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Reimagining Cancer Treatment

Syndax 

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

LADENBURG THALMANN 2016 HEALTHCARE CONFERENCE •

Strong leadership team

Spearheaded by leading oncology drug developer

CHIEF EXECUTIVE

PRIOR EXPERIENCE



Briggs W. Morrison, M.D.
Chief Executive Officer



CMO, Exec. VP, Global Medicines Dev.



Head of Medical Affairs, Safety and Regulatory Affairs



Clinical development of all novel anti-cancer drugs

President, COO



Michael A. Metzger



CTO, Co-Founder



Peter Ordentlich,
Ph.D.

X-CEPTOR



Chief Development Officer



Michael L. Meyers,
M.D., Ph.D.



Chief Financial Officer



Allan L. Shaw



Company Strategy

Entinostat
Breast
Cancer

Entinostat
Immuno-
oncology

New
molecules

Financing & Staffing

With an expected IND filing in 2016, two potential best-in-class molecules in clinical studies

		Preclin	Ph 1	Ph 2	Ph 3	Indication
Entinostat (HDAC inhibitor)	Ph 3 trial in combination with hormone therapy					HR+ MBC
	Three trials exploring five PoC indications in combination with PD(L)-1 antibodies					NSCLC, melanoma, TNBC, ovarian
	Multiple IST/NCI sponsored trials testing immuno-oncology combos					Solid tumors
SNDX-6352 (Anti-CSF-1R)	Trials initiating 4Q2016					Solid tumors

HR+ MBC = hormone receptor positive metastatic breast cancer; NSCLC = non-small cell lung cancer; TNBC = triple negative breast cancer; IST = investigator sponsored trial; NCI = National Cancer Institute

Company Strategy

Entinostat
Breast
Cancer

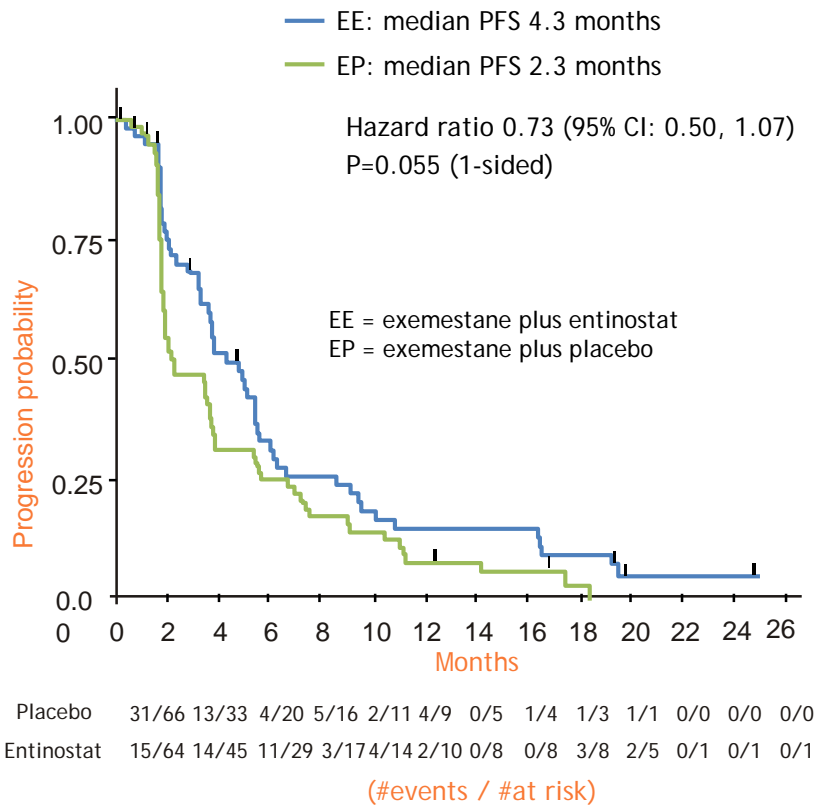
Entinostat
Immuno-
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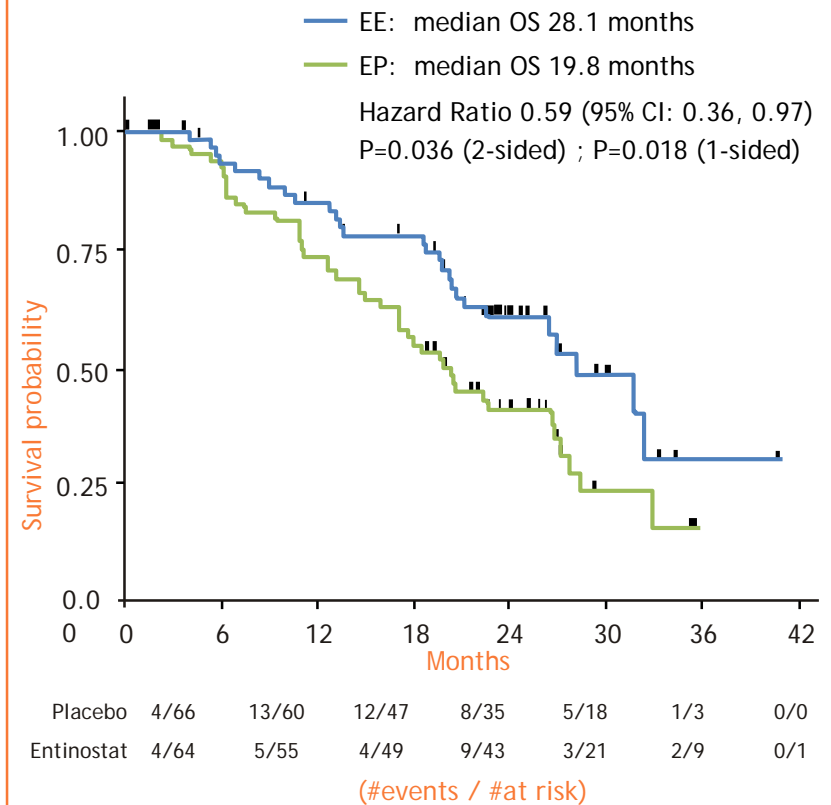
Financing & Staffing

Phase 2 trial resulted in breakthrough therapy designation for entinostat + Aromasin® in advanced HR+ breast cancer

Progression-Free Survival



Overall Survival



Source: Yardley, Denise A., et al. *Journal of Clinical Oncology* 31.17 (2013): 2128-2135.

Entinostat-exemestane combination is generally well tolerated

Adverse Event ^(a)	Exemestane + Entinostat (N=63)			Exemestane + Placebo (N=66)		
	Any Grade (G) n (%)	G3 n (%)	G4 n (%)	Any Grade (G) n (%)	G3 n (%)	G4 n (%)
Fatigue	30 (48%)	7 (11%)	1 (2%)	17 (26%)	2 (3%)	–
Nausea	25 (40%)	3 (5%)	–	10 (15%)	1 (2%)	–
Neutropenia ^(b)	19 (30%)	8 (13%)	1 (2%)	–	–	–
Vomiting	13 (21%)	3 (5%)	–	3 (5%)	–	–
Headache	9 (14%)	3 (5%)	–	7 (11%)	–	–
Hypophosphataemia	4 (6%)	3 (5%)	–	3 (5%)	1 (2%)	–

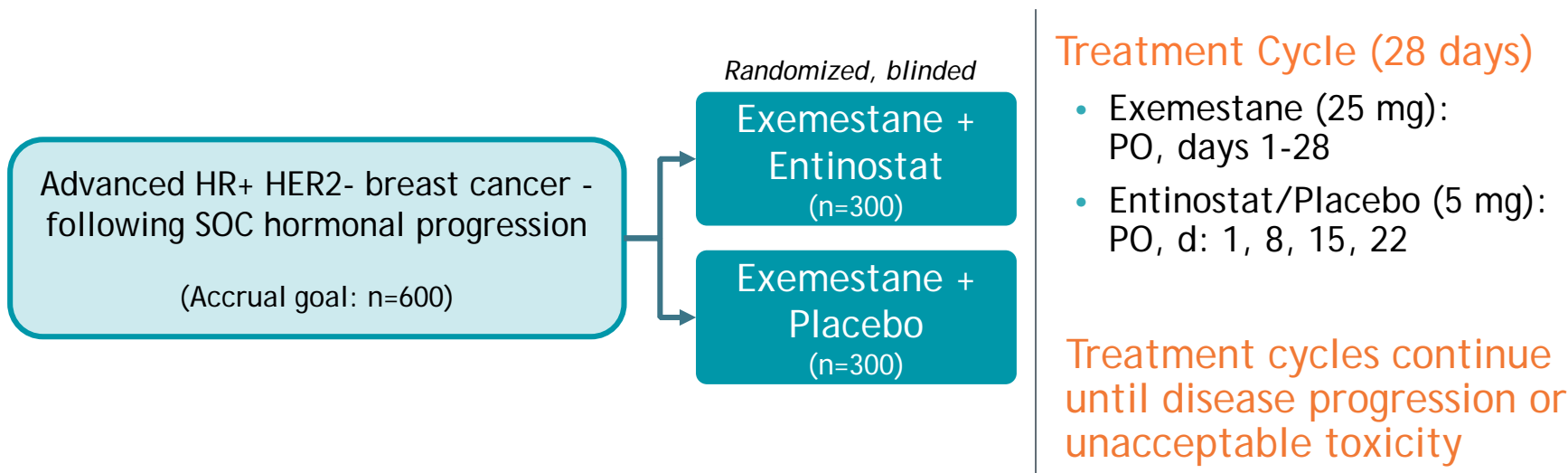
(a) Grade 3 and 4 AEs occurring in >5% in exemestane plus entinostat group; Safety Population; Treatment-emergent AEs, regardless of treatment-attribution

(b) None of these eight grade 3 and 4 patients experienced febrile neutropenia or associated infections during the time of the neutropenia. One patient with non-measurable bone-only disease was given a myeloid growth factor for neutrophil support; patient had history of neutropenia and growth factor usage.

E2112

Phase 3 registration trial in advanced HR+, HER2- breast cancer patients

Exemestane +/- Entinostat



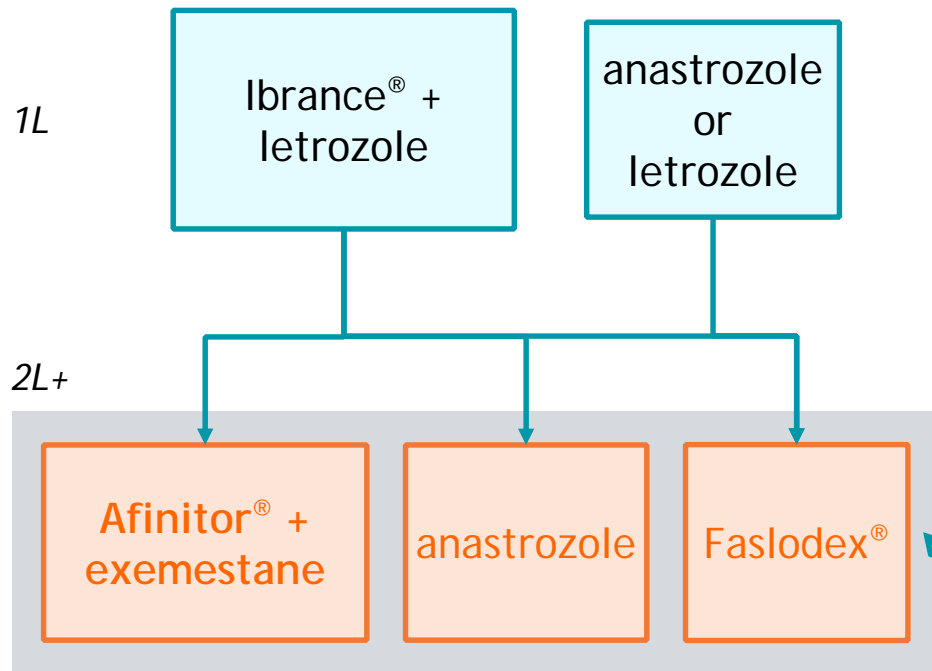
Enrollment has exceeded 50% of the accrual goal

Trial Highlights:

- FDA reviewed trial under SPA process
- Two primary endpoints: PFS and OS
- PFS readout is expected no sooner than 2H 2017
- Combination has been granted Breakthrough Therapy Designation by the FDA

Second-line HR+ metastatic breast cancer may represent a significant market opportunity

Leading treatment options -
HR+/HER2- Advanced Breast Cancer



- CDK4/6 inhibitor Ibrance® rapidly became a first-line (1L) standard-of-care (SoC)
- Afinitor + exemestane most common second-line (2L) combination despite toxicity and lack of an OS benefit

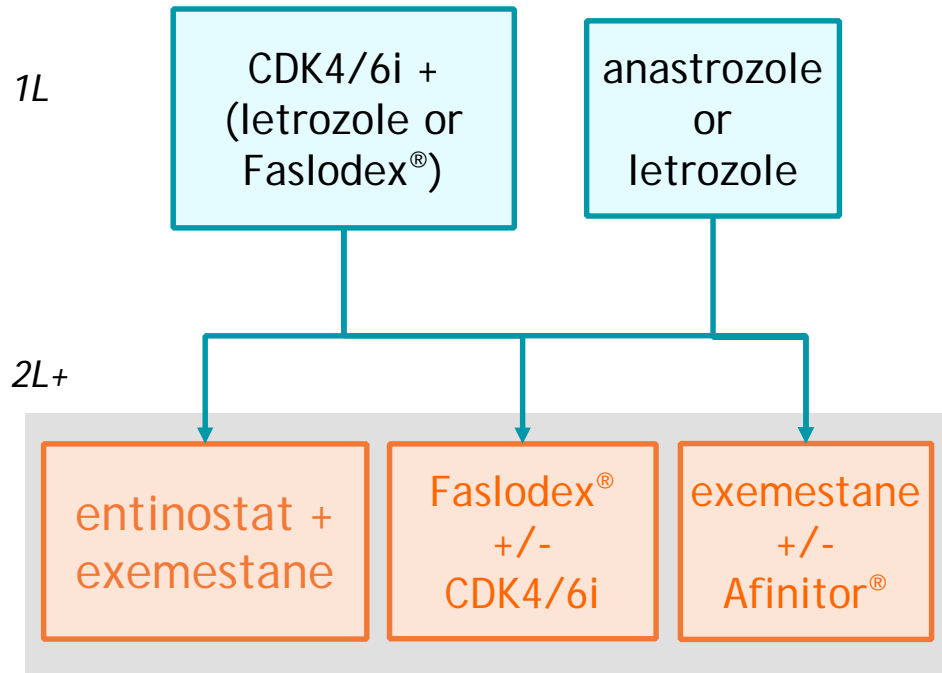
~34,000 patients receive hormone therapy¹ after 1st line

¹LEK estimate

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

Entinostat could supplant Afinitor with a survival benefit

Potential Future SoC -
HR+/HER2- Advanced Breast Cancer



- Additional CDK4/6 inhibitors primarily compete in 1L
- Entinostat + exemestane likely becomes 2L SoC with positive OS

No other combination has shown an OS advantage over hormone therapy alone

Source: DataMonitor 2016 Breast cancer: HR+/HER2- Disease Coverage Report; Novartis 2015 earnings presentation

Company Strategy

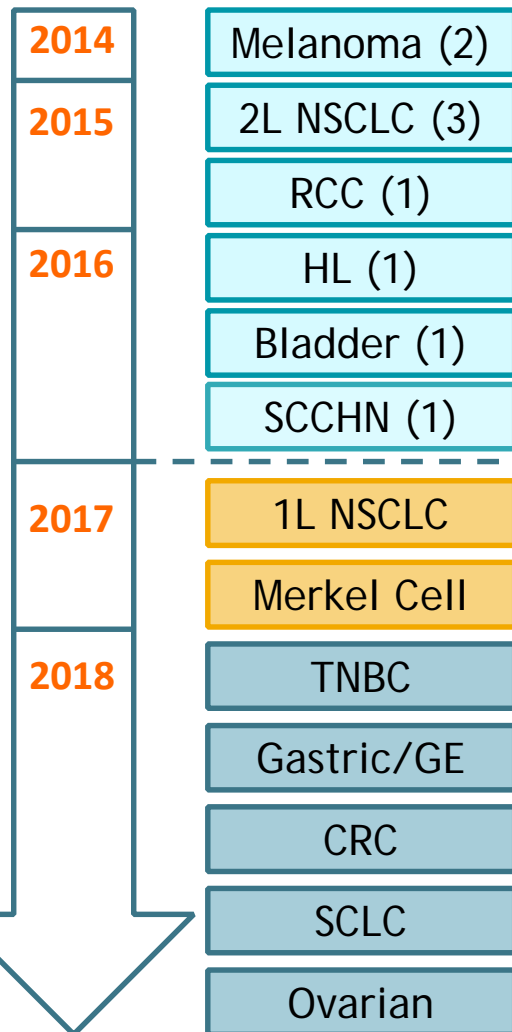
Entinostat
Breast
Cancer

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Immuno-
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New
molecules

Financing & Staffing

Immuno-Oncology (IO) is rapidly defining new therapeutic standards

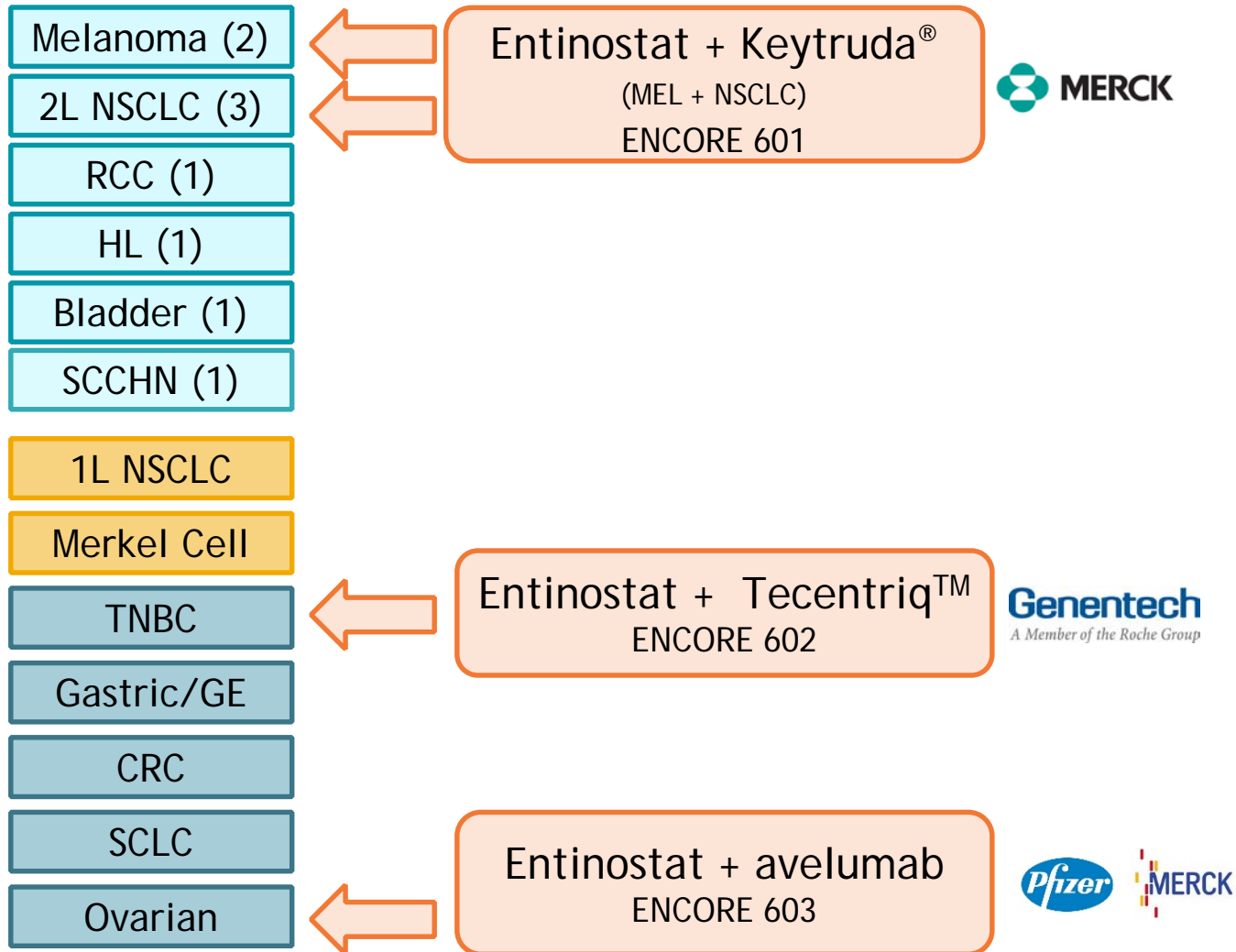


- Since late 2014, three PD(L)-1 inhibitors have received nine FDA approvals for six different tumors

- Recent data suggest additional approvals in 2017
 - Head and neck: Opdivo® trial stopped early
 - 1L PDL-1+ NSCLC: Positive PFS and OS for Keytruda®
 - Merkel Cell: Avelumab filing with Phase 2 data
- Phase 3 results expected in six new tumor types as well NSCLC and melanoma in 2017 and 2018

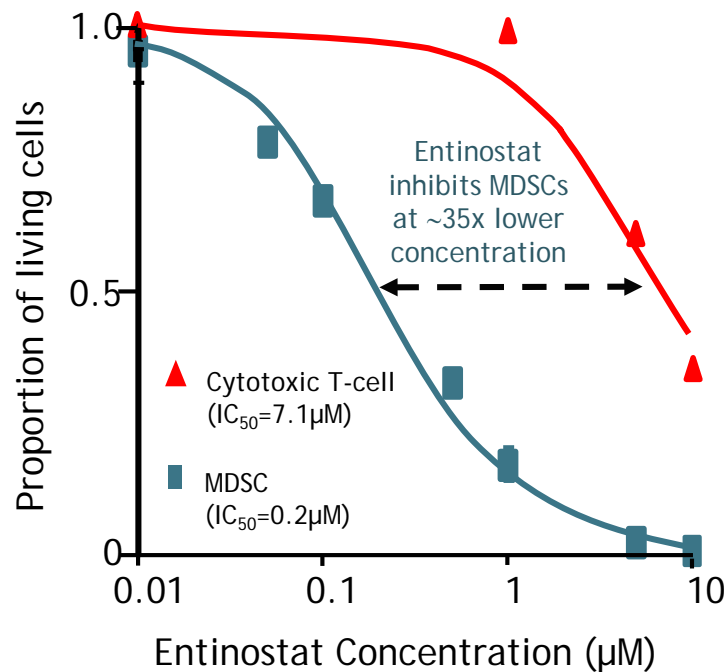
Source: *clinicaltrials.gov*; company press releases

Immuno-Oncology (IO) is rapidly defining new therapeutic standards

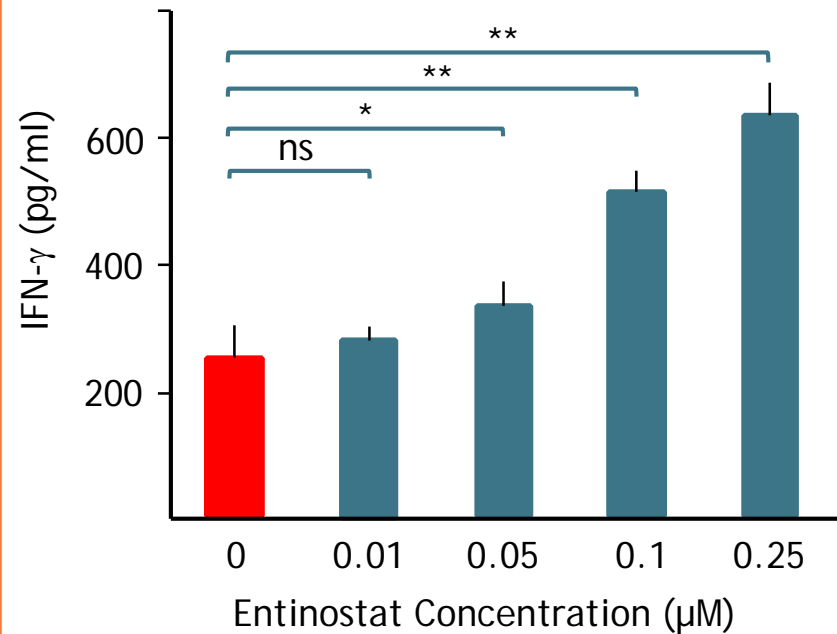


Entinostat inhibits immuno-suppressive cells by reducing their proliferation and function

Entinostat reduces MDSC growth at concentrations that spare cytotoxic T-cells



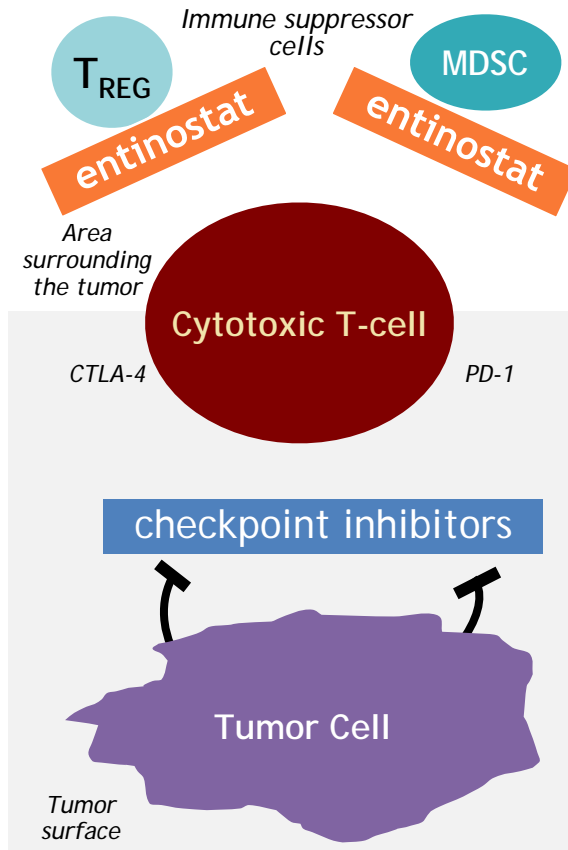
Entinostat inhibits MDSCs function restoring interferon gamma (IFN_γ) secretion by cytotoxic T-Cells



* P < 0.05, ** P < 0.01, ns, not significant

Source: Kim, et al. PNAS 111.32 (2014): 11774-11779

Entinostat's differentiated mechanism targets immuno-suppressive tumor microenvironment



Myeloid-derived suppressor cells (MDSCs)

- Suppress cytotoxic T-cells
- Levels increased in cancer patients
- Higher levels correlate with poor prognosis
- Higher levels correlate with poor response to checkpoint inhibitors

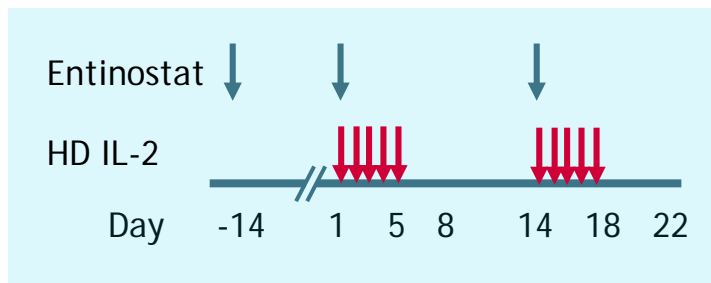
Regulatory T-cells (Tregs)

- Suppress cytotoxic T-cells
- Recruited and activated by cancer cell
- Higher levels correlate with poor prognosis
- Higher levels correlate with poor response to checkpoint inhibitors

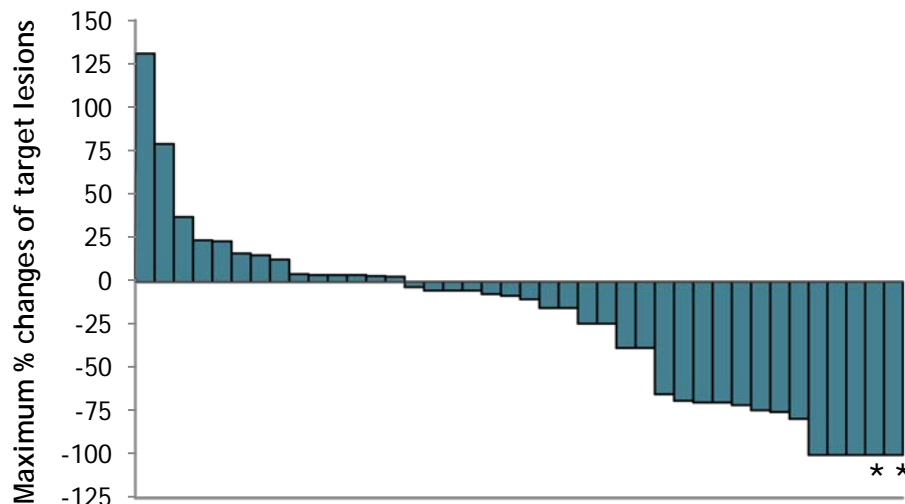
Entinostat may increase anti-tumor effect of high dose IL-2 by modulating immuno-suppressive cells

NCI-7870 Phase 1b/2 Entinostat + High Dose IL-2 in Metastatic Renal Cell Carcinoma

- Is response rate of combo greater than IL-2 alone? (ORR 20%)
- Dosing
 - Entinostat: 3 or 5 mg P.O.
 - HD IL-2: 600,000 U/kg Q8hr



- 41 patients evaluated



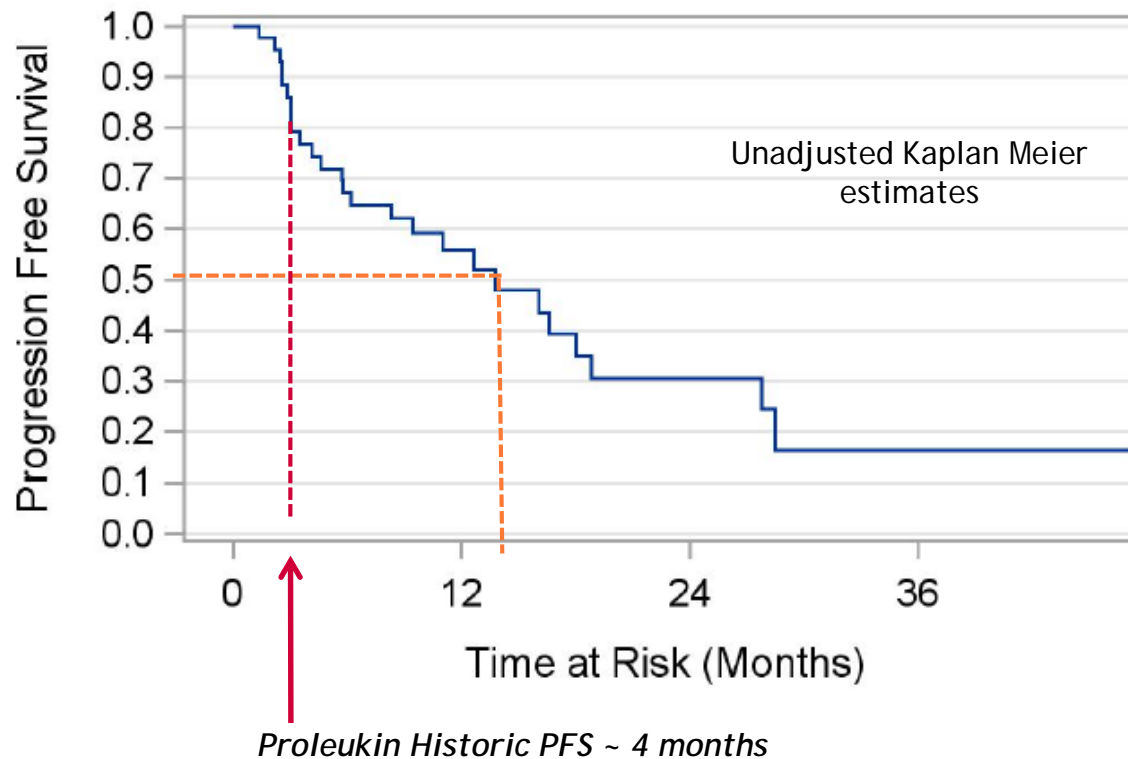
* Subcentimeter non-target lesions present

- Overall Response rate 37% (95% CI 22-53%)
- CR 7% (n = 3)
- PR 29% (n = 12)
- SD > 6 mos 22% (n = 9)

Source: Pili R et al ASCO 2016

Entinostat, IL-2 combination appears to substantially increase median PFS over IL-2 alone

Entinostat - Proleukin median PFS = 13.8 mos [95% CI 6.2,18.8]



Source: Pili R et al ASCO 2016

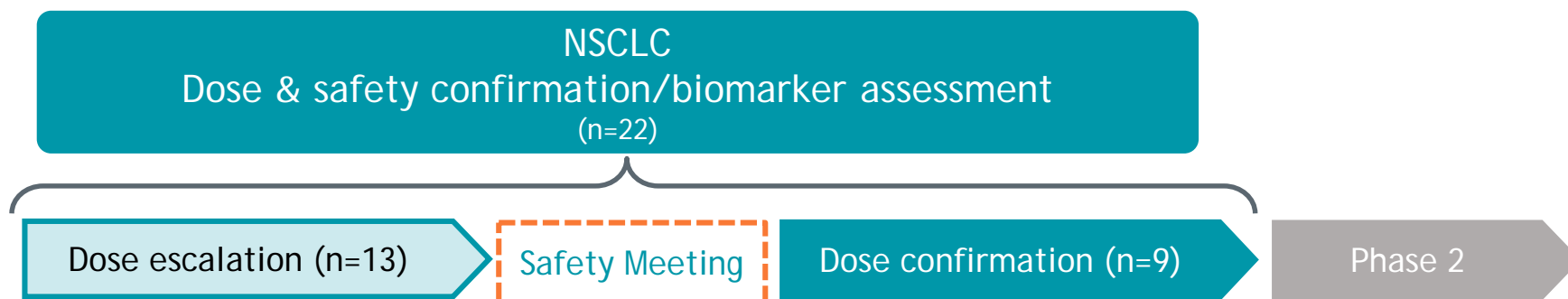
ENCORE 601

First signal-seeking trial

KEYTRUDA® + Entinostat



Phase 1b:
open-label



Phase 1 Trial Milestones:

- Completed accrual for dose escalation stage (3mg and 5mg)
- Positive safety assessment made; 5mg dose progressed
- Dose confirmation safety assessment complete
- Phase 1b data presentation anticipated Q4 2016

ENCORE 601

First signal-seeking trial across 3 indications

KEYTRUDA® + Entinostat



Phase 2:

Simon 2-stage, open-label

Stage 1	Go/No go Threshold	Stage 2	Total n
NSCLC - PD-(L)1 - naïve (n=13)	3/13	NSCLC - PD-(L)1 - naïve (n=33)	n=46
NSCLC - PD-(L)1 - progressors (n=20)	2/20	NSCLC - PD-(L)1 - progressors (n=36)	n=56
Melanoma - PD-(L)1 - progressors (n=13)	2/13	Melanoma - PD-(L)1 - progressors (n=21)	n=34

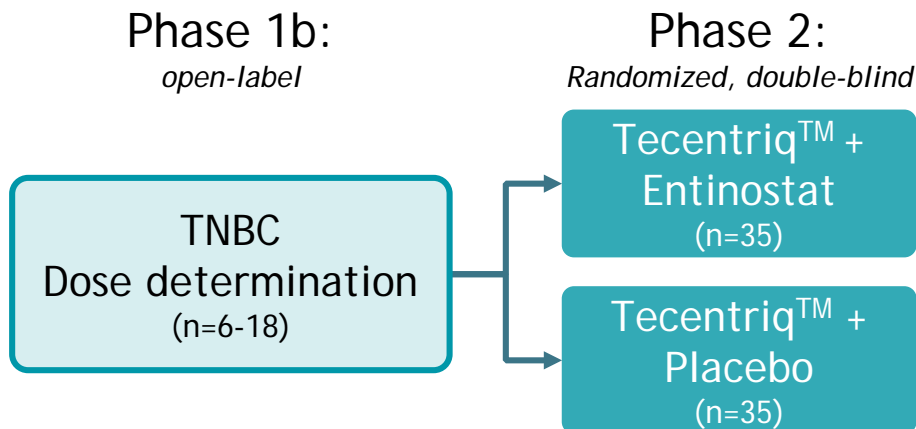
Phase 2 Trial Milestones:

- Phase 2 patient enrollment initiated Q3 2016
- Anticipate making go/no go decision to progress to Stage 2 in Q1 2017

ENCORE 602

Collaboration with another industry innovator

Tecentriq™ +/- Entinostat



Trial Centers

Primary: **UCLA** Health

CRO: Translational Research in
Oncology Group (TRIO)

Primary Endpoints

- Phase 1b - Establish Phase 2 dose
- Phase 2 - PFS using RECIST 1.1

Secondary Endpoints

- ORR
- OS
- Safety & tolerability

Trial Milestones:

- Initiated Phase 1b dose determination stage in June 2016
- Phase 1b data presentation anticipated 1H 2017

ENCORE 603

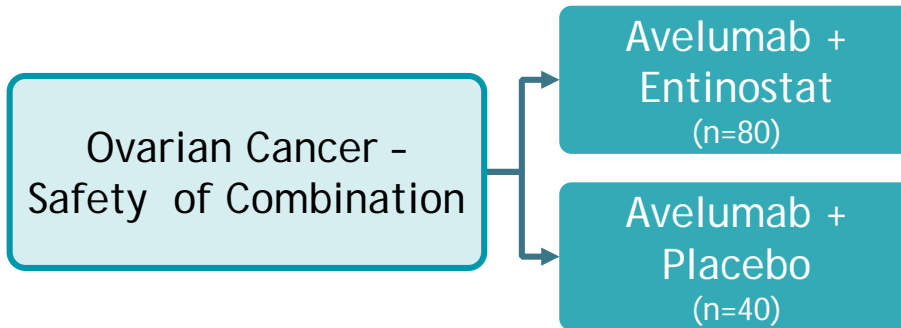
Seeks to demonstrate the breadth of entinostat efficacy

Avelumab +/- Entinostat



Phase 1b:
open-label

Phase 2:
Randomized, double-blind



Primary Endpoints

- Phase 1b - Establish safety of the combination
- Phase 2 - PFS using RECIST 1.1

Secondary Endpoints




- ORR
- OS
- Safety & tolerability

Trial Milestones:

- First patient anticipated to be dosed Q4 2016

ENCORE Clinical Trial Programs

- The ENCORE trials are designed to assess entinostat's ability to enhance checkpoint efficacy
- Entinostat-checkpoint inhibitor combination trials are expected to generate multiple milestones over the next 12 months

Entinostat-checkpoint combinations			Anticipated data presentation	
Trial	Partner	Indication	2H16	1H17
ENCORE 601		NSCLC - PD(L)-1 naïve	Phase 1b RP2D	Phase 2; 1 st Stage
		NSCLC - PD(L)-1 refractory		Phase 2; 1 st Stage
		Melanoma		Phase 2; 1 st Stage
ENCORE 602	 <small>A Member of the Roche Group</small>	TNBC		Phase 1b safety, RP2D
ENCORE 603		Ovarian		Phase 1b safety

RP2D = Recommended Phase 2 Dose

Company Strategy

Entinostat
Breast
Cancer

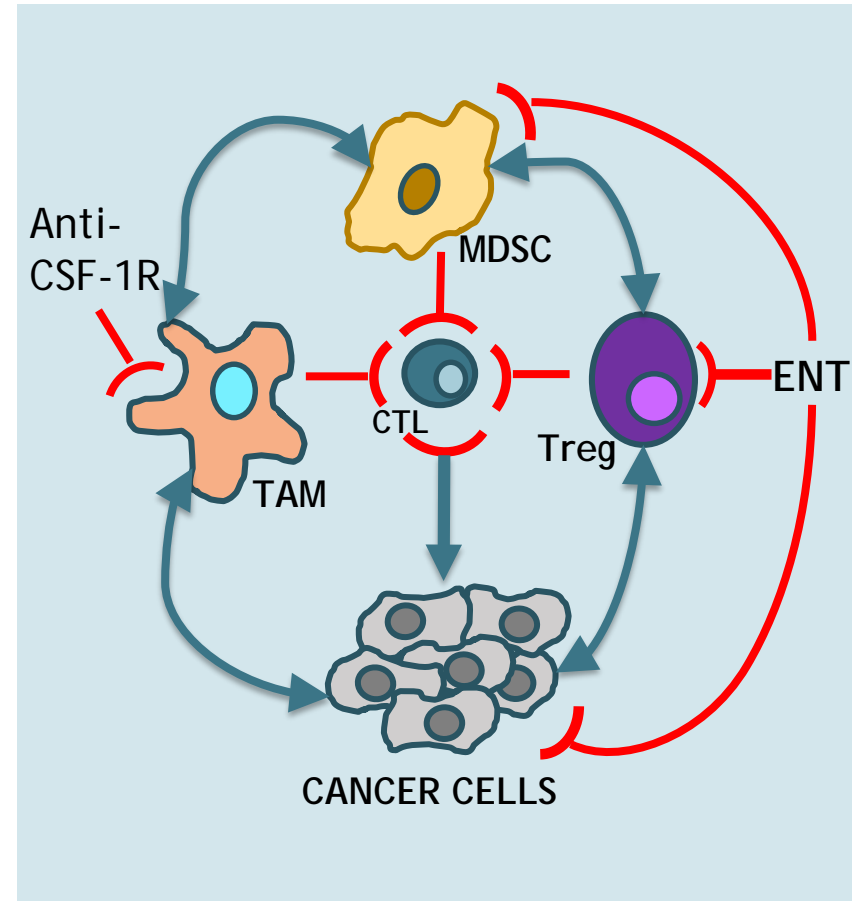
Entinostat
Immuno-
oncology

New
molecules

Financing & Staffing

CSF-1R regulates proliferation, survival, differentiation, and chemotaxis of mononuclear phagocytes

- CSF-1R is expressed on mononuclear phagocytic cells, including immunosuppressive TAMs
- Anti-CSF-1R Ab depletes TAMs and increases tumor infiltrating lymphocytes
 - Inhibition shows clinical activity in diffuse-type giant cell tumor
 - Preclinical synergistic anti-tumor activity seen with immune checkpoint inhibitors

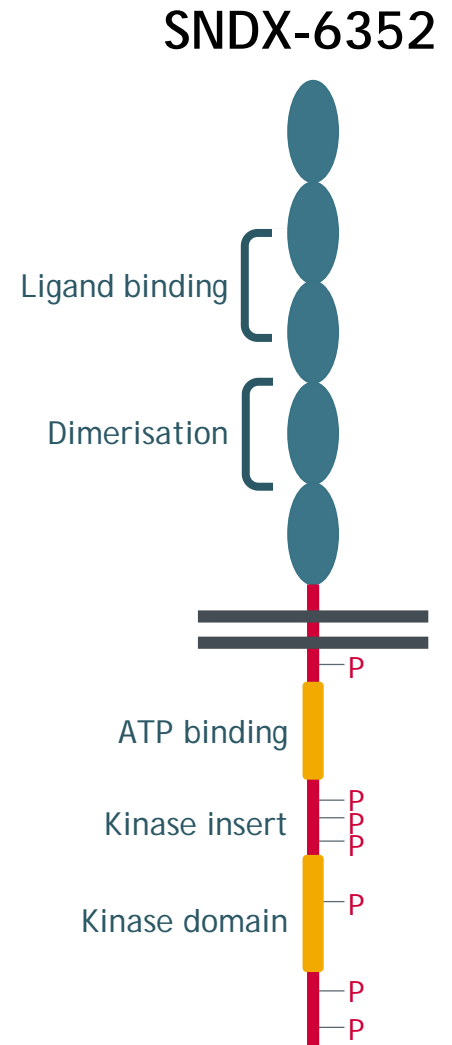


MDSC - myeloid derived suppressor cell; TAM - tumor associated macrophage; Treg - regulatory T lymphocyte; CTL - cytotoxic T cell; ENT - entinostat; CSF-1R - colony stimulating factor -1 receptor

Source: data on file

Syndax anti-CSF-1R antibody properties

- SNDX-6352, developed at UCB as UCB6352
- High affinity, humanized IgG4P ($K_D = 4-8 \text{ pM}$)
- Demonstrated binding to ligand binding domain; blocks CSF-1 and IL-34 binding
- Inhibits ligand induced monocyte activation
- No evidence of antibody mediated receptor internalization or activation
- IND-enabling studies completed by UCB



Source: data on file

Company Strategy

Entinostat
Breast
Cancer

Entinostat
Immuno-
oncology

New
molecules

Financing & Staffing

Anticipated Syndax data announcements

Timing	Study	Indication	Phase	Milestone	Sponsor/Study #
2H16	Entinostat + KEYTRUDA®	NSCLC	1b	RP2D	Syndax/ENCORE 601
1H17	Entinostat + Tecentriq™	TNBC	1b	Safety	Syndax/ENCORE 602
	Entinostat + KEYTRUDA®	NSCLC, MEL	2	Go/No Go 1 st Stage	Syndax/ENCORE 601
	Entinostat + avelumab	Ovarian	1b	Safety	Syndax/ENCORE 603
	SNDX-6352	Solid Tumors	1	SAD	Syndax/TBD
2H17	Entinostat + <i>exemestane</i>	HR+ BC	3	PFS data	NCI/E2112 (Syndax)
	Entinostat + avelumab	Ovarian	1b	RP2D	Syndax/ENCORE 603
	SNDX-6352	Solid Tumors	1	MAD	Syndax/TBD

Cash expected to fund key milestones into mid-2018

Milestones Anticipated

- Achieve PFS endpoint in entinostat Phase 3 clinical trial in advanced HR+ Breast Cancer
 - File NDA for entinostat in HR+ Breast Cancer
- Complete Phase 1b/2 IO-entinostat combination trials with:
 - KEYTRUDA[®] (pembrolizumab)
 - Tecentriq[™] (atezolizumab)
 - Avelumab (phase 1b)
- File IND for SNDX-6352
- Complete SNDX-6352 Phase 1 program

As of 6/30/16: Cash balance \$125.5M¹; Shares Outstanding 17.8 M²

¹ Includes cash, cash equivalents and short-term investments, ² Common stock and common stock equivalents 20.9 M

Thank you. Questions?

Syndax 