

# Fourth-Quarter 2016 Results

## February 28, 2017

# Safe Harbor Statement

To the extent that statements contained in this presentation are not descriptions of historical facts regarding TESARO, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements regarding the expected timing of the launches of niraparib and VARUBI IV in the U.S., the expected timing of our planned commercial launches of niraparib and oral rolapitant in Europe, the expected launch of our EAP in Europe, the expected timing of finalizing our registration program for niraparib in lung cancer, the expected timing of initiation of our TSR-042 registration program, the expected approval of the rolapitant IV NDA, the expected timing of data from our TOPACIO, AVANOVA and other ongoing clinical trials, our expected cash utilization during the first half of 2017, and our expectation to achieve our various key 2017 corporate objectives. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and pre-clinical development programs, clinical development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding our ongoing discussions with and potential actions by regulatory authorities, uncertainties regarding regulatory approvals, including with respect to the ultimate approval and indication for niraparib, uncertainties regarding certain expenditures, risks related to manufacturing and supply, and other matters that could affect the availability or commercial potential of our drug candidates. TESARO undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see TESARO's Annual Report on Form 10-K for the year ended December 31, 2015, and Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.



**Lonnie Moulder**  
Chief Executive Officer

# Fourth-Quarter 2016 Update

## Recent Business Highlights

### Commercial

- ▶ U.S. launch of VARUBI continues with sequential unit volume growth for 4Q 2016
- ▶ Pre-launch preparations ongoing in support of niraparib commercialization in the U.S. and Europe

### Regulatory

- ▶ Niraparib NDA accepted for priority review by FDA
- ▶ Niraparib MAA under review by EMA
- ▶ Positive opinion for VARUBY® MAA rendered by EMA's CHMP
- ▶ VARUBI® IV NDA on track for resubmission to enable 1H 2017 approval

### Pipeline

- ▶ Phase 2 TOPACIO and Phase 2 AVANOVA combination trials continue to enroll
- ▶ BRAVO, PRIMA, and QUADRA trials ongoing
- ▶ Dose and schedule identified for TSR-042
- ▶ Phase 1 dose escalation study of TSR-022 enrolling
- ▶ Lead candidate for PD-1/LAG-3 identified

### Corporate

- ▶ International commercial HQ established and European operations span 17 countries
- ▶ Niraparib EAP initiated in U.S.
- ▶ Planning underway to launch niraparib EAP in Europe shortly
- ▶ Follow-on offering completed, resulting in \$224M in net proceeds

# Strategy to Drive Growth



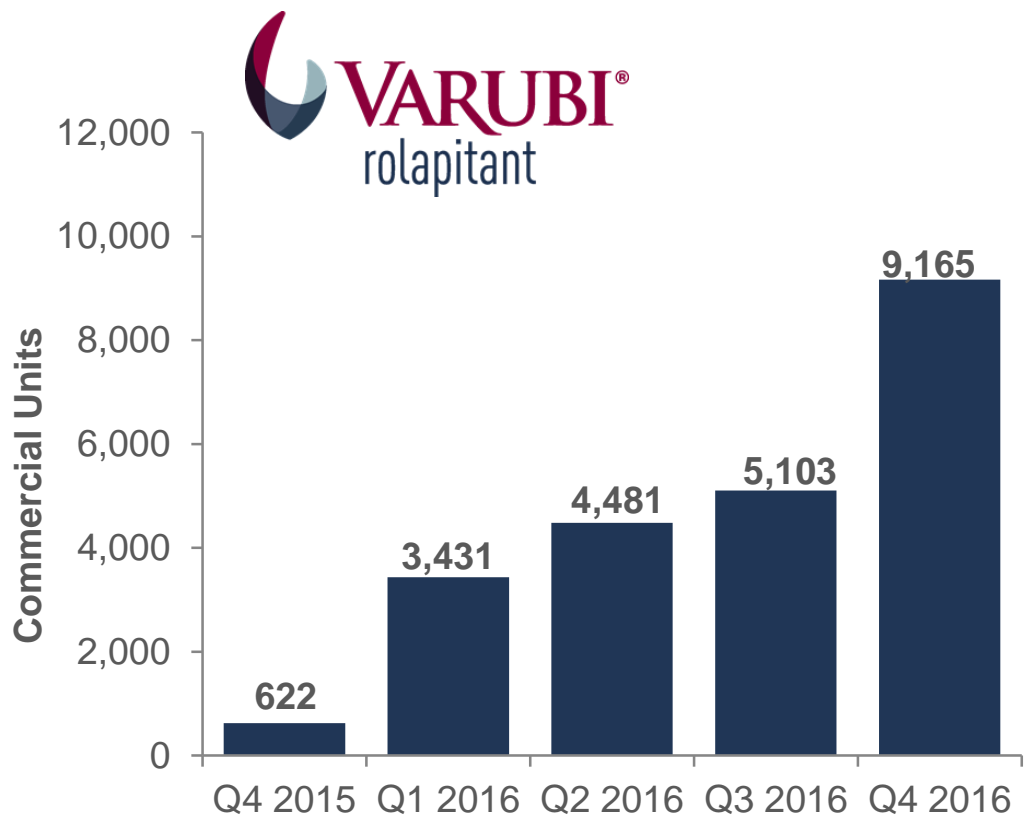
**Establishing VARUBI® Brand Profile with U.S. Oral Launch Ahead of Planned 2017 IV Launch**





**Tim Pearson**  
Chief Financial Officer

# Commercial Launch Update



## Continued Growth in VARUBI Units and Account Penetration

- ~9,165 commercial doses<sup>1</sup> provided during Q4
- Greater than 40% share of U.S. oral NK-1 market in December<sup>2</sup>

Data as of 02.28.2017

<sup>1</sup> Source: Specialty distributor and specialty pharmacy pull through data

<sup>2</sup> Share of the oral NK-1 market is based on IMS NSP Emend® and Akynzeo® units and TESARO actual demand

# Q4 2016 Financial Results

	Three Months Ended December 31, 2015	Three Months Ended December 31, 2016
Product Revenue, net	--	\$2,469
License, Collaboration and Other Revenues	\$230	1,756
<b>Total Revenues</b>	<b>\$230</b>	<b>\$4,225</b>
<b>Expenses:</b>		
Cost of Sales – product	--	\$518
Cost of Sales – intangible asset amortization	\$268	464
Research & Development	42,852	71,514
Selling, General & Administrative	27,910	54,526
Acquired In-process R&D	1,000	9,000
<b>Total Expenses</b>	<b>72,030</b>	<b>136,022</b>
Loss from Operations	(71,800)	(131,797)
Interest Income / (Expense)	(3,959)	(3,670)
Provision for Income Taxes	--	(1,475)
<b>Net Loss</b>	<b>(\$75,759)</b>	<b>(\$136,942)</b>
<b>Loss per Share</b>	<b>(\$1.89)</b>	<b>(\$2.60)</b>

► Cash & cash equivalents totaled approximately \$786M as of December 31, 2016

Unless otherwise noted, figures are in thousands, except for per-share data.





**Mary Lynne Hedley, Ph.D.**  
**President & Chief Operating Officer**



# Development Programs Update

## VARUBI® (rolapitant)

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- › Oral VARUBI MAA under review by EMA; CHMP rendered positive opinion
- › Anticipate launch of oral VARUBY in Europe in 2Q 2017

## Niraparib

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- › MAA under review by EMA
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- › TOPACIO and AVANOVA combination trials continue
- › New indication opportunities and combination approaches continue to be evaluated

## I-O Platform

- › TSR-042 (anti-PD-1 mAb) dose and schedule identified; Phase 1b expansion to begin 1H 2017
- › TSR-022 (anti-TIM-3 mAb) Phase 1 trial ongoing
- › TSR-033 (anti-LAG-3 mAb) IND submission planned for 2Q 2017
- › Anti-LAG-3/PD-1 bi-specific antibody candidate selected
- › MD Anderson collaboration ongoing; goal to identify first clinical candidate in 1H 2017
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NDA: New Drug Application

IV: Intravenous

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I-O: Immuno-oncology

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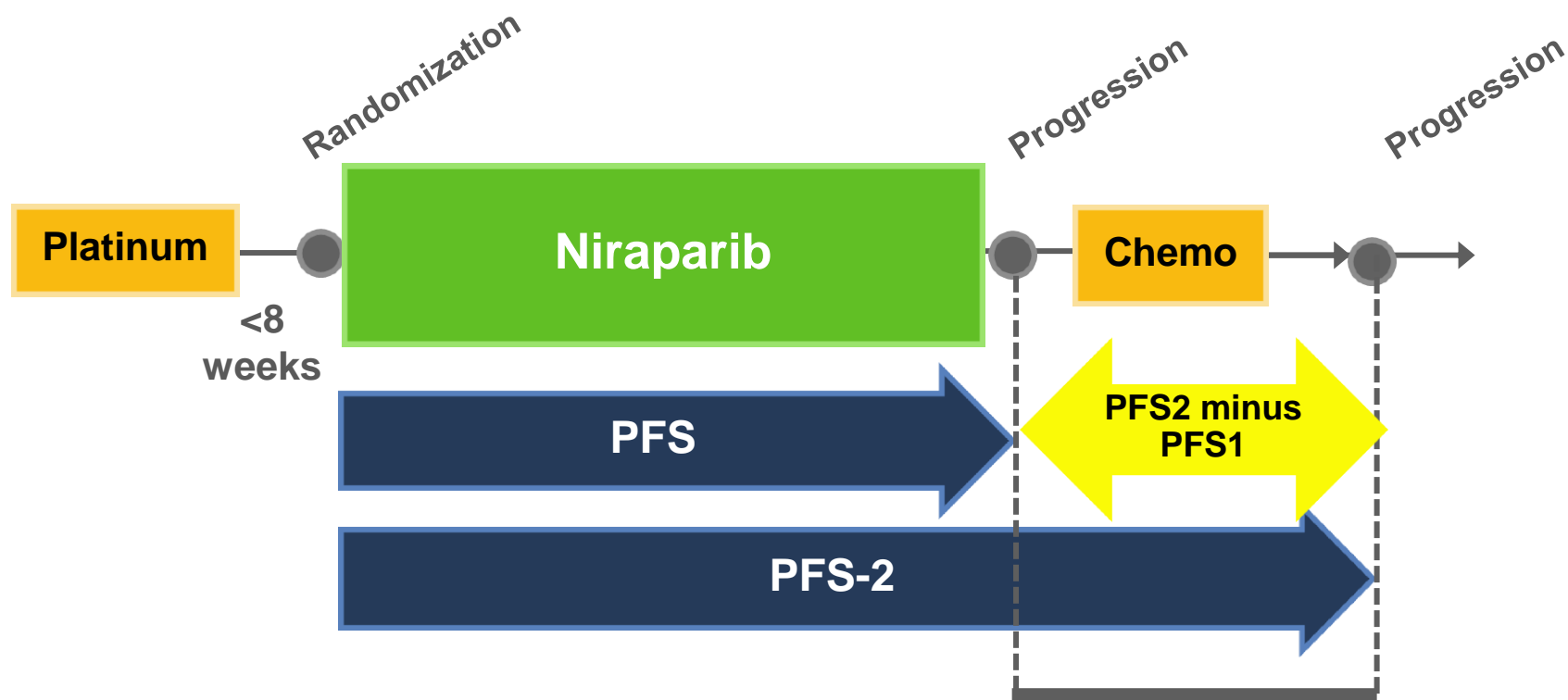
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# Niraparib Benefit Was Durable



**PFS2 minus PFS1 showed that niraparib had no impact on the effectiveness of subsequent chemotherapy; details to be presented at SGO**

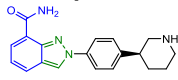
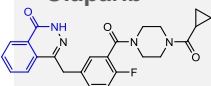
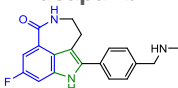
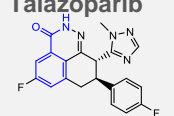
# Niraparib Delivers Anti-Tumor Activity, Selective, Durable, and Near Complete (>90%) PARP Inhibition

## Off-Target Activity of PARP Inhibitors

Product	DNA Repair		Multiple Functions (Off Target)											
	PARP1	PARP2	PARP3	TNKS1	TNKS2	PARP6	PARP7	PARP8	PARP10	PARP11	PARP12	PARP14	PARP15	
Niraparib	Red	Red	Grey	Grey	Grey	Grey	Grey	Grey	Green	Grey	Grey	Grey	Grey	
Olaparib	Red	Red	Yellow	Grey	Green	Grey	Grey	Grey	Green	Grey	Grey	Grey	Grey	
Rucaparib	Red	Red	Yellow	Green	Green	Grey	Grey	Grey	Green	Grey	Grey	Grey	Grey	
Talazoparib	Red	Red	Yellow	Yellow	Red	Green	Grey	Green	Grey	Grey	Grey	Grey	Grey	

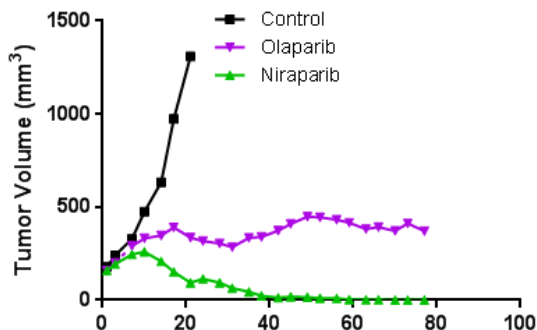
■ <10nM    
 ■ 10–100nM    
 ■ 100–1µM    
 ■ >1µM

## PKDM Properties of PARP Inhibitors

PARPi	Permeability $P_{app}^*$ ( $10^{-6}$ cm/s)	Volume of Distribution V/F (L)	Bioavail- ability F (%)	Half life $t_{1/2}$ (h)	P-gp	BCR P
<b>Niraparib</b> 	15–18	≥ 1100	73	50–90 <sup>a</sup>	S	S I (+++) <sub>b</sub>
<b>Olaparib</b> 	3–8	167	64	12	S	I(+) <sup>c</sup>
<b>Rucaparib</b> 	7	113–262	36	17–19	S	S
<b>Talazoparib</b> 	NA	287	NA	40 <sup>a</sup>	NA	NA

## Niraparib induced Tumor Regression

- ▶ PDx tumor model<sup>1</sup>
- ▶ Daily dosing near MTD for each drug
- ▶ Tumor stasis with olaparib
- ▶ Tumor regression with niraparib



**Clinical Activity of a PARP Inhibitor Should not be Extrapolated Across the Class, Particularly Across a Broad Patient Population**

\* > 10, High Permeability; < 10, Low Permeability  
 a QD dosing; b IC<sub>50</sub> ~ 6 µM; c IC<sub>50</sub> ~ 100 µM; NA = Not available; S = Substrate; I = Inhibitor; 1. Mikule et al ECCO 2017



# A Portfolio of Opportunities

Compound	Therapeutic Area	Discovery	Pre-clinical	Ph 1	Ph 2	Ph 3	Registration
Niraparib	Recurrent Ovarian Cancer (NOVA) <sup>1</sup>	[Progress bar spanning Discovery, Pre-clinical, Ph 1, Ph 2, and Ph 3]					FDA & EMA
	Ovarian Cancer Treatment (QUADRA)	[Progress bar spanning Discovery, Pre-clinical, Ph 1, and Ph 2]					
	1L Ovarian Cancer (PRIMA)	[Progress bar spanning Discovery, Pre-clinical, Ph 1, and Ph 2]					
	BRCA+ Breast Cancer (BRAVO)	[Progress bar spanning Discovery, Pre-clinical, Ph 1, and Ph 2]					
Niraparib + KEYTRUDA® (pembrolizumab)	Triple Negative Breast & Ovarian Cancers	[Progress bar spanning Discovery, Pre-clinical, Ph 1, and Ph 2]					
Niraparib + bevacizumab	Ovarian Cancer (AVANOVA) <sup>2</sup>	[Progress bar spanning Discovery, Pre-clinical, Ph 1, and Ph 2]					

- Global collaboration and license agreement with Janssen to develop and commercialize niraparib specifically for prostate cancer announced in April 2016

<sup>1</sup> Priority Review Granted; PDUFA date is June 30, 2017

<sup>2</sup> In collaboration with ENGOT, the European Network for Gynaecological Oncological Trial groups

# Potential to Combine with an Anti-PD-1 mAb

## Phase 1/2 TOPACIO Trial Niraparib + Pembrolizumab

Triple-negative breast cancer (TNBC) and Recurrent,  
Platinum-Resistant Ovarian Cancer

Phase 1 Cohorts: OC and TNBC; up to 36 Patients

DL2: 6 patients  
N: 300 mg d1-21  
P: 200 mg d1

DL1: 6 patients  
N: 200 mg d1-21  
P: 200 mg d1

DL-1: 6 patients  
N: 200 or 300 mg d1-14  
P: 200 mg d1

DL-2: 6 patients  
N: 200 or 300 mg d1-7  
P: 200 mg d1

Recommended  
Phase 2 Dose

Phase 2 Study:  
42 Ovarian Pts  
48 TNBC pts

### Objectives

- ▶ Phase 1: Evaluate DLTs and establish Phase 2 dose
- ▶ Phase 2: Response rate by RECIST
- ▶ Exploratory biomarker work planned

- ▶ PARPi have the potential to promote a tumor microenvironment that complements I-O approaches to result in broader and more durable responses than monotherapy
- ▶ <20% of triple negative breast (TNBC) and ovarian cancer (OC) patients respond to anti-PD-1 therapy<sup>1,2</sup>
- ▶ Patients with platinum resistant ovarian cancer and non-biomarker selected TNBC patients are less sensitive to PARPi<sup>3</sup>
- ▶ Promising initial combination activity observed in TOPACIO
  - Safety/tolerability and RP2D established
  - Phase 2 is ongoing
  - Data to be presented at a future medical meeting
- ▶ Potential for applicability in other tumors sensitive to anti-PD-1 therapy (lung, bladder, head and neck)

<sup>1</sup> 2014 SABC

<sup>2</sup> *J Clin Oncol* 32:5s, 2014 (suppl; abstr 5511)

<sup>3</sup> Rucaparib package insert; Gelmon, *Lancet Oncol.* ,2011 Sep;12(9):852-61

# Potential to Combine with Bevacizumab

## Phase 1/2 AVANOVA Trial Niraparib + Bevacizumab

Recurrent, platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer w/high-grade serous/endometrioid histology

Phase 1, N = 12

Phase 2, N=94  
Stratify on HRD and PFI (>6-12 months or 12+ months)

Niraparib: 300mg  
Bevacizumab:  
15mg/kg

Niraparib:  
300mg

### Objectives

- ▶ Phase 1: Safety and tolerability of bevacizumab-niraparib combination
- ▶ Phase 2: Progression-Free Survival (PFS) in niraparib vs. niraparib + bevacizumab

- ▶ Potentially synergistic activity via simultaneous inhibition of anti-angiogenesis and DNA repair
  - Goal to improve PFS with bevacizumab or niraparib monotherapy
  - Supported by VEGFi + PARPi exploratory work (Avastin and others)
- ▶ Promising initial combination activity observed in AVANOVA
  - Safety/tolerability established in Phase 1
    - 4 HRD+ (3 BRCAmut) (75% CR/PR + 1 SD)
    - 5/12 (42%) ORR
    - Median duration of treatment in all patients 41.7 weeks (91% of patients without progression; ASCO 2016)
  - Phase 2 is ongoing
    - 80% power for HR 0.57 (8 vs. 14 months)
  - Data to be presented at a future medical meeting
- ▶ Potential applicability in ovarian, CRC, GBM

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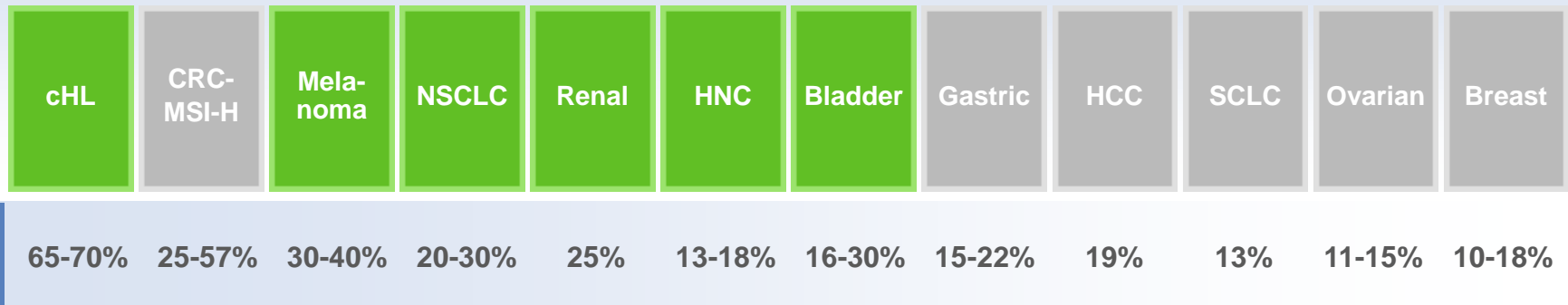
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# PD-1/L1 Inhibitors Are Effective Across Multiple Indications

## Key Indications in Late-Stage Development

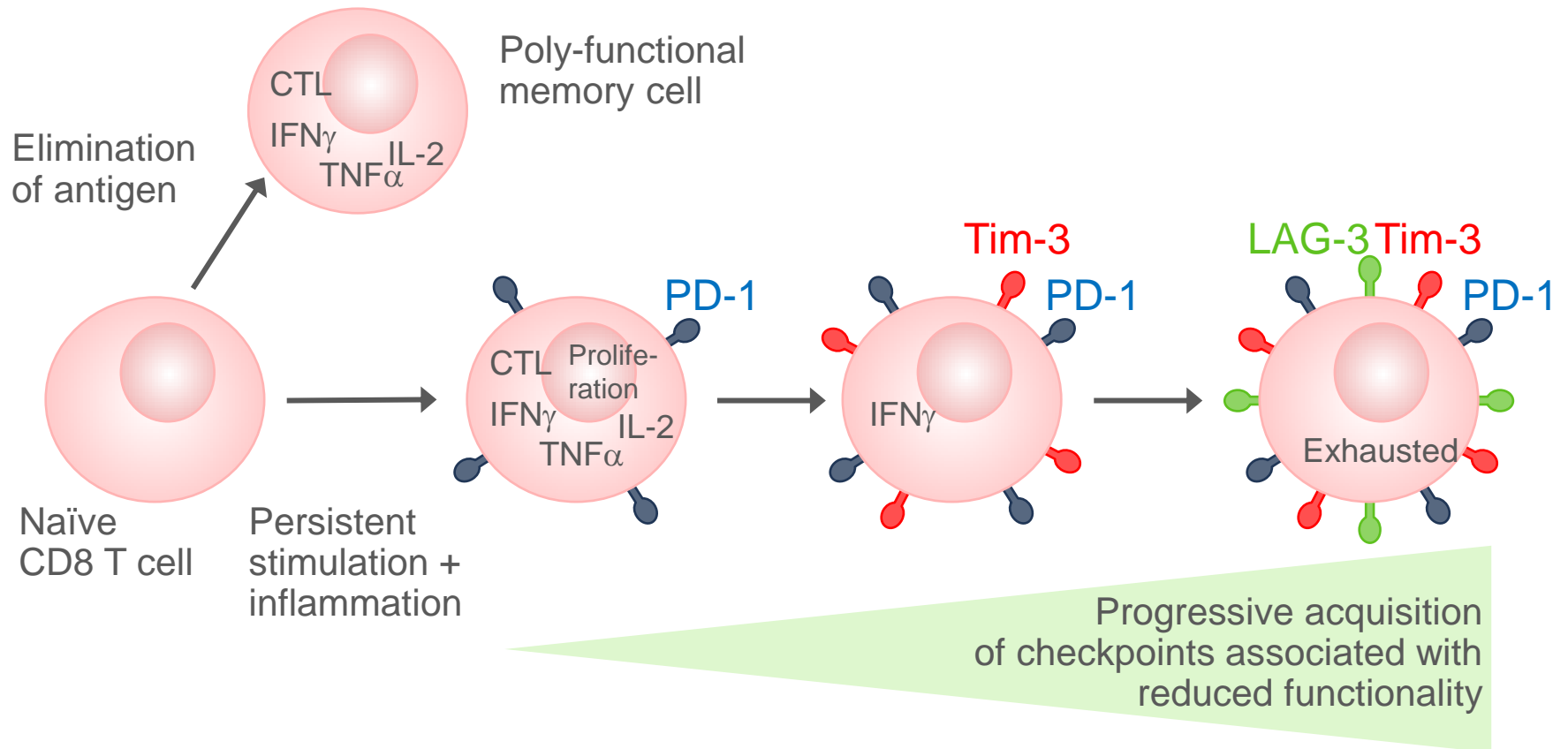


Approved Indications

- A large unmet need still exists for the many patients who don't respond
- Goal is to improve responses and duration via combination approaches

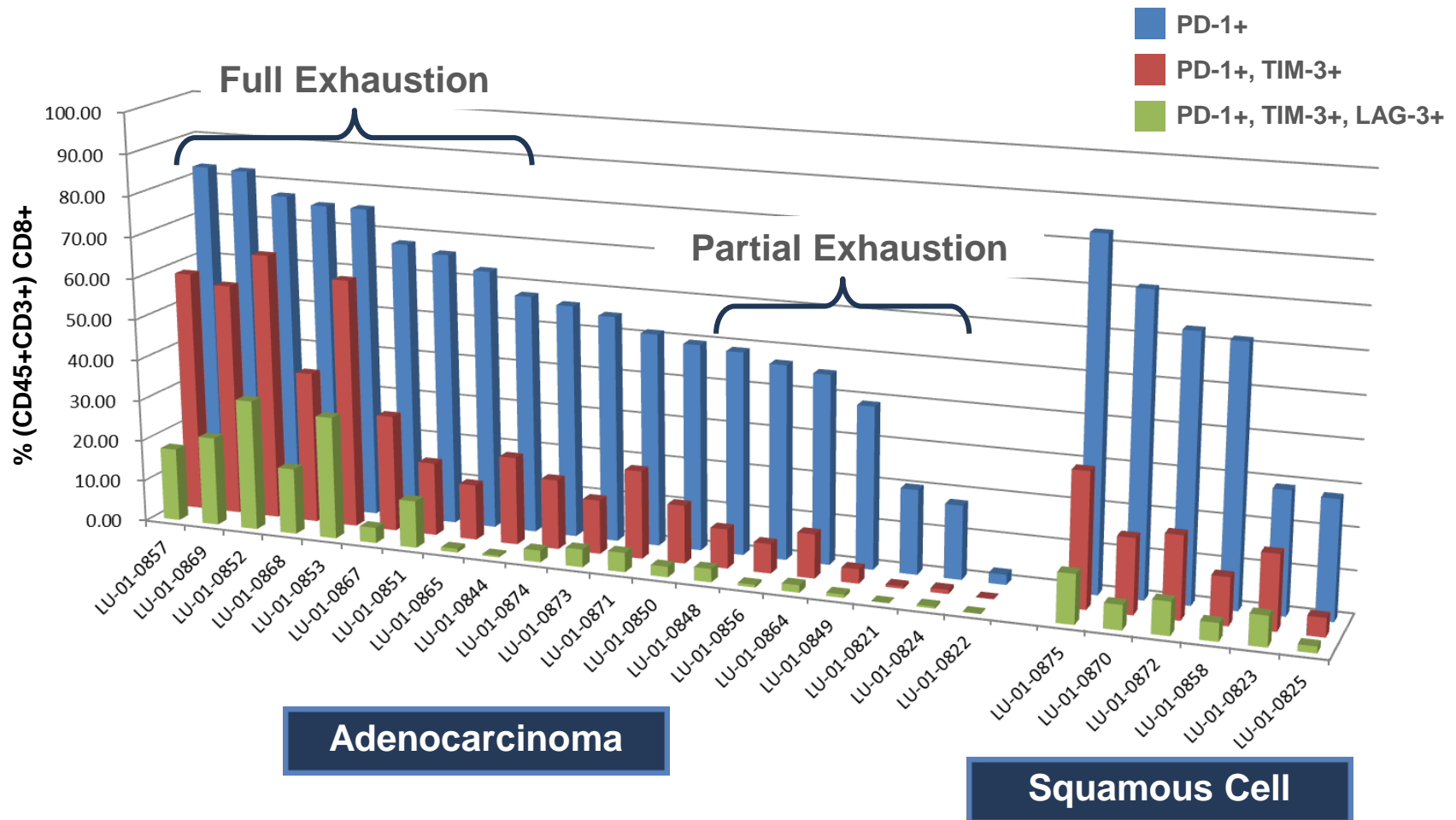


# Loss of T cell Function Associated with Progressive Expression of Checkpoint Molecules



**PD-1 is One of Several Checkpoints Associated with Exhausted T-cells with e.g., Reduced Proliferative and Cytokine Releasing Capacity**

# A Subset of CD8+PD-1+ T Cells Express High Levels of TIM-3 in NSCLC





**Lonnie Moulder**  
Chief Executive Officer

# Corporate Goals

## VARUBI<sup>®</sup> (rolapitant)

- ▶ Launch VARUBI IV into the U.S. market in mid-2017, pending FDA approval
- ▶ Launch VARUBY oral in Europe in 2Q 2017, pending EMA approval

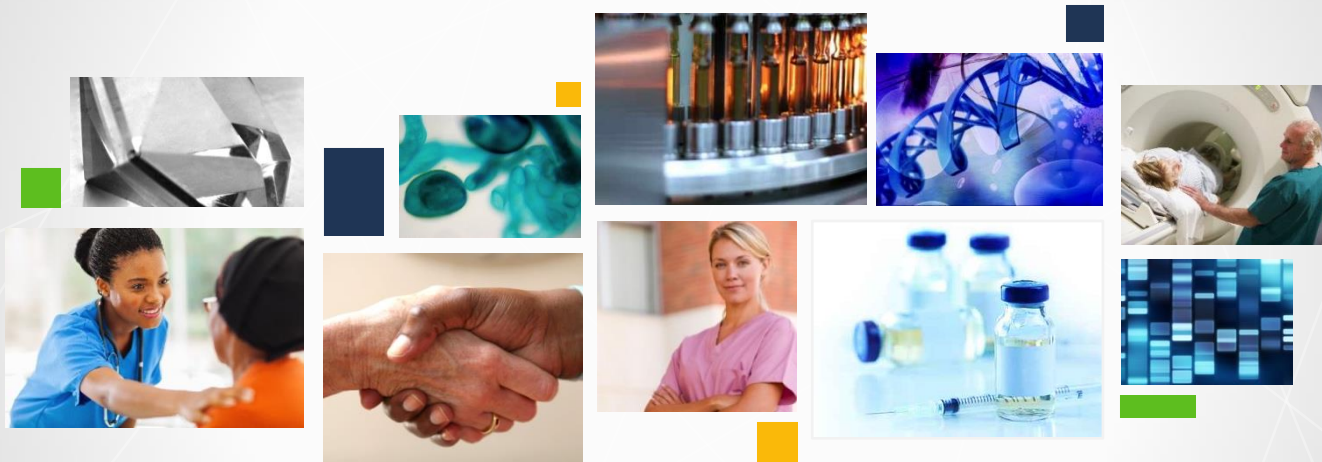
## Niraparib

- ▶ Continue commercial preparations in support of the launches of niraparib in the U.S. in 1H 2017 and Europe by year-end 2017, pending regulatory approvals
- ▶ Report initial data from TOPACIO trial at upcoming medical meeting
- ▶ Finalize a potential lung cancer registration strategy in 1H 2017 and initiate development program
- ▶ Report QUADRA data in 2H 2017
- ▶ Report Phase 3 BRAVO data in 2H 2017
- ▶ Report AVANOVA data in 2H 2017
- ▶ Determine the potential registration strategy for niraparib plus TSR-042 in ovarian cancer and other cancers in 2H 2017
- ▶ Continue to enroll Phase 3 PRIMA trial throughout 2017

## I-O Platform

- ▶ Identify the first clinical candidate within the MD Anderson collaboration in 1H 2017
- ▶ Submit IND for TSR-033 (anti-LAG-3 mAb) in 2Q 2017
- ▶ Finalize the TSR-042 registration strategy and initiate a registration program in 1H 2017
- ▶ Identify a dose and schedule for TSR-022 (anti-TIM-3 mAb) by mid-2017
- ▶ Initiate a Phase 1 clinical trial of TSR-022 in combination with an anti-PD-1 mAb in mid-2017

# Q&A



# Fourth-Quarter 2016 Results

## February 28, 2017