



# IMMUNOMEDICS, INC.

## *Advanced Antibody-Based Therapeutics*



Oncology



Autoimmune Diseases

November 2017

# Forward-Looking Statements

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*This presentation, in addition to historical information, contains certain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements may involve significant risks and uncertainties, and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, new product development (including clinical trials outcome and regulatory requirements/actions); competitive risks to marketed products; forecasts of future operating results; availability of required financing and other sources of funds on acceptable terms, if at all; as well as those discussed in the Company's filings with the Securities and Exchange Commission.*



# Evolving the Strategy to Drive Shareholder Value

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*Old Strategy*



- “ Conducted a thorough, multi-faceted review by new Board of Directors
- “ Focused on organizational, operational, clinical and regulatory capabilities
- “ Led by independent experts with best-in-class experience



**Resulted in new set of mandates and strategic objectives for Immunomedics**



# New Vision For Value Creation

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**Become a fully-integrated biopharmaceutical company pursuing multiple ways to maximize value for all stakeholders**

- “ **Bring IMMU-132 to Market On Our Own**
  - . Initially focused on metastatic triple-negative breast cancer (mTNBC) in the 3<sup>rd</sup> line setting
- “ **Develop plans to expand IMMU-132 commercially beyond mTNBC**
- “ **Evaluate strategic opportunities with regional partners for IMMU-132**
- “ **Explore potential partnerships for other product candidates in clinical pipeline**



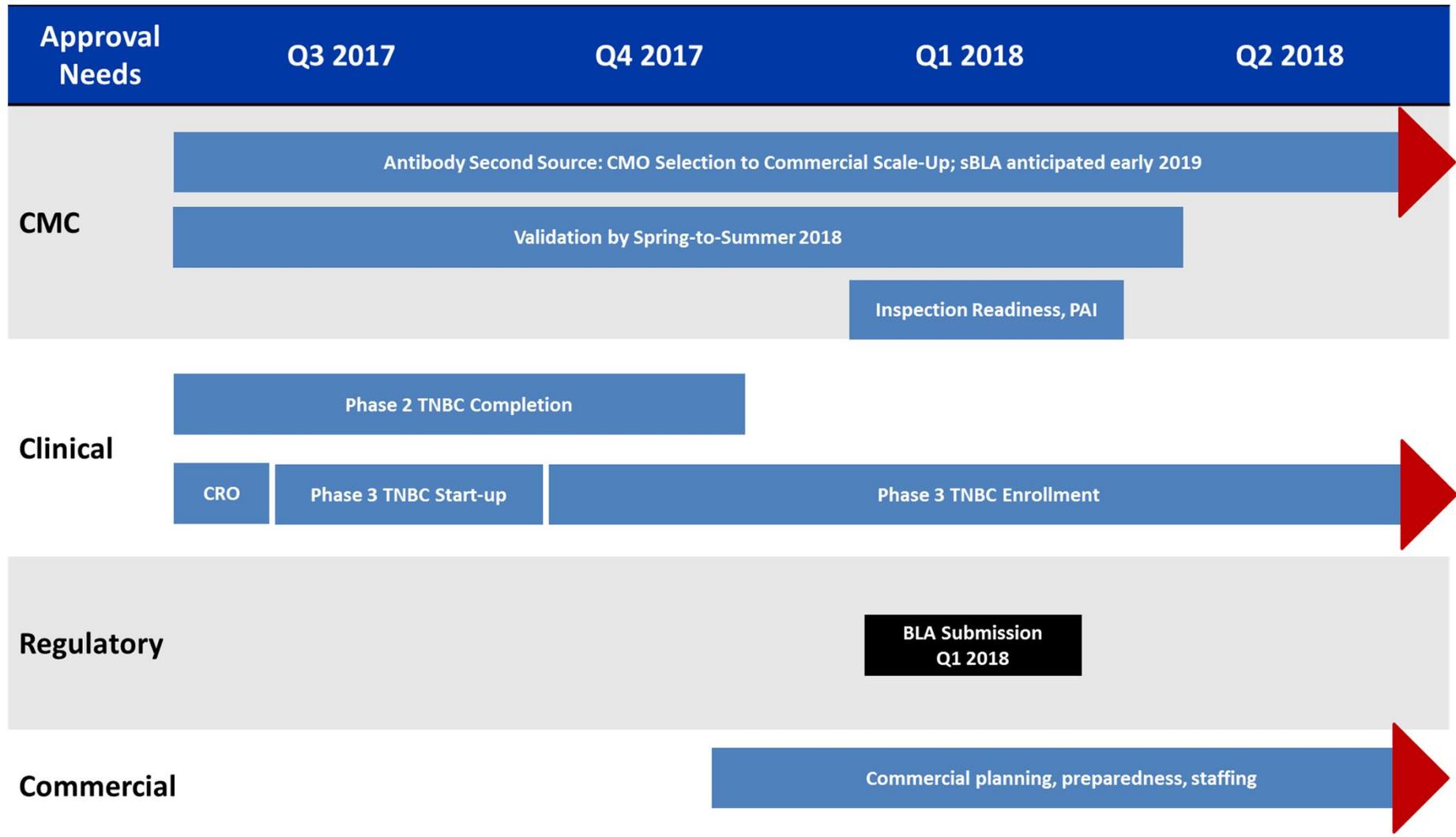
# Key Business Objectives for 2017/2018

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- “ **Submit BLA for Accelerated Approval in mTNBC**
  - As planned in the first quarter of 2018
  
- “ **Continue confirmatory Phase 3 study in mTNBC**
  - First patient dosed in November 2017 in the U.S.
  
- “ **Continue CMC preparations for commercial launch**
  - Pre-approval inspection activities continue
  - Commercial drug manufacturing continues
  
- “ **Continue Phase 2 basket trial**
  - Metastatic urothelial, metastatic castrate-resistant prostate, metastatic breast, and other cancers
  
- “ **Build out Company leadership team**
  - Identify and hire best-in-class CEO and executive leaders
  - Orient towards becoming a commercial entity



# Proposed Timeline for AA in mTNBC



# Anticipated Upcoming Events

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<b>Program</b>	<b>Event</b>	<b>Expected Timing</b>
<b>IMMU-132</b>	<b>Present updated Phase 2 data in mTNBC at SABCS</b>	<b>December 2017</b>
<b>IMMU-132</b>	<b>Submit BLA to FDA for accelerated approval in mTNBC</b>	<b>Q1 2018</b>



# IMMU-132 (Sacituzumab Govitecan): Overview

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## “ Breakthrough Therapy designation granted in mTNBC

- Fast Track designation in TNBC, small-cell and non-small-cell lung cancers
- Orphan Drug designation in small-cell lung and pancreatic cancers

## “ Targets Trop-2

- Highly expressed on many solid cancer cells
- Internalizes rapidly into target cancer cells when bound
- Ideal target for enhanced drug delivery with ADCs

## “ Strong results in Phase 2 study for mTNBC

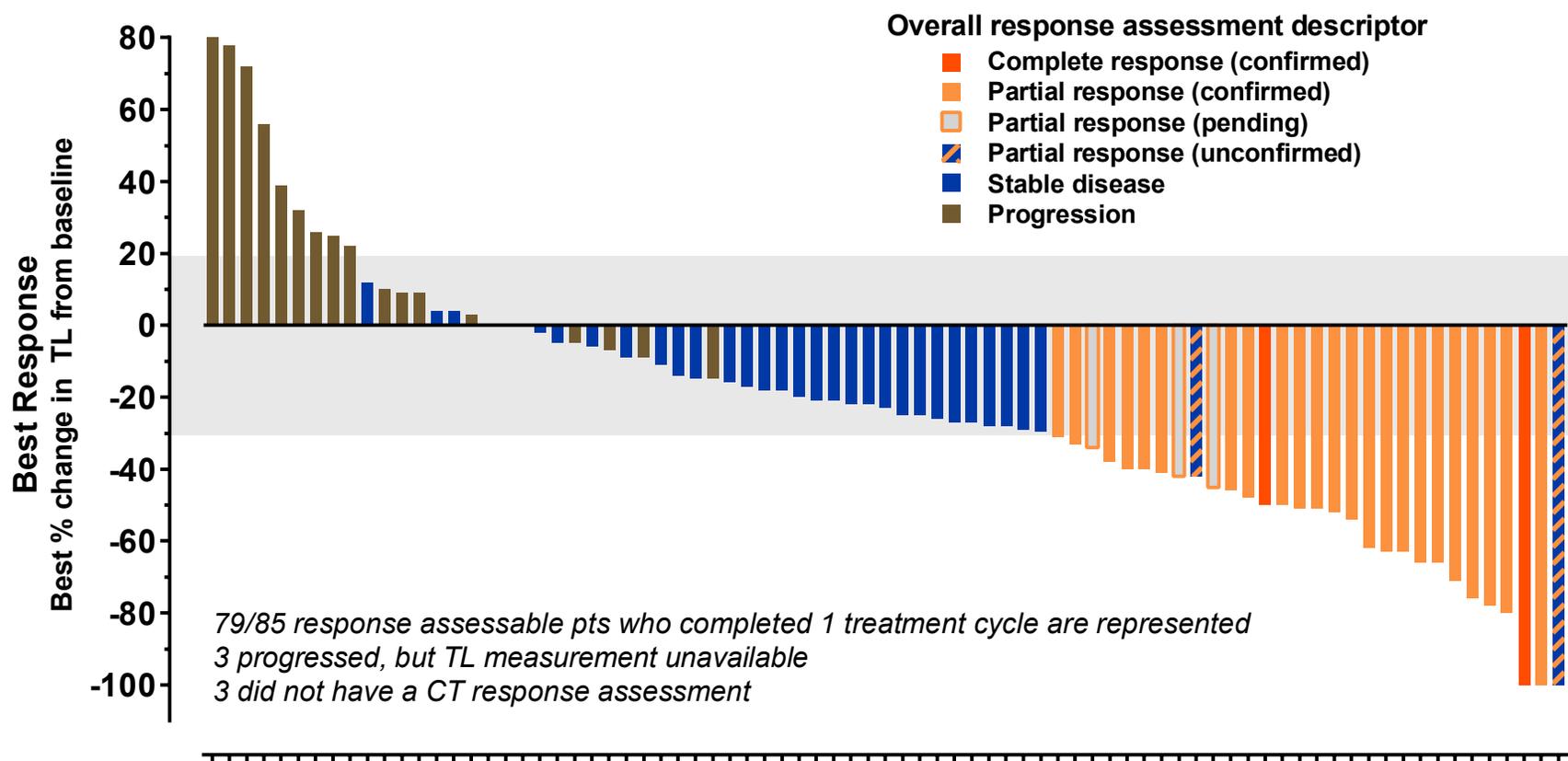
- 29% ORR in 85 patients treated
- Promising durable responses
  - “ Achieved median PFS / OS of 6.0 / 18.8 months, respectively
- Acceptable safety profile in heavily pretreated patients



# IMMU-132: Best Response from mTNBC Patients (N=85)

Confirmed ORR (RECIST 1.1) = 29%

Median # prior therapies = 5 (range, 2 – 12)



# Triple-Negative Breast Cancer Facts

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- “ **~15% of all breast cancer diagnosed**
- “ **No optimal standard therapy in the adjuvant or metastatic setting**
- “ **Metastatic TNBC**
  - . Median survival ~12 months
  - . Short PFS - ~1.7 to 3.7 months
- “ **Large unmet need in the breast cancer community**



# Phase 3 Confirmatory Trial Design in mTNBC

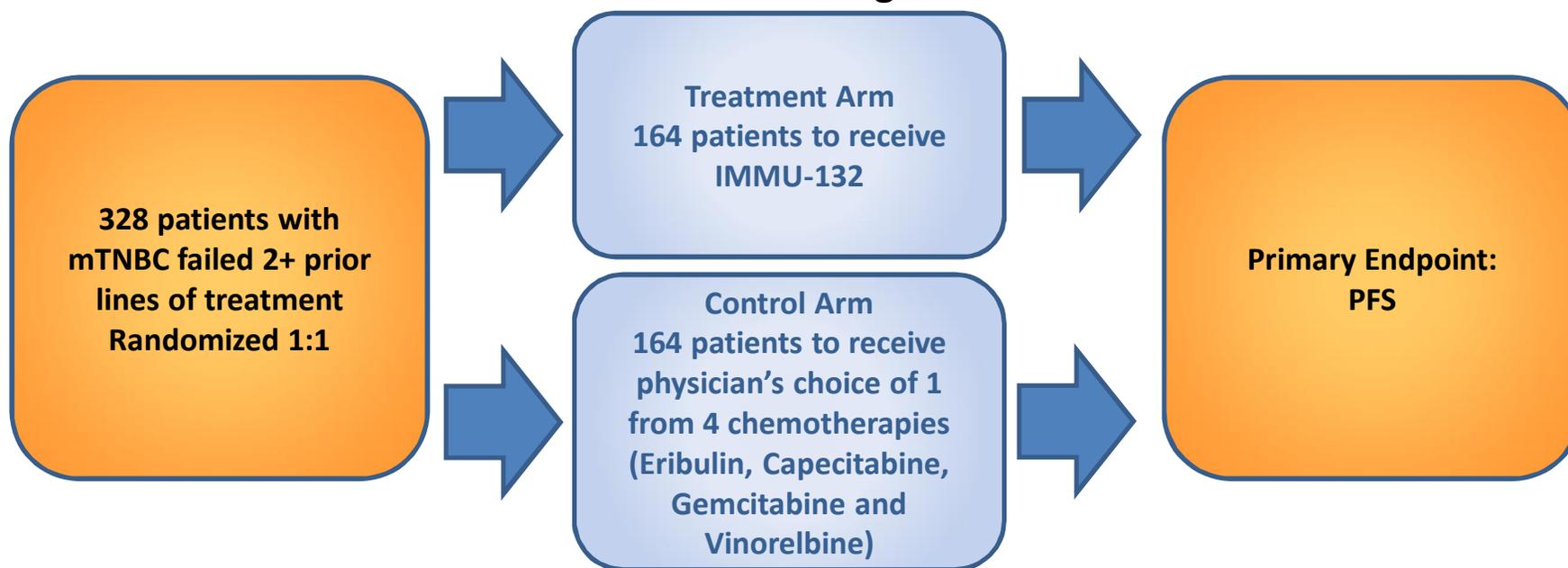
## Designed to Replicate Success

- Primary endpoint is PFS
- Two arms: IMMU-132 vs physician's choice of 1 from 4 chemotherapies
- 328 patients to be enrolled, 1:1 randomization

## Attention to Execution

- Trial will be conducted under a SPA and is expected to take ~3 years
- Key powering considerations:
  - 99% powering for PFS

## Phase 3 Design



# What Makes IMMU's ADCs Different?

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- “ **Unique approach to ADC therapeutics for cancer**
  - Highly cancer-specific antibodies based on 30 years of experience
  - Utilize antibodies with dual activity
  - Moderately potent payloads → increased therapeutic index
- “ **Proprietary linker designed for SN-38**
  - High drug-to-antibody ratio (~7.6:1)
  - Rapid payload release at or inside tumor
- “ **SN-38 payload**
  - Active metabolite more potent than parent compound, irinotecan (a commonly used chemotherapeutic)
  - ADCs' unique chemistry avoids low solubility and selectively delivers SN-38 to the tumor



# First-in-Class ADC Technology Platform

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- “ **Common properties of IMMU’s ADCs**
  - . Greater dose of drug delivered to tumor
  - . Reduced toxicity
  - . Opportunity for long-term, repeated treatments
  - . Improved therapeutic window
  
- “ **Two ADCs completed Phase 2 for solid cancers**
  - . IMMU-132 targeting Trop-2
  - . IMMU-130 targeting CEACAM5
  
- “ **One ADC in preclinical development for solid/liquid cancers**
  - . IMMU-140 targeting HLA-DR



# IMMU-132: Intellectual Property Protection

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- “ **37 issued U.S. and 22 foreign patents**
  - . Covering composition of matter, synthesis and uses
- “ **IP coverage through 2036 (plus potential term extension up to 5 years) protecting**
  - . Methods of treating cancer over broad range of dosages
  - . Methods of production, and certain combination therapies
  - . Composition of matter patents expire in 2023 in the U.S., and in 2029 in Europe
- “ **Patent applications prosecuted in all major countries**
  - . Patents issued in Australia, Canada, China, Europe, Israel, Japan, Mexico and South Korea



# Sufficient Cash Runway to Reach AA in mTNBC

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<b>Cash balance</b>	<b>\$140 million</b>
<b>Debt (convertible senior notes)</b>	<b>\$20 million</b>
<b>Basic shares outstanding</b>	<b>152 million</b>
<b>Market capitalization</b>	<b>\$2.13 billion</b>



# IMMU-132: Additional Efficacy Data

Patients with at least one post-treatment response evaluation

Cancer Type <sup>1</sup>	Number of Patients	Confirmed % ORR <sup>2</sup>	DOR	PFS <sup>3</sup>	OS <sup>3</sup>
			Medians (months / 95% CI)		
TNBC	85	29%	10.8 (6.8 – 12.7)	6.0 (5.0 – 7.1)	18.8 (11.5 – 20.6)
UC	41	34%	12.6 (7.5 – 12.9)	7.1 (5.0 – 10.7)	16.1 (10.5 – 17.2)
SCLC	50	14%	5.7 (3.6 – 19.9)	3.7 (2.1 – 4.3)	7.5 (6.2 – 8.8)
NSCLC	47	19%	6.0 (4.8 – 8.3)	5.2 (3.2 – 7.1)	9.5 (5.9 – 16.7)

<sup>1</sup> TNBC = triple-negative breast, UC = urothelial, SCLC = small-cell lung, NSCLC = non-small-cell lung cancer

<sup>2</sup> Objective response rate (%ORR) = (complete response + partial response)/number of patients

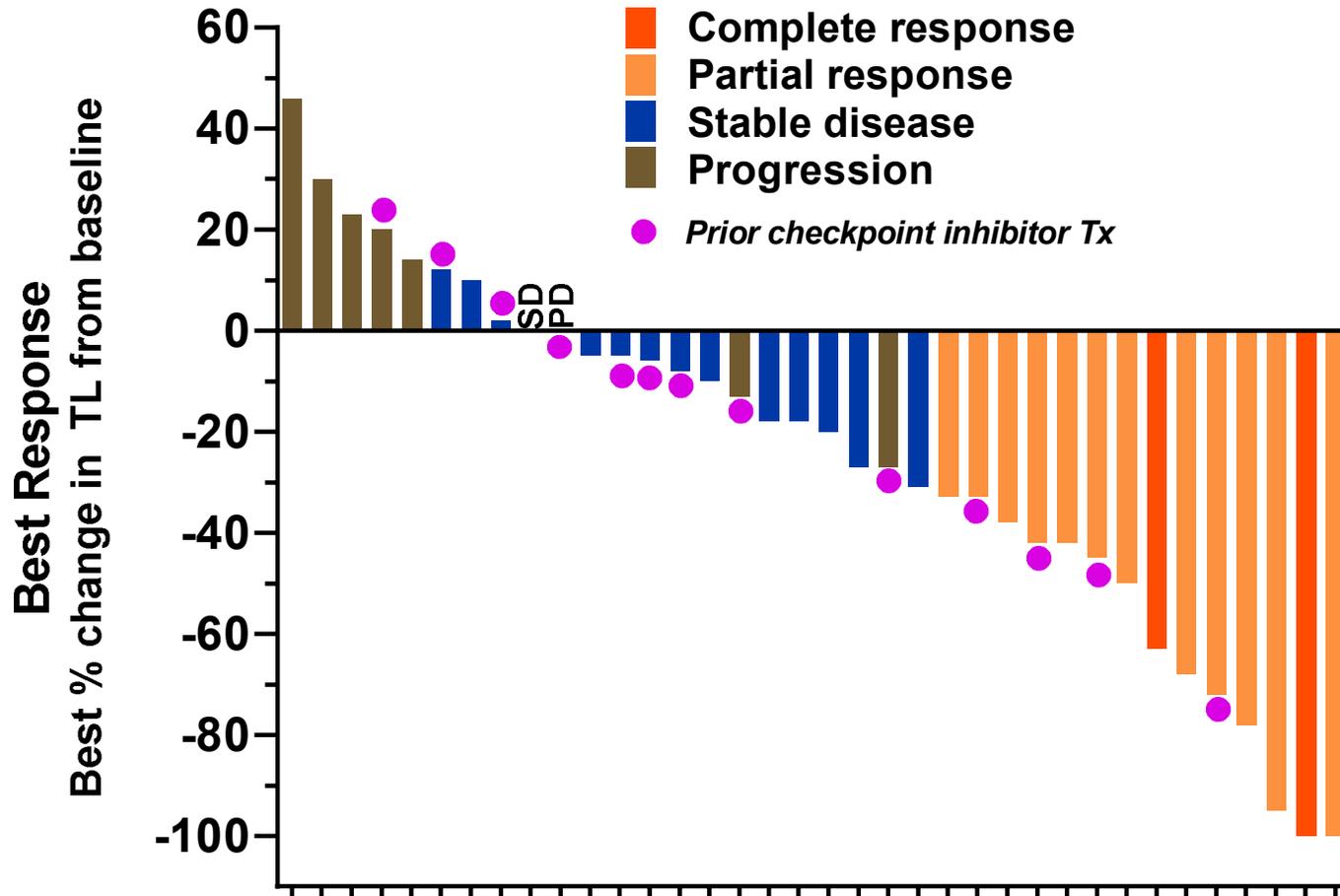
<sup>3</sup> Based on number of intention-to-treat patients of 89, 41, 50 and 54 for TNBC, UC, SCLC and NSCLC, respectively



# IMMU-132: Best Response from mUC Patients (N=41)

Confirmed ORR (RECIST 1.1) = 34%

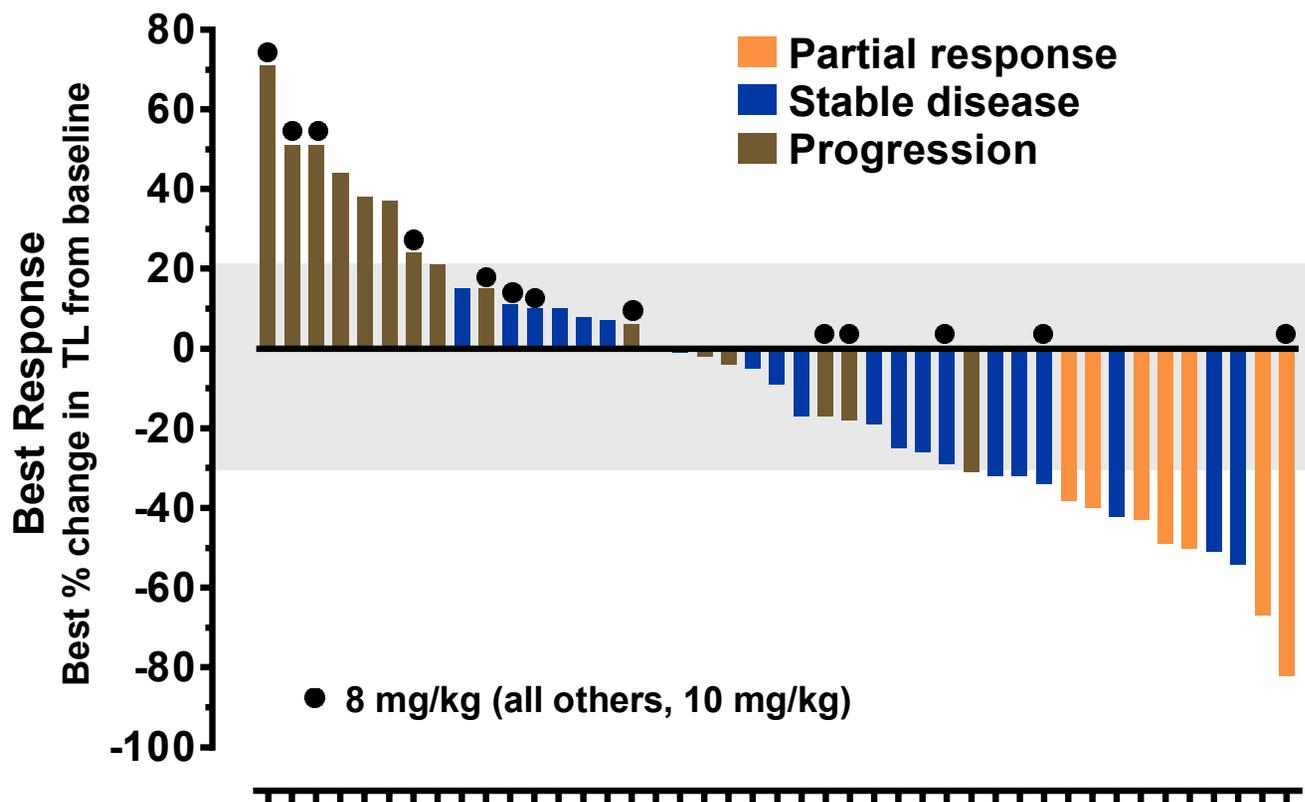
Median # prior therapies = 3 (range, 1 – 6)



# IMMU-132: Best Response from mSCLC Patients (N=50)

Confirmed ORR (RECIST 1.1) = 14%

Median # prior therapies = 2 (range, 1 – 7)



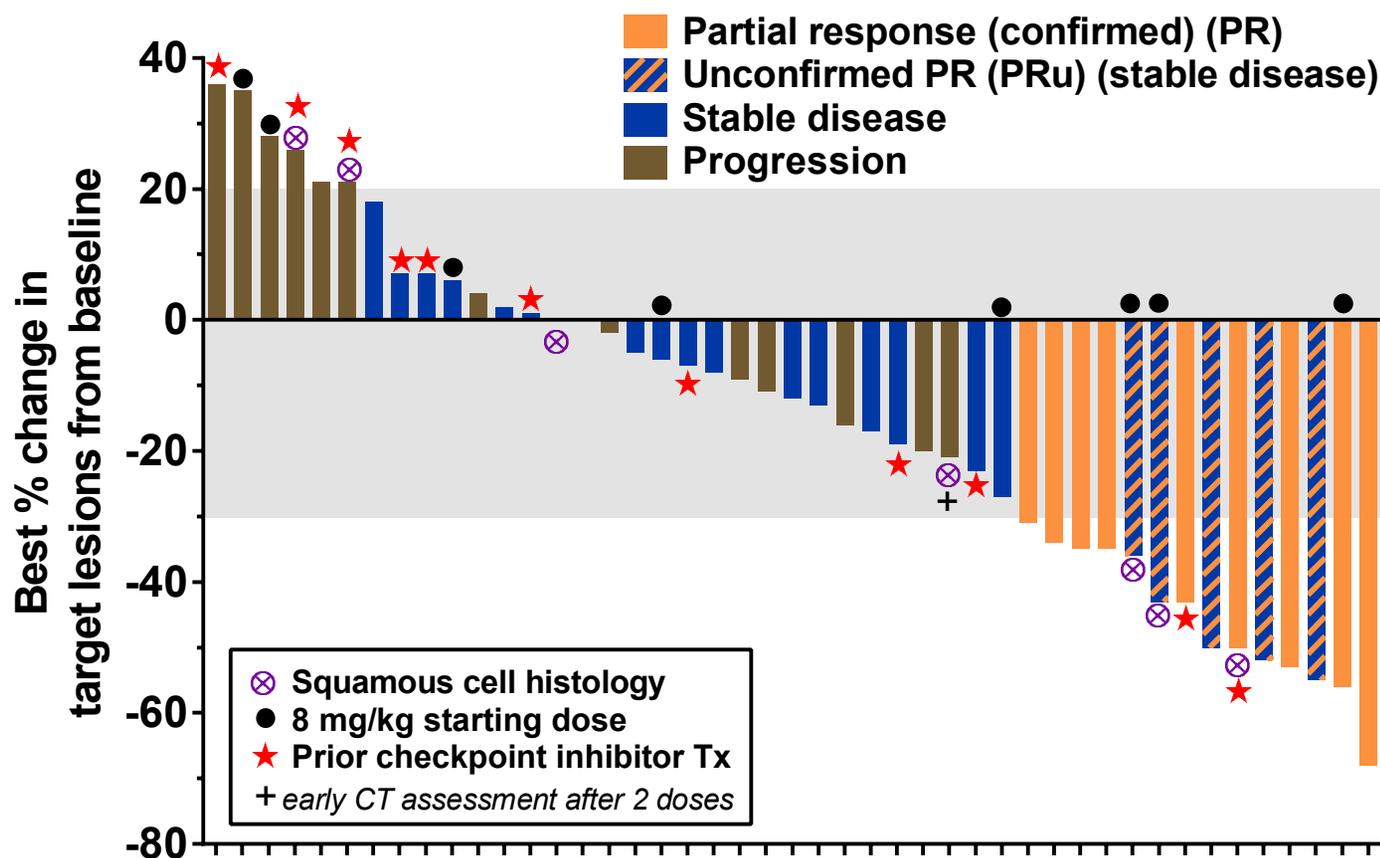
43/50 response assessable pts who completed 1 treatment cycle are represented  
7 pts did not complete 1 treatment cycle and did not have a CT-response assessment



# IMMU-132: Best Response from mNSCLC Patients (N=47)

Confirmed ORR (RECIST 1.1) = 19%

Median # prior therapies = 3 (range, 2 – 7)



# IMMU-132: Mild, Predictable and Manageable Toxicity

Starting Dose of 10 mg/kg (N=361 Patients)		
Interim Adverse Events (ranked by Grades 3+)	Grade 3+	All Grades
<b>Neutropenia</b>	<b>25%</b>	<b>37%</b>
Anemia	8%	28%
<b>Diarrhea</b>	<b>7%</b>	<b>41%</b>
Fatigue	7%	32%
<b>Febrile neutropenia</b>	<b>5%</b>	<b>5%</b>
Nausea	4%	46%
Vomiting	3%	28%
Alopecia	N/A	25%

“ Camptosar (irinotecan) US Prescribing Information (USPI) “boxed warnings”

- Early and late forms of diarrhea can occur (Grades 3 & 4: 38%)
- Severe myelosuppression may occur (Neutropenia: Grades 3 & 4: 31%)



# Broad Pipeline of Antibody-Based Therapies



## First-in-Class Antibody-Drug Conjugate (ADC) Programs

### IMMU-132/sacituzumab govitecan (anti-Trop-2-SN-38 ADC)

Metastatic triple-negative breast cancer

*FDA granted BTB*

Metastatic solid cancers (urothelial/lung/endometrial/prostate)

### IMMU-130/labetuzumab govitecan (anti-CEACAM5-SN-38 ADC)

Metastatic colorectal cancer

### IMMU-140 (anti-HLA-DR-SN-38 ADC)

Solid and liquid cancers

## Other Product Candidates

Epratuzumab (anti-CD22) for pediatric acute lymphoblastic leukemia\*

Veltuzumab (anti-CD20) for cancer and autoimmune diseases

Milatuzumab (anti-CD74) for autoimmune diseases

IMMU-114 (anti-HLA-DR) for hematologic malignancies

(E1)-3s (T-cell-redirecting bispecific antibody)



# IMMU-130: Active in Metastatic Colorectal Cancer

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- “ **Mechanism of action**
  - . Binds to CEACAM5 on colorectal and other tumor cells
  - . SN-38 is released locally from IMMU-130 for diffusion into tumor cells
  
- “ **Promising activity in metastatic CRC previously treated with irinotecan therapy**
  
- “ **Acceptable safety profile in heavily pretreated patients (n=86, all doses, Grade 3 and 4)**
  - . Neutropenia (16%)
  - . Diarrhea (7%)
  - . Leukopenia (11%)
  
- “ **Repeated doses given over months without interfering host antibodies**



# IMMU-130: Efficacy in Metastatic Colorectal Cancer

	Once-Weekly Dosing	
	8 mg/kg	10 mg/kg
Number of Patients	21	22
Median Progression-Free Survival (PFS) (months)	4.6 (3.9 – 6.1)	3.6 (2.1 – 6.0)
Median Overall Survival (OS) (months)	7.5 (5.7 – 16.1)	6.4 (5.0 – 11.2)

**Median PFS of 4.0 months and median OS of 6.7 months in 23 patients with prior treatment with regorafenib**

