Heavily Pretreated Esophagogastric Cancer

On Study 1 Year, Response -33.9%
Failed prior anti-PD-L1 + IDOi

Best Overall Response of Evaluable Patients (By Central Imaging Analysis)

Partial Response	2/16 (12.5%)
Stable Disease	5/16 (31.3%)
Progressive Disease	9/16 (56.3%)

REGARD	Ramucirumab + BSC	Placebo + BSC
Population	2 nd -3 rd line GEJ + Gastric	
ORR	3.4%	2.6%
SD	45%	21%
PFS	2.1 months	1.3 months



Representative Target Lesion

Baseline

Left Adrenal Met = 30.8 mm



4 Month Scan

Left Adrenal Met = 11.0 mm

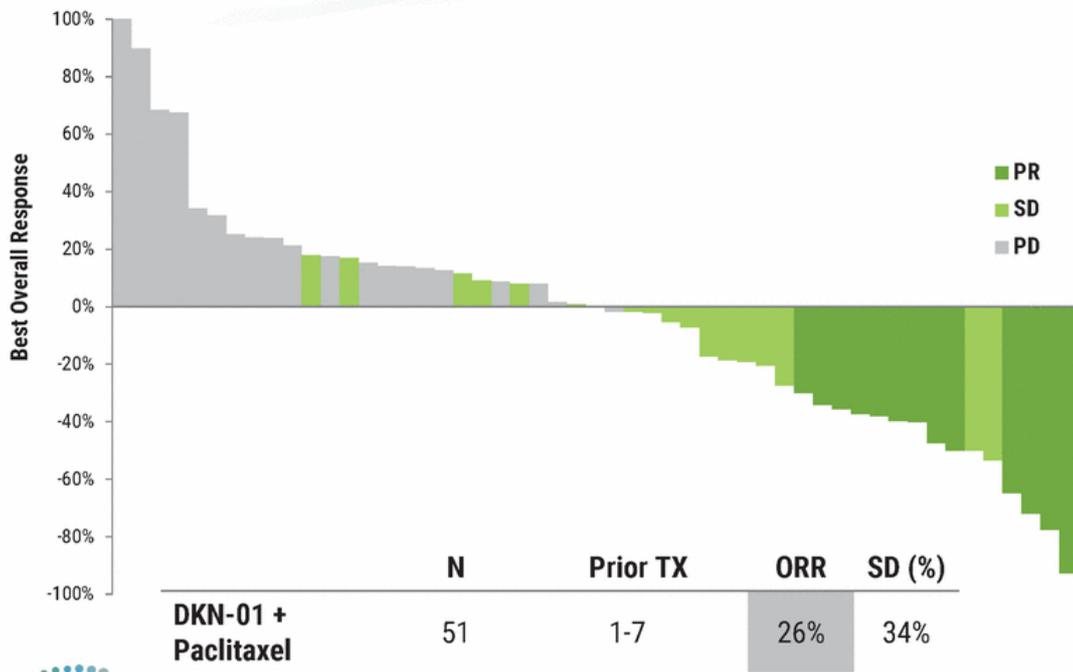


Data as of March 2018

7

Copyright © 2018

Combination with Paclitaxel in Esophagogastric Cancer All Patients



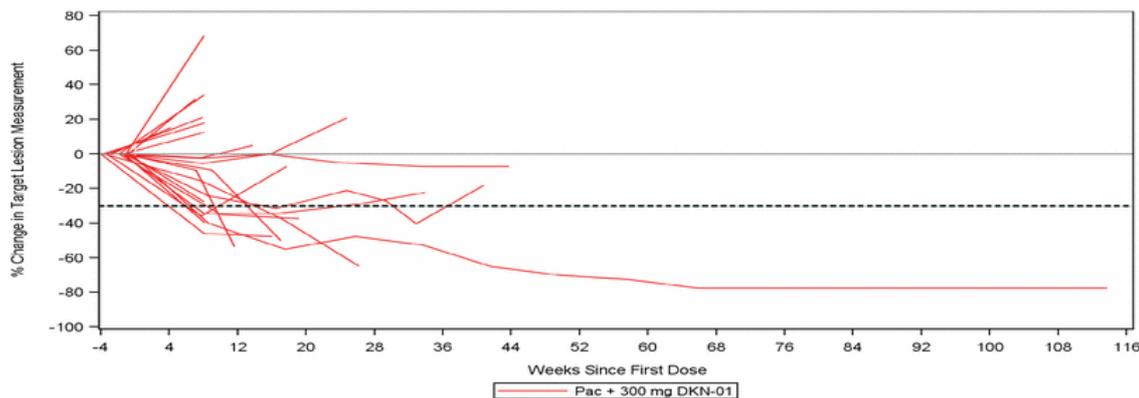
Data as of March 2018

8

Copyright © 2018

Clinical Activity of DKN-01 + Paclitaxel in Taxane Naive Patients

Tumor Burden Change Over Time
(Each Line Represents an Individual Patient)



Efficacy Benchmarks	Response Rate	DCR
DKN-01 + Paclitaxel (Taxane Naive)	41%	73%
Ramucirumab + Paclitaxel Rainbow Study	28%	80%
Paclitaxel Mono Rainbow Study	16%	64%

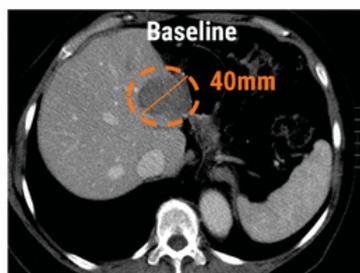
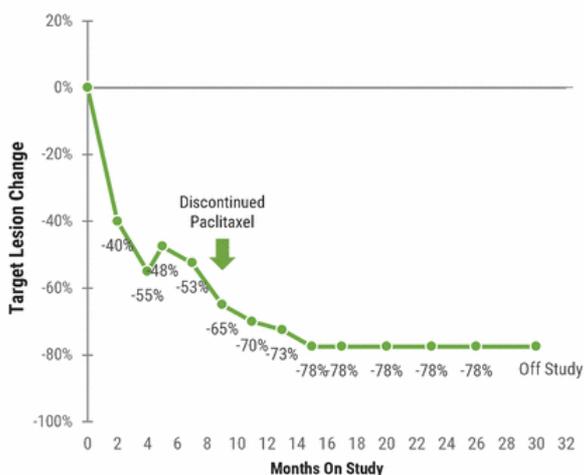


Data as of August 2017

9

Copyright © 2018

Durable DKN-01 Response in Patient with Beta-Catenin Mutation with Esophagogastric Cancer



10

Copyright © 2018

Immunologic Activity of DKK1 Inhibition

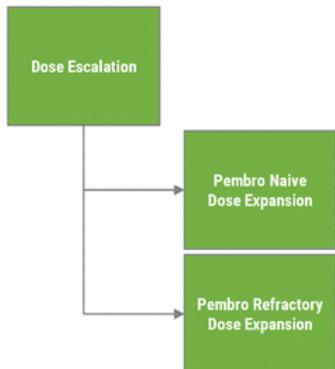
- Inhibition of DKK1 targets innate immunity
 - Reduces Myeloid Derived Suppressor Cells (MDSC)
 - Enhances NK cell activity
 - Increases expression of PD-L1
 - Induces transcription of T cell chemoattractants

➔ **DKN-01 mechanism complementary with checkpoint inhibitors**



DKN-01 + Checkpoint Inhibitor Combination Studies

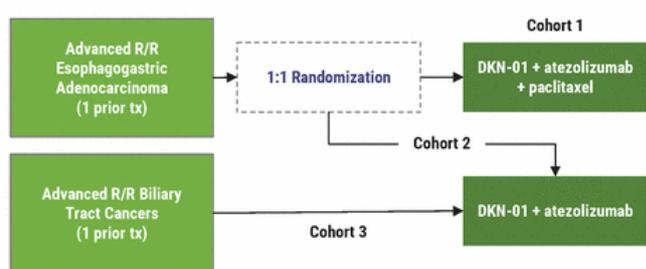
DKN-01 in combination



Study in collaboration with



DKN-01 ± paclitaxel in combination



Study in collaboration with



Clinical Activity in Dose Escalation with Keytruda

- Two partial responses in patients with immune resistant phenotype
- Dose expansion cohorts actively enrolling

DKN-01 Dose	Prior a-PD-1 or a-PD-L1	Medical History	MSI	TMB	PD-L1	Best Overall Response	Status
300	Naive	53 M w/GEJ, s/p FOLFOX/trastuzumab, FOLFIRI	MSS	N/D	neg	Partial Response (-82%)	Cycle 10
	Naive	59 M w/GEJ s/p FOLFOX	MSS	I	neg	Partial Response (-42%)	Cycle 10
	Naive	74 M w/GC s/p ECF and ramucirumab/paclitaxel	MSS	L	neg	Stable Disease (non-measurable at baseline)	Off Study - Cycle 5
	Naive	61 M w/GEJ s/p FOLFOX, ramucirumab/paclitaxel and irinotecan	MSS	N/D	N/D	Stable Disease (+3%)	Off Study - Cycle 3
	Naive	63 M w/ EC s/p FOLFOX and XELOX	MSS	L	pos	Not Evaluable	Off Study - Cycle 1
	Refractory	62 M w/GEJ s/p anti-PD1 (PD), and ramucirumab/paclitaxel	N/D	N/D	N/D	Stable Disease (+10%)	Off Study - Cycle 4
150	Naive	67 M w/EC, s/p FOLFOX, ramucirumab + paclitaxel, irinotecan	N/D	N/D	N/D	Progressive Disease (+26%)	Off Study - Cycle 1
	Refractory	69 F w/GC, s/p FOLFOX, anti-PDL1 for 2 years with PD	MSS	I	neg	Stable Disease (-10%)	Cycle 10



Data as of June 2018

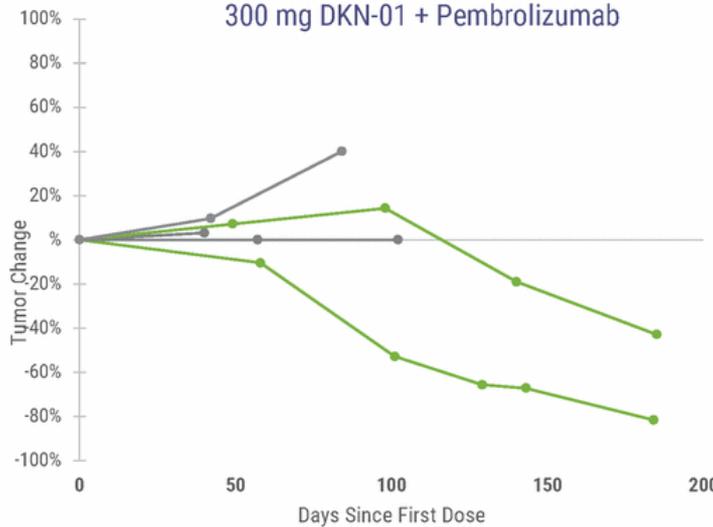
MSI = Microsatellite Instability, MSS = Microsatellite Stable, TMB = Tumor Mutational Burden, I = Intermediate, L = Low, N/D = Not Done/Not Available

13

Copyright © 2018

Durability and Depth of Response

Target Lesion Change Over Time
Dose Escalation Patients
300 mg DKN-01 + Pembrolizumab



Benchmark Studies

	KN-061	KN-059	KN-180
	Pembro	Pac	Pembro
ORR	11.1%	12.5%	10%
SD		17%	21%
PFS	1.5 m	4.1 m	2.0 m
PD-L1+ ORR	15.8%	13.6%	14%
PD-L1- ORR		6.4%	6%
PD-L1+ SD		17.6%	22%
PD-L1- SD		14.7%	12%

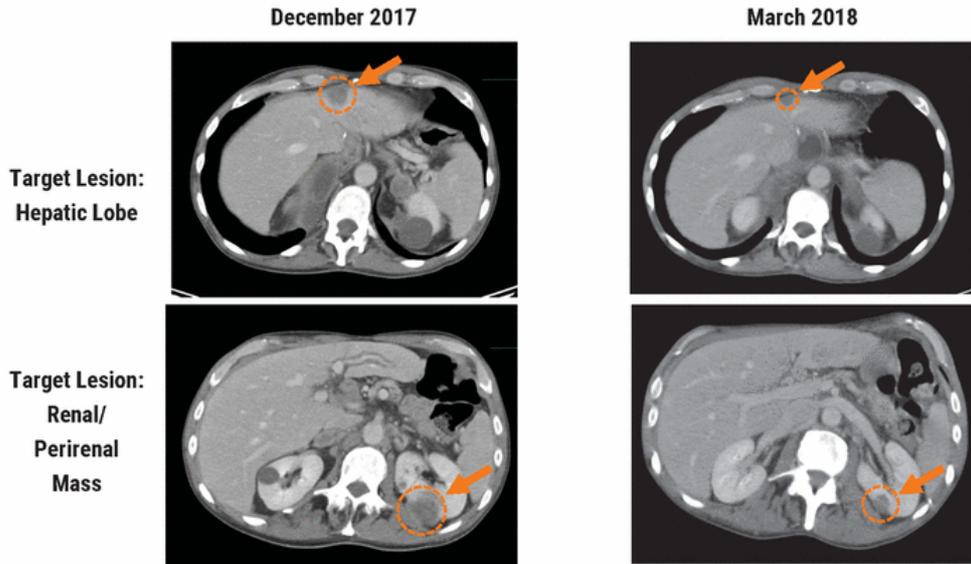


14

Copyright © 2018

Partial Responses in Patients with Immune Resistant Phenotype

- Ongoing confirmed partial response (-82%), patient in Cycle 10



Partial Responses in Patients with Immune Resistant Phenotype

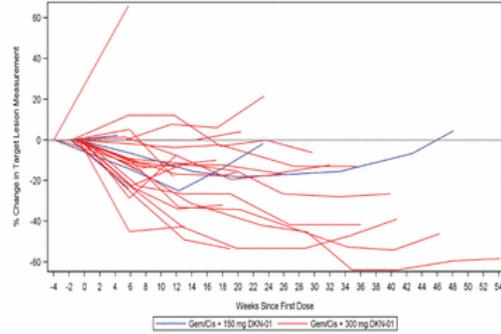
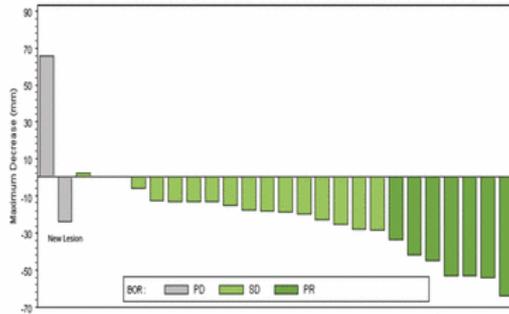
- Ongoing partial response (-42%) with declining CA 19-9; patient in Cycle 10



	1/17/2018 1002	1/29/2018 0729	2/14/2018 0735	2/20/2018 0731	3/5/2018 0813	3/12/2018 0934	3/26/2018 0750	4/2/2018 0810	4/23/2018 0738	5/1/2018 0905	5/7/2018 0809	5/14/2018 0743
TUMOR/MALIGNANCY M...												
CA 199	844.0 *	1071.4 *	959.3 *	970.0 *	721.5 *	678.3 *	615.3 *	605.0 *	617.8 *	631.5 *	549.9 *	548.2 *

DKN-01 in Advanced Biliary Tract Cancer

ORR 31.8%, DCR 95.5%
PFS 9.4 months



DKN-01 + gemcitabine/cisplatin in treatment-naïve advanced BTC

Historical gemcitabine/cisplatin studies:

- Overall response rates: 19.5 to 25.5%
- Disease control rate: 68.3 to 81.4%
- PFS: 5.8 to 8 months

Data presented at ASCO 2017

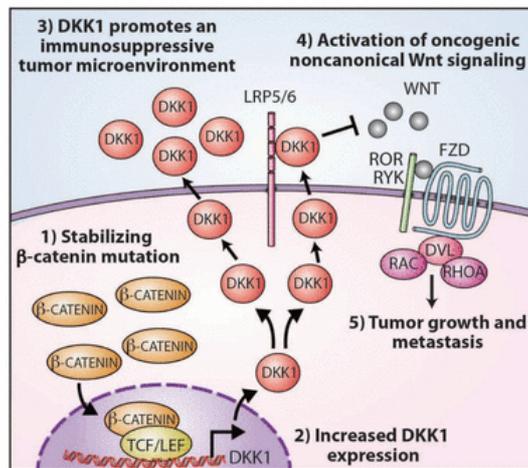


17

Copyright © 2018

Selecting Patients for DKN-01 Treatment

- Beta-catenin turns on production of DKK1
- DKK1 is overexpressed in cancers with beta catenin activating mutations
- Patients with mutations in beta-catenin and/or elevated levels of DKK1 have poor prognosis
- Patients with beta catenin mutations potentially more responsive to DKK1 targeted therapy



18

Copyright © 2018

Key Wnt Biomarker Populations

	Esophagogastric Cancer 	Hepatobiliary Cancer 	Uterine and Ovarian Cancer 
US Incidence	Esophagus: 17,000 Stomach: 28,000	Liver: 40,000 Biliary: 6,000	Endometrial: 61,000 Ovarian: 22,000
β-catenin Mutational Frequency	Gastric 6-9% of patients	Hepatocellular Carcinoma 27-36% of patients	Endometrioid 29-30% of patients
Leap Clinical Plans	Arm in esophagogastric study	Investigator Sponsored Study at University of Mainz	Ongoing study

Study in Gynecologic Cancers with Wnt Biomarkers

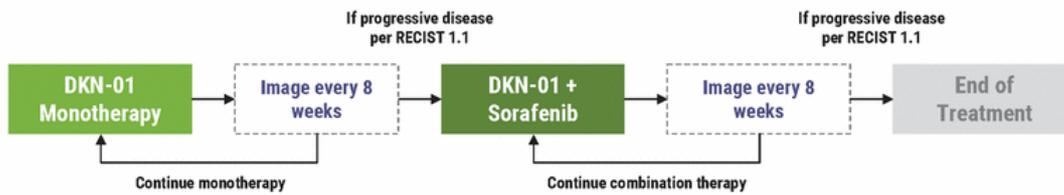
DKN-01 as a monotherapy and in combination with paclitaxel

Study enriched for activating β -catenin mutations and/or Wnt signaling alterations (50% of patients)

	Groups	Planned n
Epithelial Endometrial	Monotherapy	21
	DKN-01 + Paclitaxel	31
Epithelial Ovarian	Monotherapy	21
	DKN-01 + Paclitaxel	21

Hepatocellular Carcinoma Study Design

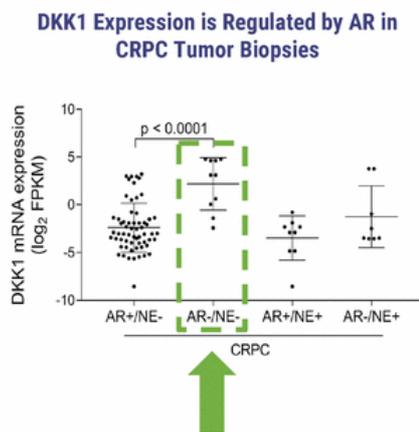
- Study of patients with treatment-naive advanced hepatocellular carcinoma with DKN-01 monotherapy and in combination with sorafenib



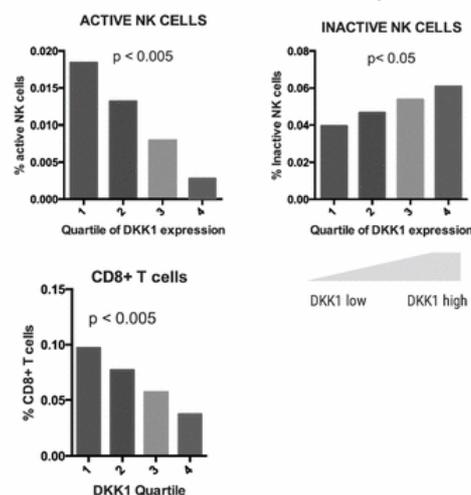
- Investigator sponsored study at 5+ sites, based at the University Medical Center of the Johannes Gutenberg-University Mainz in Germany
- Two-part study evaluating two DKN-01 dose levels (dose escalation and dose expansion phases)
- Target sample size of 70 patients
 - Enriched for patients with Wnt pathway activation

DKK1 in Prostate Cancer

- Strong rationale for combination with AR therapies in non-neuroendocrine subtypes due to increased expression of DKK1 and reduction of inflammatory immune infiltrate

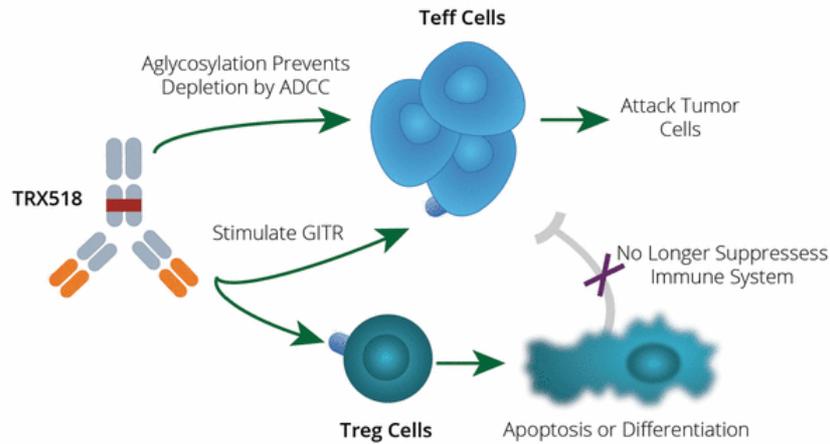


CIBERSORT Analysis Shows DKK1 Expression Associated with Reduced Inflammatory Infiltrate

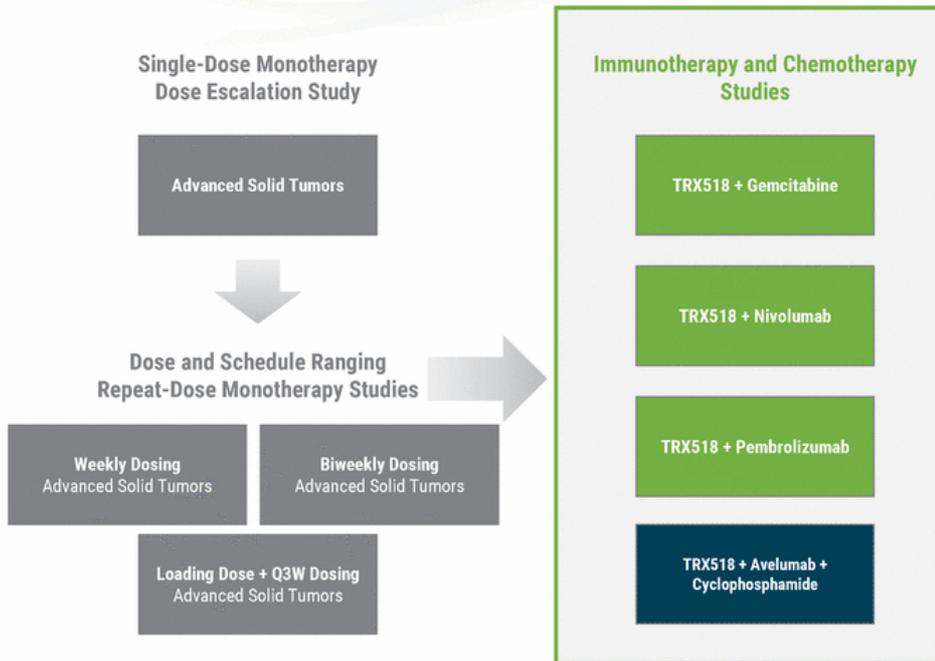


TRX518: Engineered to Maximize GITR Activation of Immune Response to Tumors

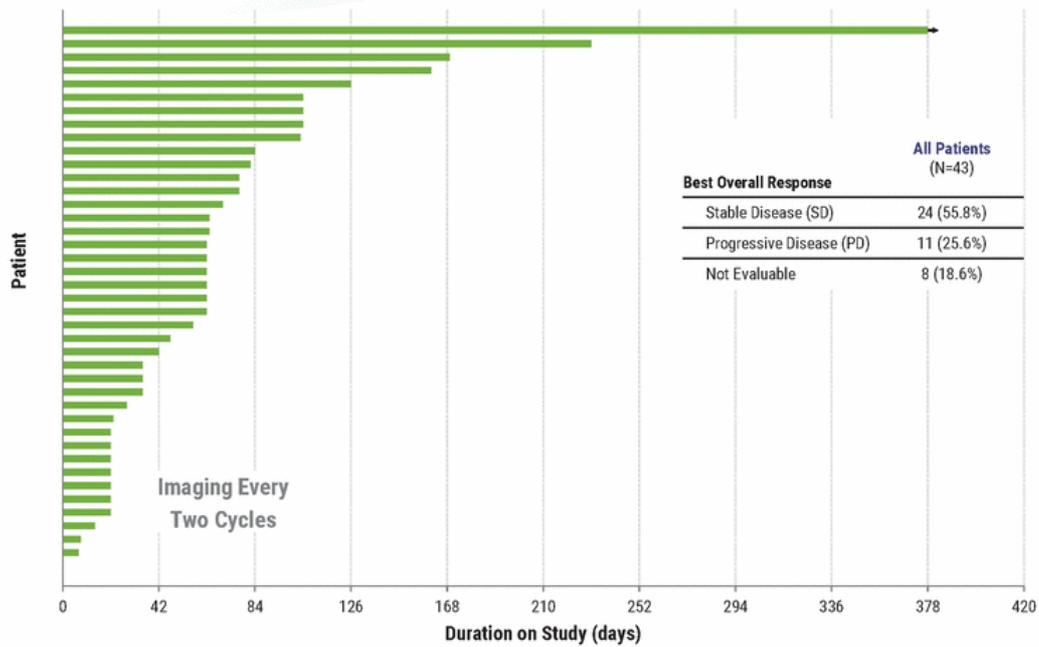
- TRX518 is a differentiated, humanized non-depleting IgG1 GITR agonist mAb
- GITR agonist without FcR binding signals to and does not deplete GITR expressing T cells



Advancing TRX518 Clinical Development



Stable Disease Achieved in Over 50% of Patients on TRX518 Multidose Monotherapy



Data as of June 2018

25

Copyright © 2018

TRX518 Monotherapy Patient with Long-Term Stable Disease

- Hepatocellular carcinoma patient
- Currently in Cycle 21 with 15% reduction in liver lesion
- Failed prior CTLA4/PD-L1 therapy
- Paired tumor biopsy analysis
 - Reduction in Treg cells
 - Increase in CD8/Treg ratio



Data as of July 2018

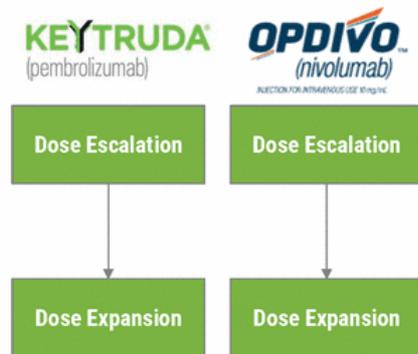
26

Copyright © 2018

TRX518 Combination Study

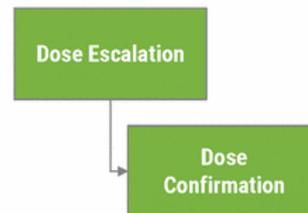
Combination with PD-1 or PD-L1 Immunotherapy

Advanced solid tumors with labeled indications either as new combination therapy or add on to best response of SD after 4 cycles



Combination with Gemcitabine

Advanced solid tumors where gemcitabine indicated



TRX518 Combination Study Clinical Update

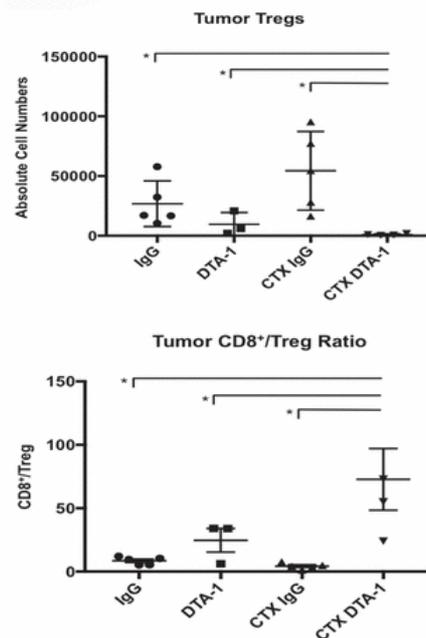
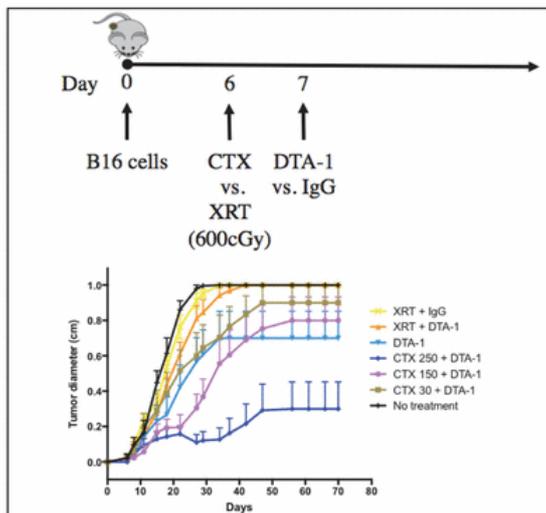
- **Keytruda Combination: enrolling in higher dose escalation group**
 - First 2 patients treated at higher dose demonstrated clinical benefit at first scan
 - Partial Response (-36%) in patient with esophageal squamous cell carcinoma
 - PD-L1 positive, MSS, TMB intermediate
 - Stable disease (-23%) in patient with ocular melanoma
 - No clinical benefit in the lowest dose group
- **Opdivo Combination: enrolling in lowest dose escalation group**
 - Enrolled 7 patients: 4 PD, 1 NE, 2 pending imaging
- **Gemcitabine Combination: enrolling in dose expansion group**
 - Dose escalation enrolled 10 patients: 3 SD, 3 PD, 1 NE, 3 pending imaging
 - No dose limiting toxicity

Treatment with agonist anti-GITR antibody after cyclophosphamide (CTX) enhances tumor immunity and efficacy

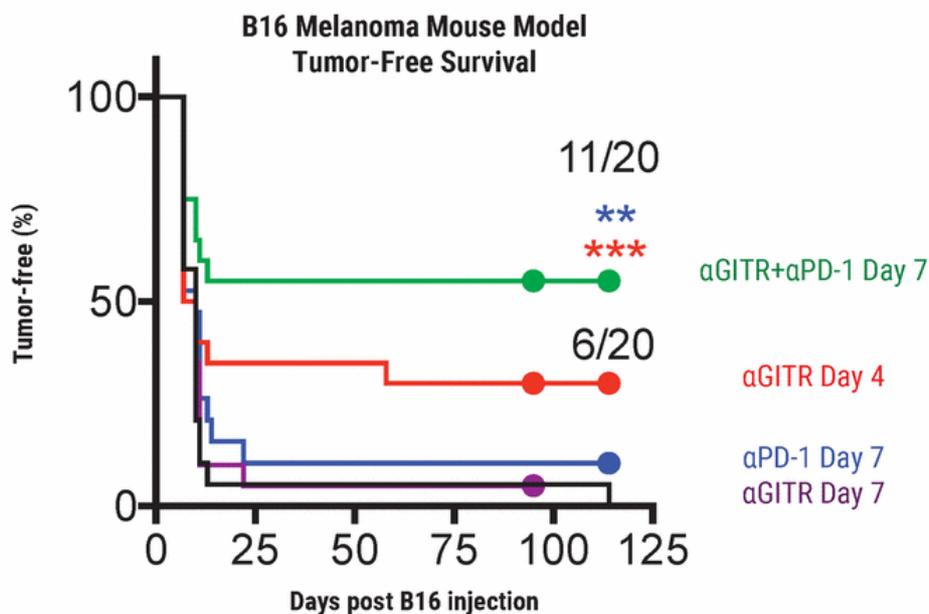
Major Findings

- CTX enhances GITR expression in proliferating immune cells
- CTX + DTA-1 decreases tumor Tregs, increases Teff/Treg ratio
- CTX + DTA-1 increases activation and memory of tumor CD8⁺ cells
- CTX synergizes with DTA-1 to treat established tumors in B16 melanoma model

CTX has Synergistic Activity with GITR agonist and modulates T cell ratios



GITR Agonist Synergizes with anti-PD-1 Therapy



Data from Zappasodi, Wolchok, Merghoub (MSKCC)

31

Copyright © 2018

Mechanistic Rationale for Triple Therapy

PD1/PD-L1 therapy blocks CD8 exhaustion complementing GITR Therapy

GITR, as a costimulatory receptor, works best when antigen primed quiescent T cells are re-stimulated with appropriately processed antigen on APC bearing GITRL

CTX promotes immunogenic cell death of tumors, enabling efficient tumor antigen presentation, complementing GITR therapy

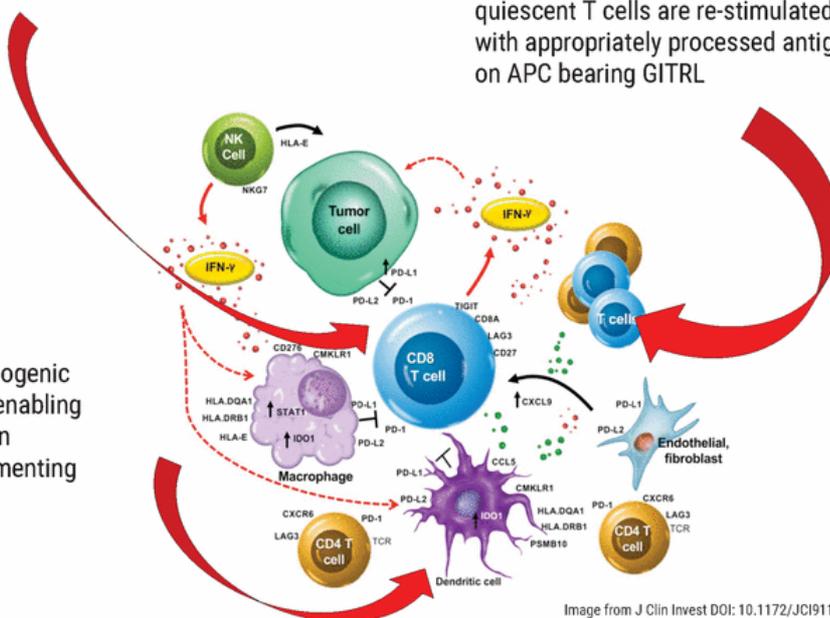


Image from J Clin Invest DOI: 10.1172/JCI91190

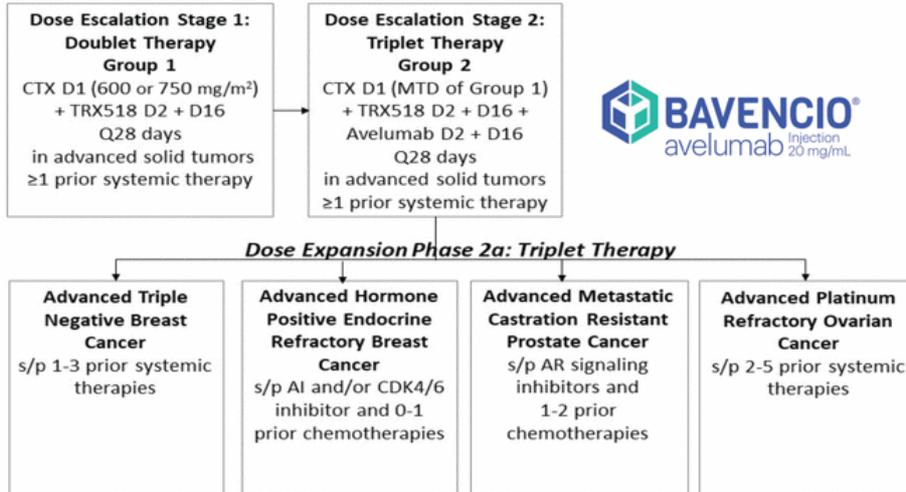
32



Copyright © 2018

TRX518 Chemoimmunotherapy Combination Study

Dose Escalation Phase 1b: Double and Triplet Therapy Stages



AI = aromatase inhibitor; AR = androgen receptor; CTX = cyclophosphamide; CDK4/6 = cyclin-dependent kinase 4/6; D = day, MTD = maximum tolerated dose; s/p = status post

Study in collaboration with



Leadership

Management Team	
Chris Mirabelli, PhD CEO	
Gus Lawlor COO	
Doug Onsi CFO	
Walter Newman, PhD Research	
Mark O'Mahony CMC & Quality	
Cyndi Sirard, MD Clinical	
Board of Directors	Scientific Advisory Board
<ul style="list-style-type: none"> Christopher Mirabelli, Chairman of the Board, CEO of Leap James Cavanaugh, Managing Director at HealthCare Ventures John Littlechild, Managing Director at HealthCare Ventures Thomas Dietz, Chairman and CEO of Waypoint Holdings Joseph Loscalzo, Chairman, Department of Medicine, Physician-in-Chief, Brigham and Women's Hospitals Nissim Mashiach, President and CEO of MacroCure Ltd. William Li, CEO of the Angiogenesis Foundation 	<ul style="list-style-type: none"> Xi He, PhD, Endowed Research Chair, Professor of Neurology, American Cancer Society Research Professor, Boston Children's Hospital and Harvard Medical School Carl F. Nathan, Professor and Chairman of Department of Microbiology and Immunology at Weill Cornell Medical College David Tuveson, Director of Research, the Lustgarten Foundation, Roy J. Zuckerman Professor of Cancer Research at CSHL Christopher T. Walsh, professor emeritus at Harvard Medical School Eric P. Winer, SVP and Chief Clinical Strategy Officer; Chief, Division of Women's Cancers, DFCI; Director, Breast Oncology Program, Susan F. Smith Center for Women's Cancers; Thompson Chair in Breast Cancer Research Institute Physician; Professor of Medicine, Harvard Medical School

Historical Financials (in thousands)

	Three Months Ended		March 31,
	March 31		2018
	2018	2017	(Unaudited)
(Unaudited)			
Operating expenses:			
Research and development	\$ 4,231	\$ 6,404	
General and administrative	2,113	3,804	
Total operating expenses	6,344	10,208	
Loss from operations	(6,344)	(10,208)	
Interest income	77	50	
Interest expense	(6)	-	
Interest expense - related party	-	(121)	
Australian research and development incentives	646	397	
Foreign currency gains (loss)	(144)	468	
Loss on change in fair value of warrant liability	(4,851)	-	
Net loss	(10,622)	(9,414)	
Accretion of preferred stock to redemption value	-	(244)	
Net loss attributable to common stockholders	\$ (10,622)	\$ (9,658)	
Net loss per share - basic and diluted	\$ (0.85)	\$ (1.39)	
Weighted average common shares outstanding basic & diluted	12,449,421	6,945,623	
Assets			
Current assets:			
Cash and cash equivalents			\$ 35,376
Research and development incentive receivable			998
Prepaid expenses and other current assets			289
Total current assets			36,663
Property and equipment, net			123
Research and development incentive receivable, net of current portion			632
Deferred tax asset			157
Other assets			1,111
Total assets			\$ 38,686
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable			\$ 4,130
Accrued expenses			1,715
Total current liabilities			5,845
Non Current liabilities:			
Warrant liability			16,713
Total liabilities			22,558
Commitments and contingencies			
Stockholders' equity:			
Common stock, \$0.001 par value; 100,000,000 shares authorized; 14,500,681 and 12,354,014 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively			
			15
Additional paid-in capital			157,290
Accumulated other comprehensive loss			(158)
Accumulated deficit			(141,019)
Total stockholders' equity			16,128
Total liabilities and stockholders' equity			\$ 38,686

Cash Balance at June 30, 2018: \$30.5 million



35

Copyright © 2018

Clinical Program Milestones

DKN-01	Immunotherapy	Esophagogastric Cancer (combination with KEYTRUDA®)	Data presented AACR 2018, Expansion 2H-18
		Esophagogastric & Biliary Cancer (TECENTRIQ® ± paclitaxel)	Investigator Sponsored Study
	Biomarker Populations	Gynecologic Cancer (mono + paclitaxel)	Interim data 2H-18
		Gastric Cancer (monotherapy + paclitaxel)	Interim data 2H-18
		Hepatocellular Carcinoma (mono + sorafenib)	Investigator Sponsored Study
	Proof of Concept	Biliary Tract Cancer (gemcitabine + cisplatin)	Efficacy data (n=51) 2H-18
Esophagogastric Cancer (mono + paclitaxel)		Data presented March 2018	
TRX518	Combination Therapy	Combination with KEYTRUDA® or OPDIVO®	Data throughout 2018-2019
		Combination with Gemcitabine	Data throughout 2018-2019
		Combination with BAVENCIO® + cyclophosphamide	First patient enrolled 1Q-19
	Proof of Concept	Solid Tumor Malignancies (mono)	Data throughout 2018



36

Copyright © 2018