

Determined to realize a future in which  
people with cancer live longer and  
better than ever before

Syndax 

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# Company strategy



# Syndax investment highlights



## Entinostat

### Combo with exemestane:

- Phase 3 data 3Q18
- \$\$B US opportunity

### Combo with anti-PD-(L)1:

- Signals in Mel, NSCLC
- Ongoing NSCLC, Mel, CRC, TNBC, Ovar trials
- Multiple data readouts

## SNDX-6352

### CSF1R antibody:

- Phase 1 multiple dose study ongoing
- Broad clinical dev potential
- Collaboration with AZ's IMFINZI®

## Menin-MLLr inh

### Onc driver specific:

- MLLr leukemias
- IND in 2019

CRC - colorectal cancer; NSCLC - non-small cell lung cancer; Mel - melanoma; TNBC - triple negative breast cancer; Ovar - ovarian cancer

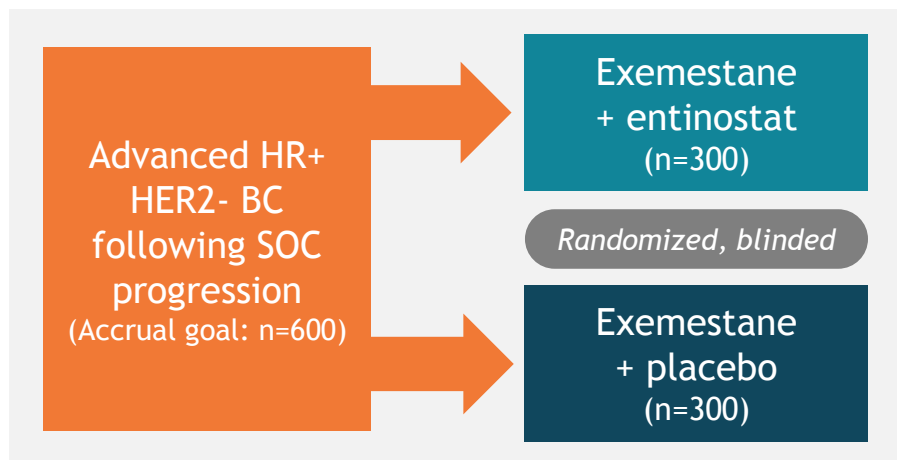
# Previous milestones

<b>ENTINOSTAT (Class 1 specific HDAC inhibitor)</b>	Update	1Q18	2Q18	3Q18	4Q18
Communicate registration strategy for entinostat in MEL			●		
ENCORE 601 - MEL (PD-1 pre-Tx) Phase 2 data presentation	ASCO		●		
ENCORE 601 - NSCLC (PD-1 pre-Tx) Phase 2 data presentation	ASCO		●		
ENCORE 601 - Go / No go decision, Stage 1 of MSS CRC cohort			●		
E2112 - Complete Phase 3 enrollment; release PFS			▬		
ENCORE 602 - Report topline TNBC results					●

<b>SNDX-6352 (anti-CSF-1R mAB)</b>	Update	1Q18	2Q18	3Q18	4Q18
Initiate Phase 1b combination trial (cancer patients)			●		
MAD trial data presentation (cancer patients)					●
Communicate Phase 2 development strategy				▬	

# E2112 to report Phase 3 data 3Q18

## E2112: Exemestane +/- entinostat



Two primary endpoints: PFS and OS



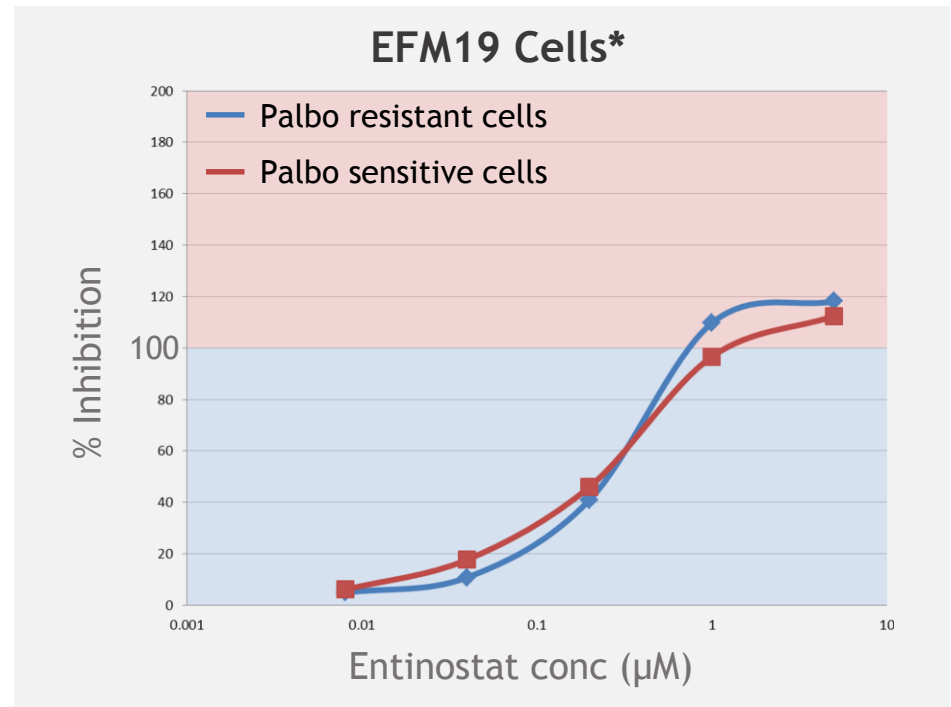
## E2112 Trial Milestones

- ✓ 4Q17: Final PFS analysis, 1<sup>st</sup> interim OS analysis complete
- ✓ 2Q18: 2<sup>nd</sup> interim OS analysis complete
- > 3Q18: Expect to Achieve full accrual, share result of PFS analysis
- > 2H18: If PFS positive, File NDA
- > 2018-20: Early trial completion possible w/May & Nov interim OS analyses

2018			2019			2020		
Jan	Feb	Mar	Jan	Feb	Mar	Jan	Feb	Mar
Apr	May	Jun	Apr	May	Jun	Apr	May	Jun
Jul	Aug	Sep	Jul	Aug	Sep	Jul	Aug	Sep
Oct	Nov	Dec	Oct	Nov	Dec	Oct	Nov	Dec

# E2112 uniquely positions entinostat as the preferred agent post-CDK4,6 inhibitor

- Physicians searching for ideal treatment regimen post CDK4,6 inhibitor
- 30-50% of pts in E2112 expected to have received a prior CDK4,6 inhibitor
- Preclinical data indicates no cross resistance



*\*Similar results observed in 2 other cell lines (MDA-MB-134 and MDA-MB-361)*

Source: Slamon - unpublished

# Entinostat: Blockbuster potential as 2<sup>nd</sup>/3<sup>rd</sup> line therapy for HR+, HER2- metastatic breast cancer

*First novel MOA in HR+ BC with Phase 3 data since CDK4/6*

Leading treatment options - HR+, HER2- advanced breast cancer

**1<sup>st</sup> line**  
hormone Tx

Anastrozole or  
letrozole +/-  
CDK4,6 inhibitor

**2<sup>nd</sup>/3<sup>rd</sup>/4<sup>th</sup> line**  
hormone Tx

Anastrozole,  
Faslodex +/- CDK4,6  
inhibitor or Afinitor-  
exemestane

**34,000 pts**

Entinostat-exemestane  
target population

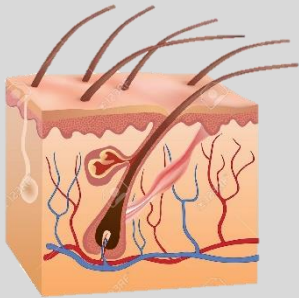
**Chemo-Tx**

Capecitabine,  
gemcitabine,  
eribulin

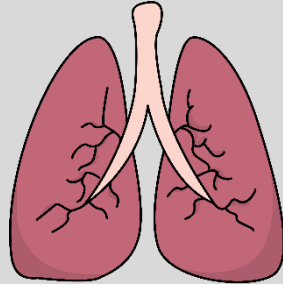
Source: DataMonitor 2016 Breast cancer: HR+/HER2- Disease Coverage Report



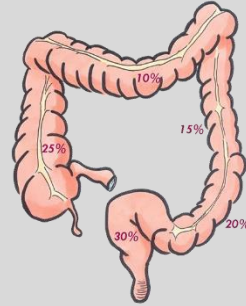
# ENCORE Clinical Trial Program: Evaluating entinostat's potential to enhance anti-PD-(L)1 efficacy



MEL



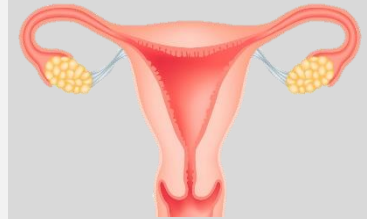
NSCLC



CRC



TNBC  
HR+ BC



OVAR

PD-(L)1

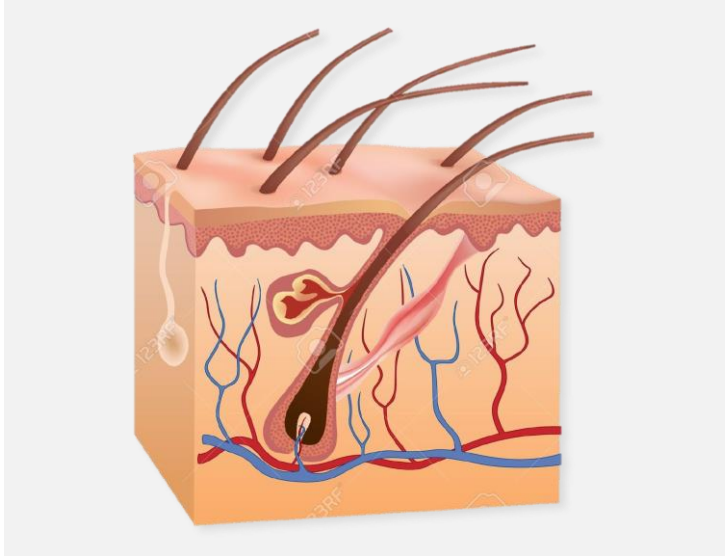
Immune cells

Tumor mutational  
burden (TMB)

Nanostring

*Focused on early signs of efficacy and biomarkers that predict clinical benefit*

# ENCORE 601 Phase 2 melanoma data 2Q18



## ENCORE 601: PD-1 REFRACTORY MEL

Clin. meaningful response rate: **~20%**

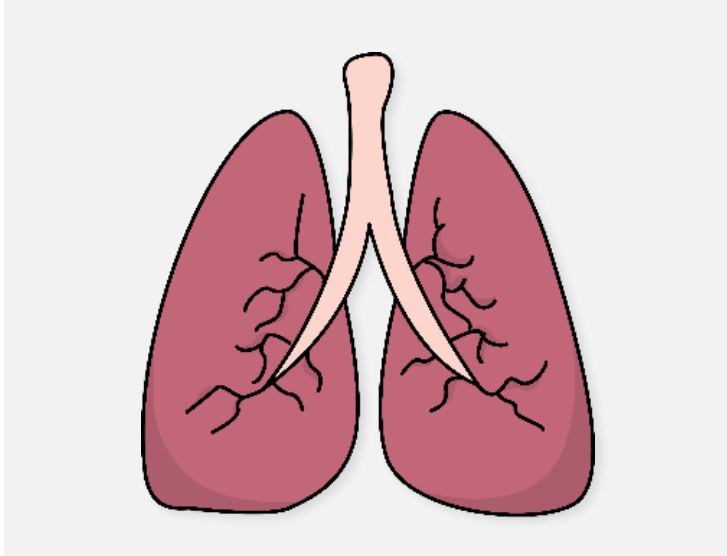
- CTLA-4 RR post PD-1<sup>1</sup>: 11-14%
- Chemo RR<sup>2</sup>: 4-11%

### Phase 2 results at ASCO

- Previously reported 4/13 responses<sup>3</sup> (ASCO 2017)
- Expanded cohort (n= 55) fully enrolled
- Ongoing biomarker analysis to predict clinical benefit

Source: 1. Long et al. Society for Melanoma Research 2016; 2. Weber et al., Lancet Oncology, 2015 (Checkmate 037, dacarbazine or paclitaxel). 3. Johnson, ML, et. al., ASCO poster 2017

# ENCORE 601 Phase 2 NSCLC data 2Q18



## ENCORE 601: PD-1 REFRACTORY NSCLC

Clin. meaningful response rate: **~15%**

### Phase 2 results at ASCO

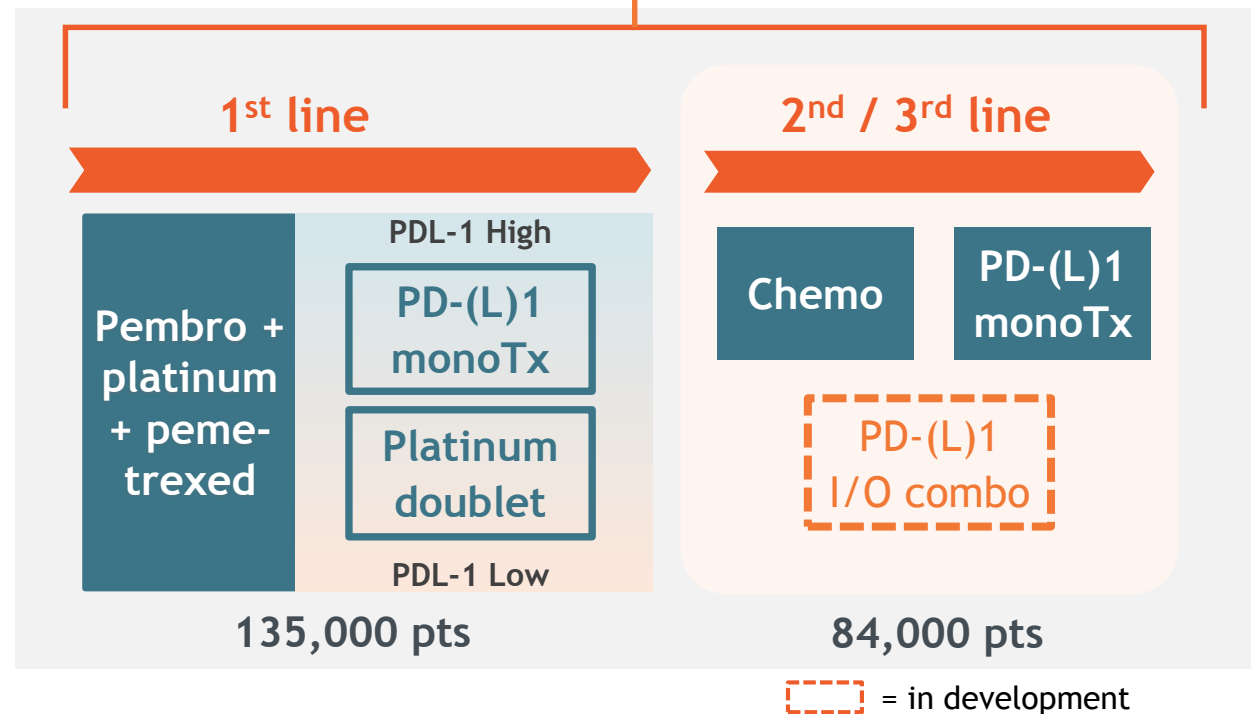
- Previously reported 3/31 responses (SITC 2017<sup>1</sup>)
- Expanded cohort (n= 76) fully enrolled
- Ongoing biomarker analysis to predict clinical benefit

Source: 1. Johnson, ML, et. al., SITC poster 2017

# Patient segmentation common in NSCLC therapy

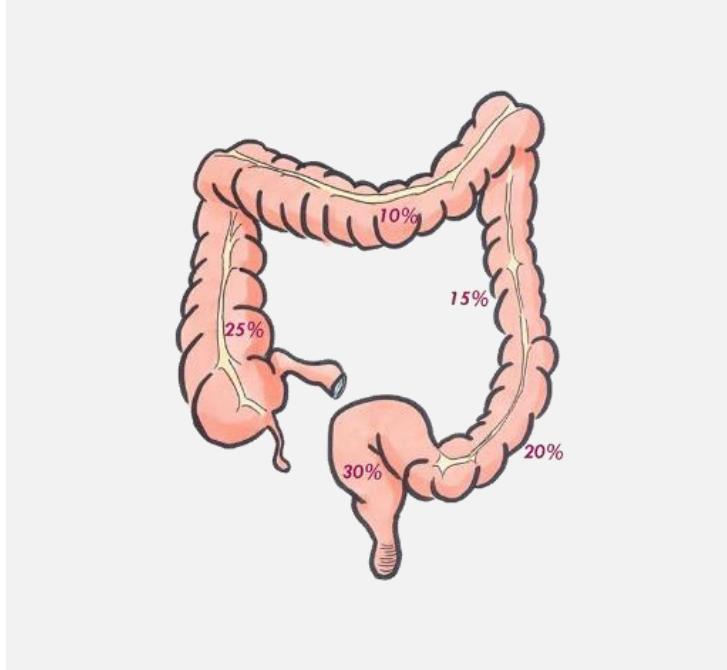
- Biomarkers used to identify responders (EGFR, ALK, PD-(L)1; TMB?, etc.)
- Selection may enable **entinostat-KEYTRUDA** to provide meaningful benefit for a subset of 2L / 3L NSCLC

## NSCLC Patient Journey by Line of Therapy (US)



Source: Kantar 2016 Treatment Architecture report; Trial Trove, SEER data

# ENCORE 601 initial Phase 2 CRC data 2Q18



## ENCORE 601: PD-1 Naïve MSS-CRC

Clin. meaningful response rate: **~15%**

- PD-1 RR<sup>1</sup>: 0%
- Stivarga RR (3 line)<sup>2</sup>: 1%

Simon 2-stage design (modified)  
Stage 1: 3/37 responses to expand  
Stage 2: enroll 47 add'l patients  
Hypothesized ORR = 15%

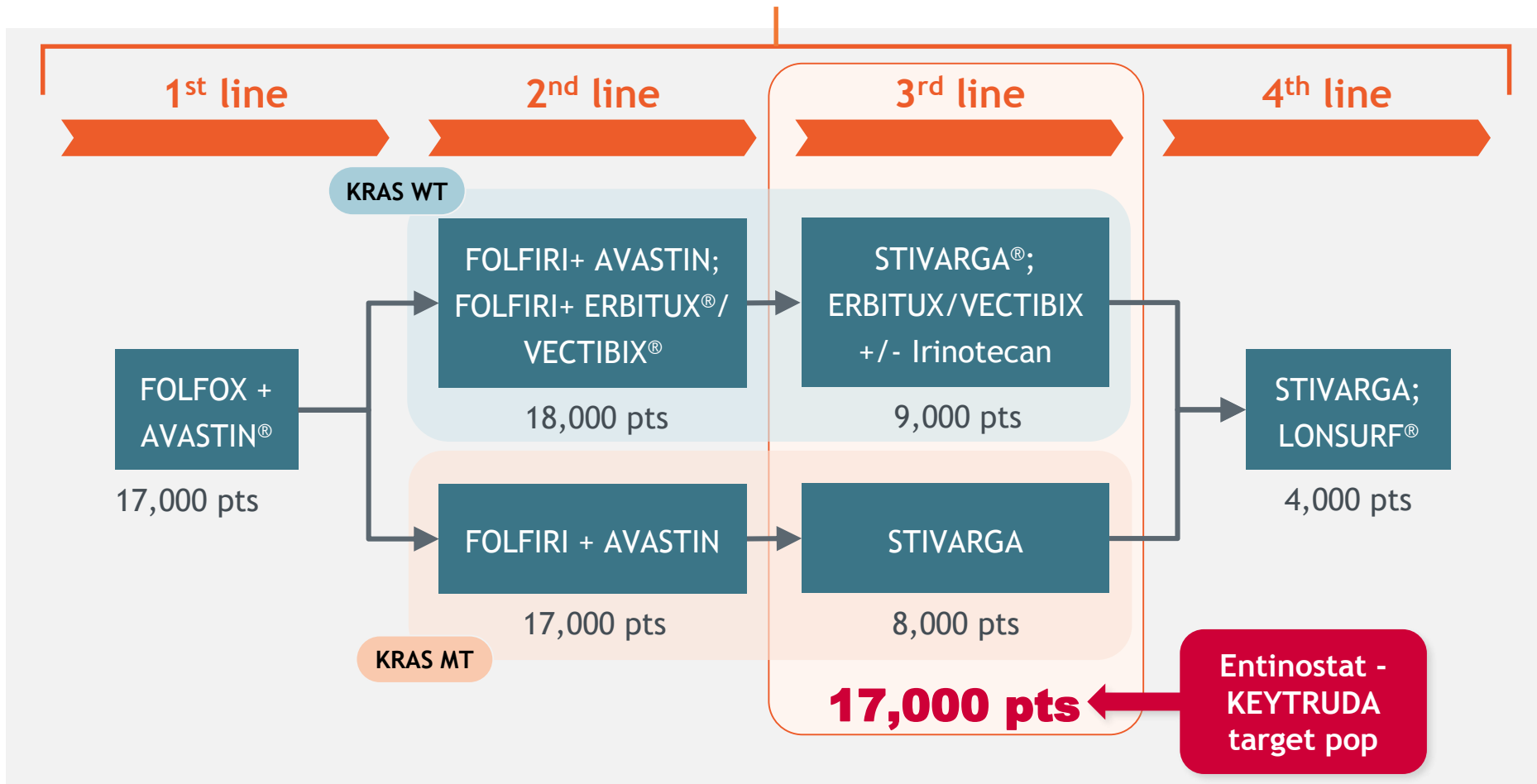
Initial data at ASCO

- Agreement w/Merck to modify study
- Ongoing biomarker analysis to predict clinical benefit

Source: 1. O'Neil et. al., PLoS ONE 12(12): e0189848 2. Stivarga Prescribing Information

# MSS-CRC represents a significant market opportunity

## MSS-CRC Patient Journey by Line of Therapy (US)



Source: Kantar 2016 Treatment Architecture report; Trial Trove, SEER data

# ENCORE 602 and 603

## ENCORE 602: TNBC

TECENTRIQ -  
entinostat  
dose determination

**Genentech**  
*A Member of the Roche Group*

TECENTRIQ +  
entinostat  
(n=35)

TECENTRIQ +  
placebo  
(n=35)

Phase 1b:  
*Open-label*

Phase 2:  
*Randomized, double-blind*

*Complete enrollment 2Q18*

## ENCORE 603: Ovarian

BAVENCIO® -  
entinostat  
dose determination

**MERCK**

**Pfizer**

BAVENCIO +  
entinostat  
(n=80)

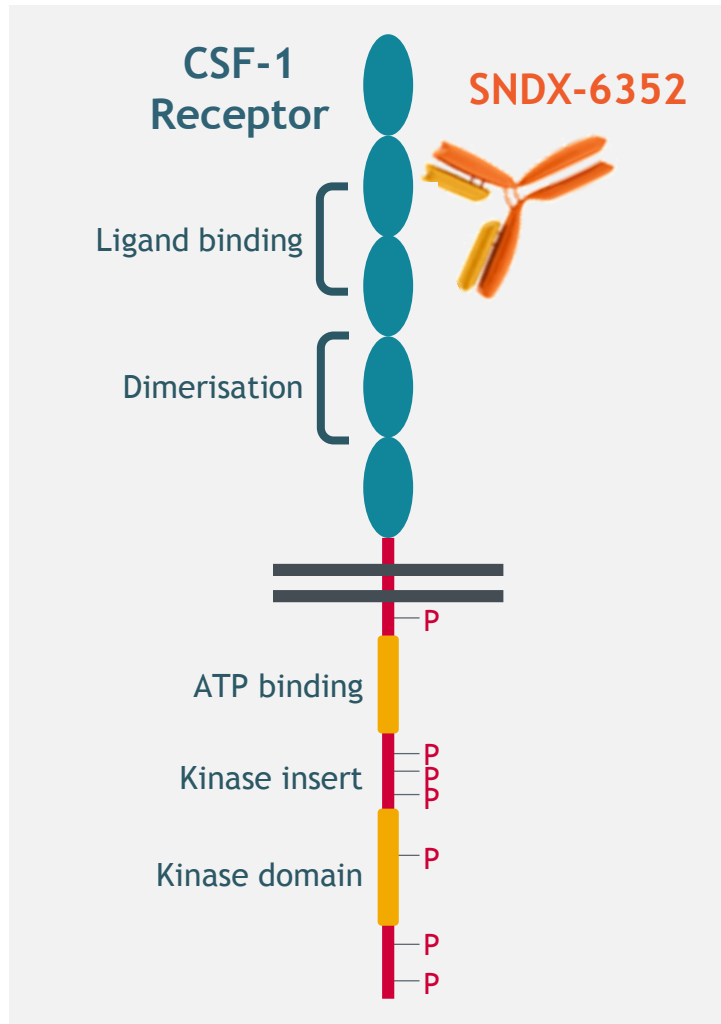
BAVENCIO +  
placebo  
(n=40)

*Enrollment completed 2Q18* ✓

### Phase 2 ENDPOINTS:

- Primary endpoint - PFS
- Secondary endpoint - Overall response rate (ORR)
- Secondary endpoint - Overall survival (OS)

# SNDX-6352: Anticipate focused Phase 2 POC program



- High affinity, IgG4 ( $K_D = 4-8 \text{ pM}$ )
- ✓ Multiple ascending dose (MAD, solid tumors) ongoing
  - Enrollment of 1<sup>st</sup> 2 cohorts complete
- ✓ Collaboration in place to broadly study combination with IMFINZI (AZ)
  - Commence work to establish safety of combination in 2Q18
- Communicate Phase 2 strategy 2H18

TAM - tumor associated macrophage; CSF-1R - colony stimulating factor -1 receptor

Source : Ordentlich, P. et al SITC 2016



# Menin-MLLr program on track for IND Filing 1H19

## MLL-r known cause of leukemias (AML, ALL, MLL)

- Major market incidence: 4,000/yr

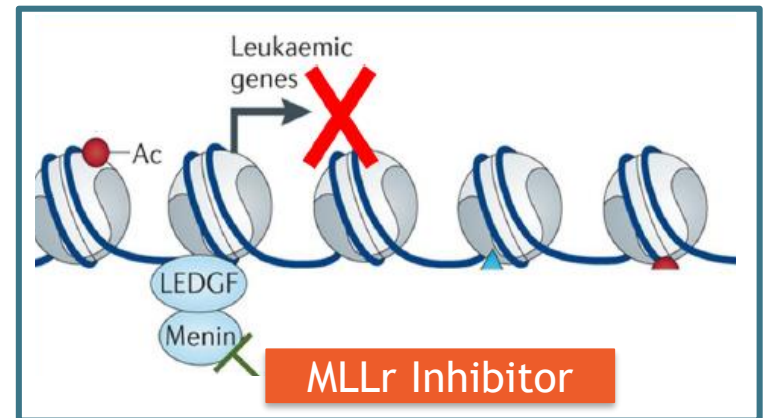
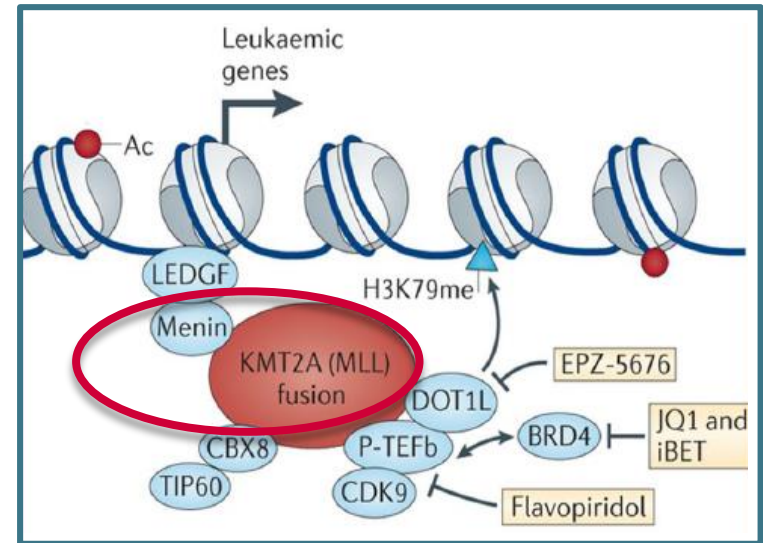
## *NPM1<sup>mut</sup>* also targeted by MLLr inhibitor

- Estimated at 25-30% of adult AML

## Other potential indications:

- MDS, ALL, AML (incl. MLL-PTD AML)
- CMML and CML
- Pancreatic Cancer
- Gain-of-function p53 mutation tumors

## VTP-50469 data presented at AACR



MLL-r = rearrangements of the Mixed Lineage Leukemia (MLL) gene

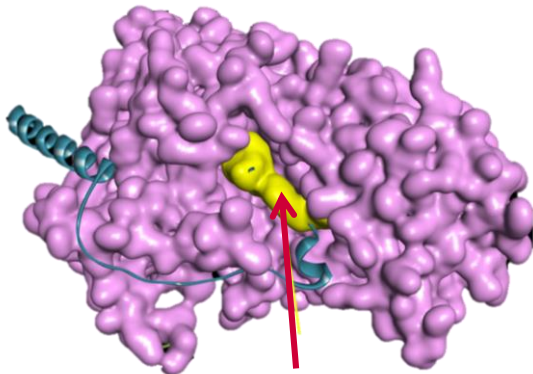
# Proven ability to build the pipeline

3Q16: UCB



SNDX-6352

4Q17: Allergan/Vitae



Menin-MLLr  
inhibitors

- Established relationships enhance identification and access to quality assets
- Clinical development leadership enables competitive advantage
- Business development continues to be a core strength of our business

# ENCORE 601 results at ASCO



Description	Lead author / poster #
Phase 2 entinostat - pembro results from PD-1 pretreated NSCLC cohort	Leena Gandhi <i>Poster board #359</i>
Phase 2 entinostat - pembro results from PD-1 pretreated Melanoma cohort	Sanjiv S. Aggarwala <i>Poster board #357</i>
Initial stage 1 entinostat - pembro results from PD-1 Naïve MSS-CRC cohort	Nilofer Saba Azad <i>Poster board #50</i>

# 1Q18 financial highlights and 2018 guidance

<b>Ticker</b>	<b>SNDX (NASDAQ)</b>	
	<b>As of March 31, 2018</b>	
<b>Cash and short-term investments</b>	<b>\$113.2 million</b>	
<b>Common shares O/S</b>	<b>24.7 million</b>	
	<b>2018 Operating Expense Guidance</b>	
	<b><u>Q2</u></b>	<b><u>2018</u></b>
<b>R&amp;D</b>	<b>\$15-18 M</b>	<b>\$62-70 M</b>
<b>Total Operating Expenses</b>	<b>\$20-23 M</b>	<b>\$82-90 M</b>

# Upcoming milestones

<b>ENTINOSTAT (Class 1 specific HDAC inhibitor)</b>	<b>2Q18</b>	<b>3Q18</b>	<b>4Q18</b>	<b>1H19</b>
ENCORE 601 - PD-1 pre-Tx NSCLC and MEL phase 2 data; initial MSS CRC data at ASCO	●			
Communicate registration strategy for entinostat in MEL	●			
ENCORE 601 - Go / No go decision, Stage 1 of MSS CRC cohort				●
E2112 - Complete Phase 3 enrollment; release PFS		●		
ENCORE 602 - Report topline TNBC results			▬	
ENCORE 603 - Report topline Ovarian results				●
<b>SNDX-6352 (anti-CSF-1R mAB)</b>	<b>2Q18</b>	<b>3Q18</b>	<b>4Q18</b>	<b>1H19</b>
Commence work to establish safety in combination with PD-L1	●			
MAD trial data presentation (cancer patients)			●	
<b>Menin MLLr inhibitor</b>	<b>2Q18</b>	<b>3Q18</b>	<b>4Q18</b>	<b>1H19</b>
File IND and initiate clinical studies				●

# Syndax investment highlights

**FDABTD**

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- Phase 3 data 3Q18
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Thank you. Questions?

Syndax 