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

Date of Report (Date of earliest event reported):
October 7, 2019

SYNDAX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37708**	**32-0162505**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Building D, Floor 3 **35 Gatehouse Drive** **Waltham, Massachusetts**	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 419-1400

(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 (see General Instruction A.2. below):

☐ 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))

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SNDX	The Nasdaq Stock Market, LLC

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 7.01. Regulation FD Disclosure.

Syndax Pharmaceuticals, Inc., a Delaware corporation ("***we***," "***us***," or the "***Company***") announces today that ECOG-ACRIN Cancer Research Group, the sponsor of our Phase 3 registration trial of entinostat plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer, E2112, notified us in advance of their October 24 – 26 biannual group meeting that the trial has passed its fifth and final interim overall survival (OS) analysis. The E2112 trial design was informed by the Phase 2b ENCORE 301 trial, the results of which led to entinostat's Breakthrough Therapy designation in HR+, HER2- breast cancer, in which patients receiving the entinostat/exemestane combination demonstrated a strong OS benefit.

The trial will now continue until the final OS analysis, which will happen when 410 deaths from among the 608 patients enrolled have occurred. Based upon our modeling of the assumed event rate, we expect this final analysis to occur in the second quarter of 2020. We have included in this filing a revised corporate presentation containing the update to the E2112 trial.

A copy of the above referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. This information, including the information contained in the presentation furnished as Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company's filings, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation of the Company dated October 7, 2019.

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.

SYNDAX PHARMACEUTICALS, INC.

By: /s/ Briggs W. Morrison, M.D.
Briggs W. Morrison, M.D.
Chief Executive Officer

Dated: October 7, 2019

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

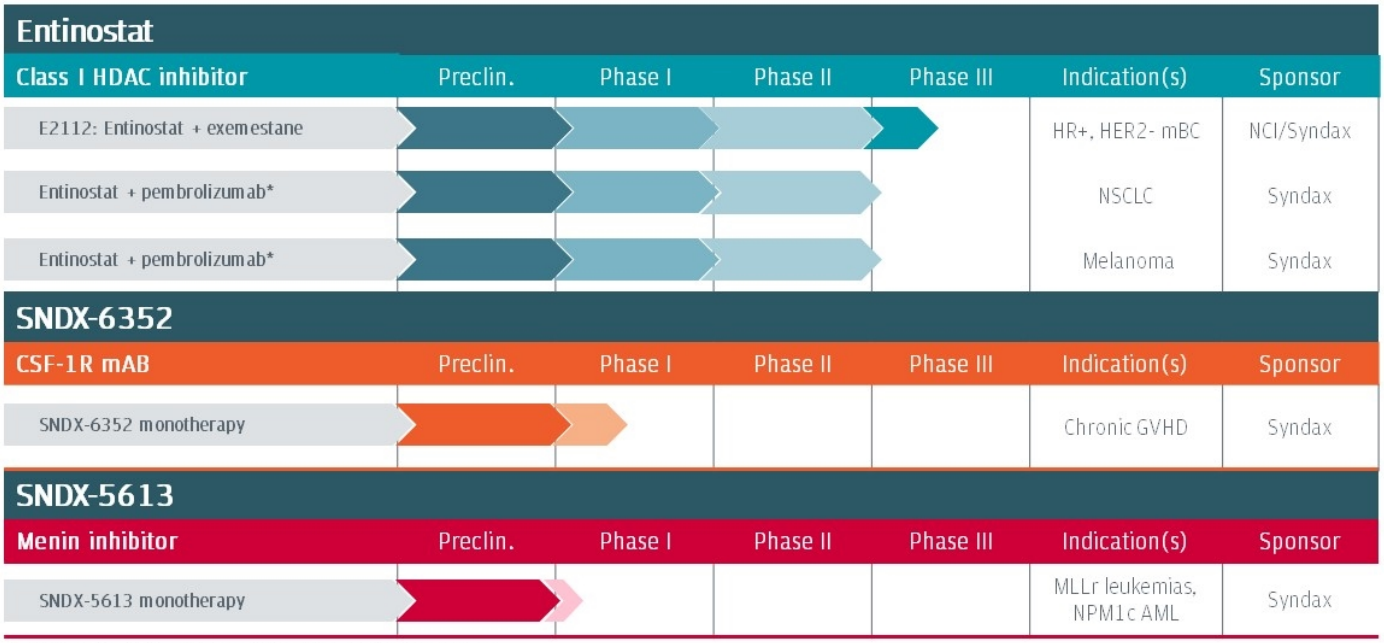
Syndax

CORPORATE PRESENTATION | OCTOBER 2019

Forward-looking statements disclosure

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate" and similar expressions (as well as other words or expressions referencing future events or circumstances) are intended to identify forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding future operations, financial results and the financial condition of Syndax Pharmaceuticals, Inc. ("Syndax" or the "Company"), including financial position, strategy and plans, the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for Syndax's product candidates, and Syndax's expectations for liquidity and future operations, are forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, failure of our collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Moreover, Syndax operates in a very competitive and rapidly changing environment. Other factors that may cause our actual results to differ from current expectations are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. New risks emerge from time to time. It is not possible for Syndax's management to predict all risks, nor can Syndax assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied. Except as required by law, neither Syndax nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Syndax undertakes no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in Syndax's expectations.

Syndax Current Pipeline



* Development on hold pending positive E2112 OS trial results

2019: Portfolio prioritization to drive value

Entinostat + exemestane

FDA BTD

Oral, Class I HDAC in HR+ mBC

- Positive OS data possible 2Q20
- NDA filing anticipated 2H20
- Efficacy in CDK4,6 treated patients
- Blockbuster potential

Potential near-term FDA approval

SNDX-5613

Oral, Menin inhibitor

- Blocks activity of MLL-fusion proteins
- IND cleared; initial data expected 2020
- Benefit expected in high need AML, ALL
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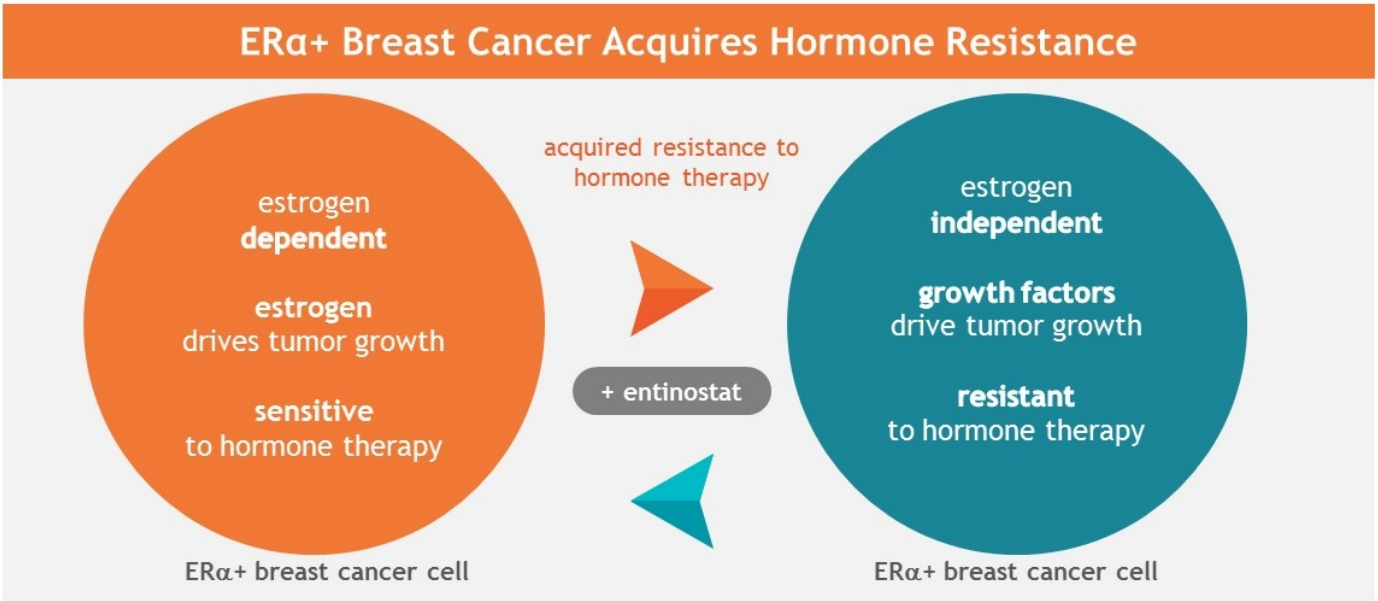
Targeted therapy provides fast to market opportunity

HR+ mBC - hormone receptor positive metastatic breast cancer; MLL - mixed lineage leukemia; AML - acute myeloid leukemia; ALL - acute lymphoblastic leukemia

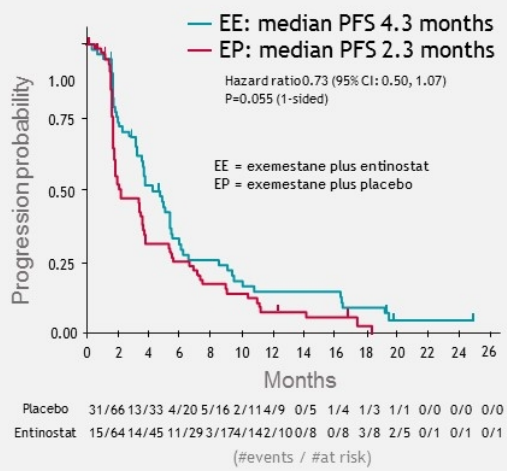

Entinostat
Breast Cancer
Immuno-oncology
SNDX-5613
Menin inhibitor
Leukemias
SNDX-6352
anti-CSF1R Ab
Immuno-oncology
GvHD
New molecules
Oncology

Entinostat re-sensitizes cancer cells

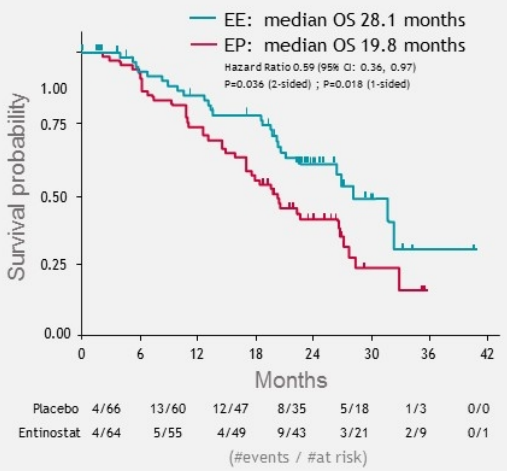


Phase 2 trial resulted in breakthrough therapy designation

Progression-free Survival

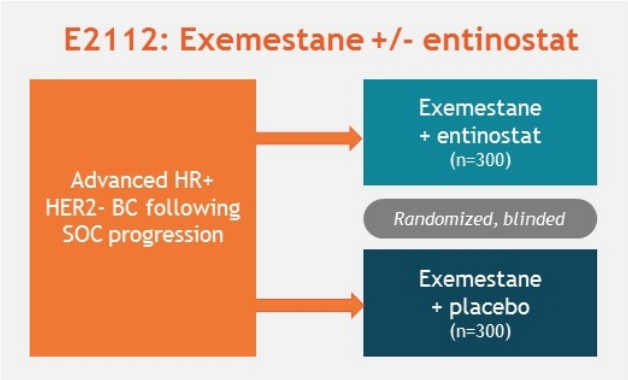


Overall Survival



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

Phase 3 E2112: Focused on overall survival



Primary endpoint: OS

FDA BTD

NATIONAL CANCER INSTITUTE

ECOG-ACRIN cancer research group
Reshaping the future of patient care

Syndax

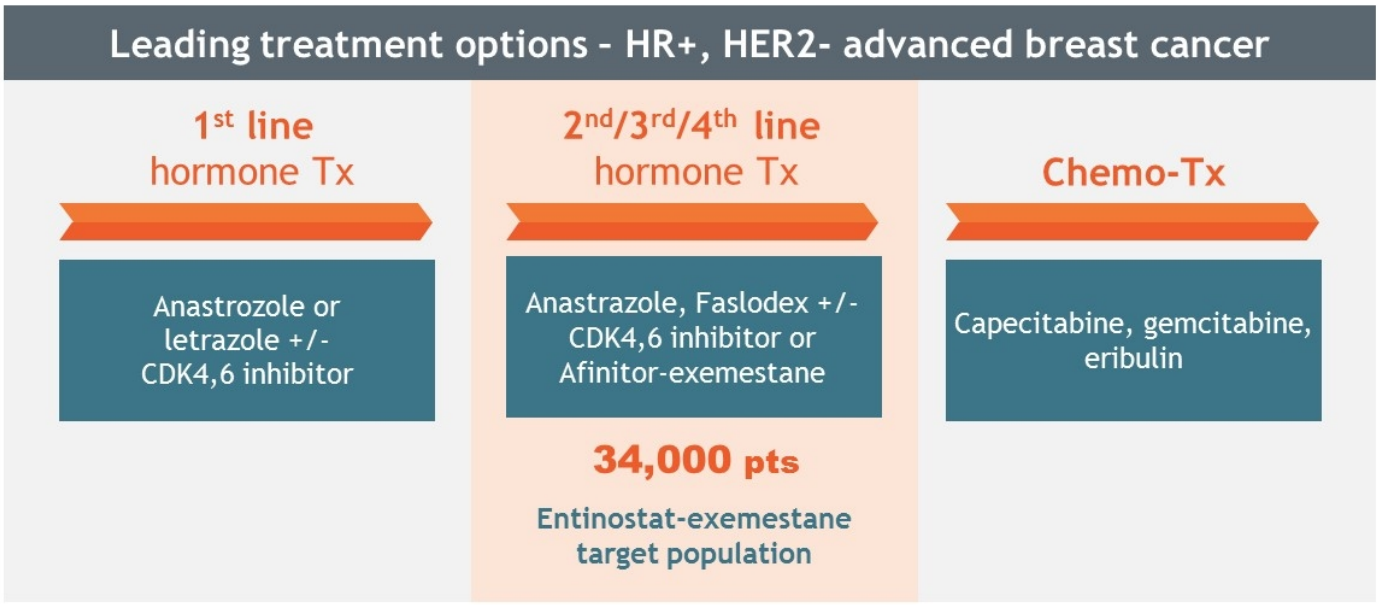
E2112 Trial Milestones

- ✓ **4Q18:** Accrual completed (n=608), PFS and interim OS analyses shared
- ✓ **4Q19:** Passed final interim OS futility
- **2Q20:** Final OS analysis

Expect to file NDA ~6 months after positive OS data

A positive OS result allows filing for full regulatory approval

Blockbuster potential as 2nd/3rd line agent



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


Entinostat
Breast Cancer
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Menin inhibitor
Leukemias
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anti-CSF1R Ab
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GvHD
New molecules
Oncology

SNDX-5613 targets novel fusion protein: fusion proteins proven to be good candidates for targeted therapies

Advantages

- Strong target validation
- Precise patient selection
- Big effect in small studies
- Molecular markers of disease status
- Rapid regulatory path

Therapies targeting fusion proteins

BCR-ABL

Tasigna
SPRYCEL dasatinib
ICLUSIG (ponatinib) tablets
gleevec

EML4-ALK

ZYKADIA ceritinib
ALUNBRIG BRIGATINIB
XALKORI CRIZOTINIB
ALECENSA alectinib

NTRK Fusions

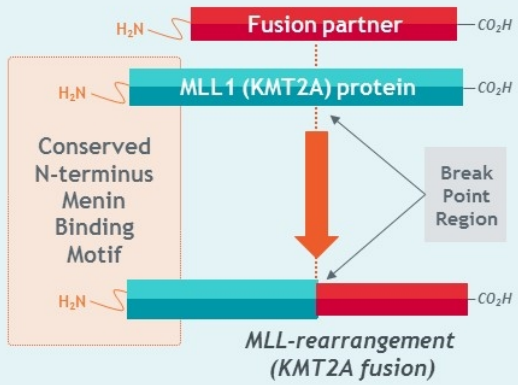
VITRAKVI (larotrectinib)
ROZLYTREK entrectinib 100mg | 200mg capsules

RET Fusions

LOXO-292 (Loxo/Lilly)
ALECENSA alectinib
BLU-667 (Blueprint)

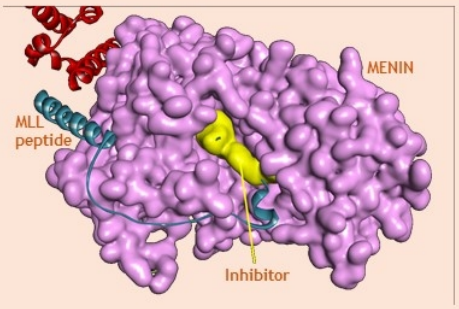
In MLLr, leukemic transformation is highly dependent on the Menin-MLL interaction

MLL1 Transformations



MLL1 fusion partner recruits oncogenic factors to transcription site[1]

Menin

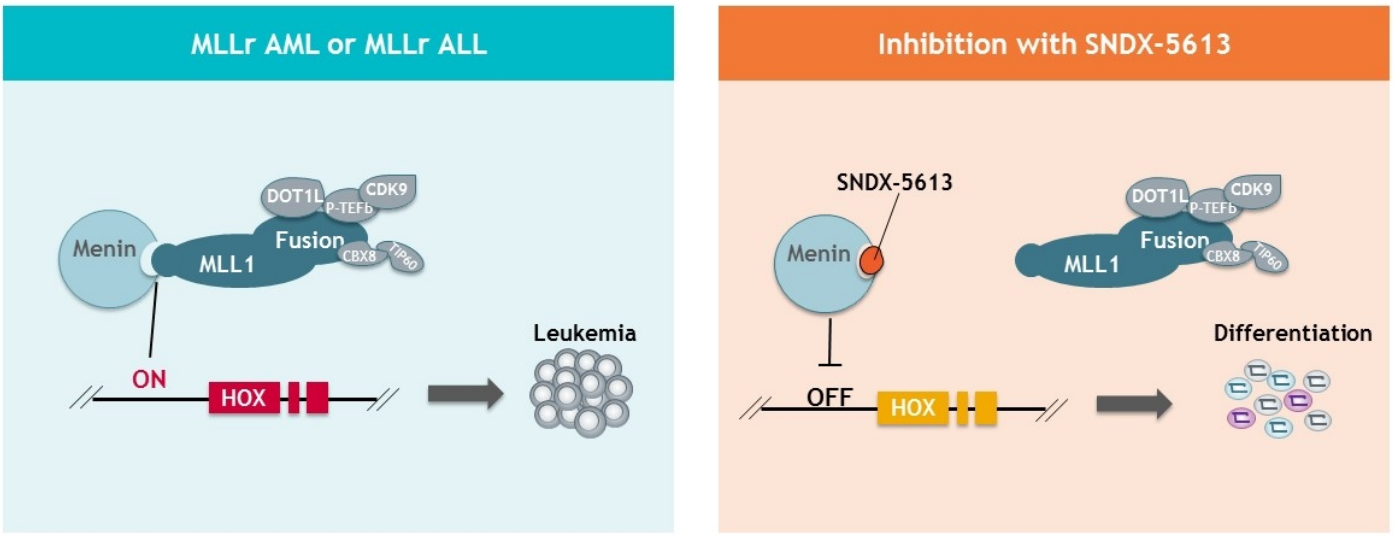


- Menin is a scaffold protein involved in gene transcription
- MLL1 N-terminus binds w/in conserved pocket on Menin

SNDX-5613 designed to block site of interaction

Source: Yokoyama A, Cell. 2005 Oct 21;123(2):207-18; Caslini C, *Cancer Res. 2007* Aug 1;67(15):7275-83.

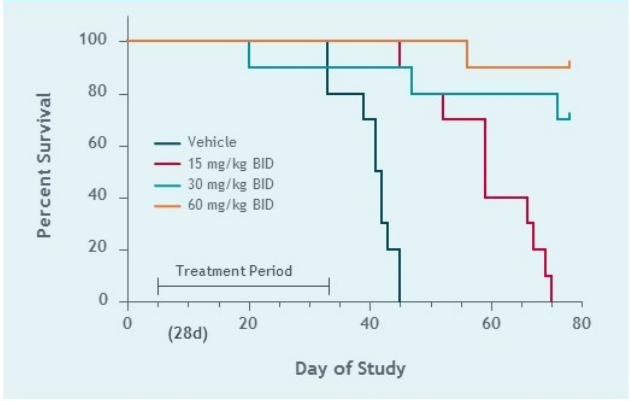
Binding of Menin to MLL1 leads to upregulation of HOX gene transcription and leukemia in MLLr AML and MLLr ALL



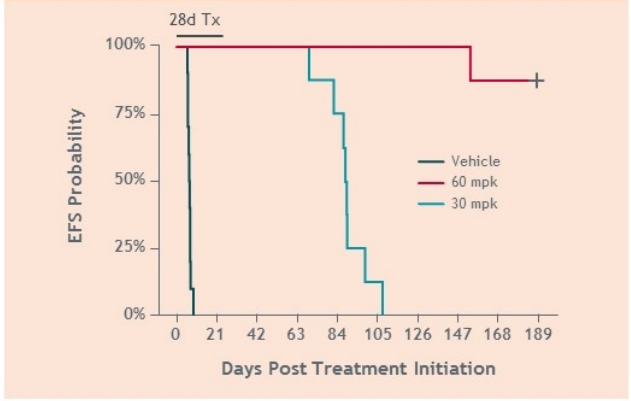
Adopted from: Uckelmann HJ, et al. Presented at ASH Annual Meeting, 2018.

Menin-MLL inhibition significantly prolongs survival in MLLr xenograft models

MLLr Cell Line Xenograft (MV4;11) (SNDX-469)



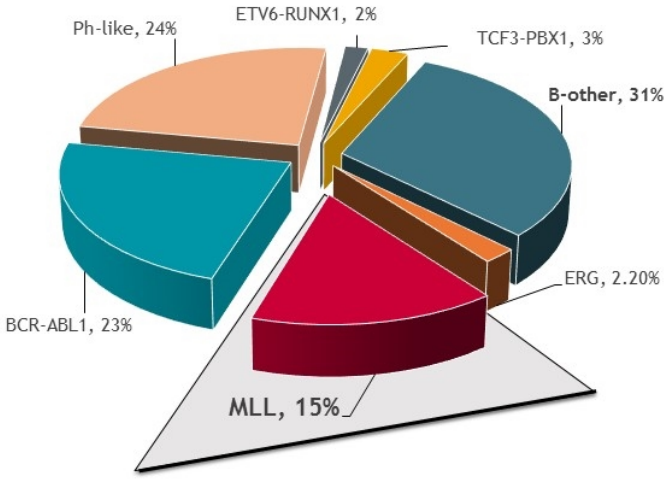
Patient Derived Xenograft (PDX) MLL-AF4 (SNDX-469)



SNDX-469 shows profound, single agent treatment benefit in multiple models

Source: Kristov, A., 2018 American Association for Cancer Research annual meeting

SNDX-5613 potentially effective in MLLr – ALL; distinct molecular subtype of ALL conferring a worse prognosis



5-year survival

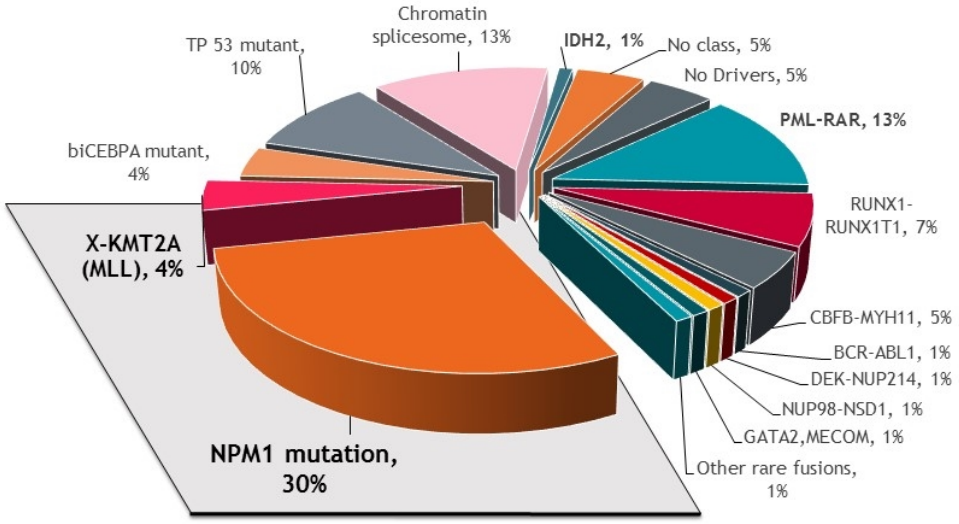
Pediatric ALL: 75%-90%

MLLr ALL: ~50% for infants and ~60% >1 yr

WW incidence ~1,000/yr
10-15% ALL, 80% infant ALL

Adopted from: Shah, B. and Nasello, D. Jan 2019; NCCN conference and meetings: Update on Management of Acute Lymphoblastic Leukemia.

SNDX-5613 poised to target MLLr and NPM1 classes of AML; distinct subsets representing ~34% of AML



WW Incidence

MLLr AML (4 - 10% AML)
~3,000 patients / year

NPM1 AML (30% AML)
~20,000 patients / year

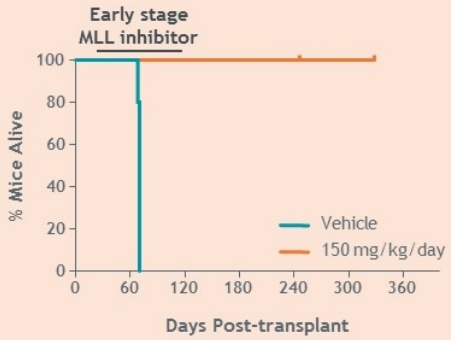
AML 5 yr survival 5% - 55%

Adopted from: Dohner, H. et al. Blood, 2017; 129(4):424-447

Preclinical models of NPM1 AML reveal profound single agent activity of Menin inhibition

- NPM1 mutation is the most frequent molecular alteration in AML
- Like MLLr, NPM1 AML depends on genes known to be sensitive to Menin-MLL interaction
- Standard AML screening identifies NPM1 mutation today

NPM1c; FLT3 ITD; PHF6 mice
(treated with SNDX-469 or vehicle)

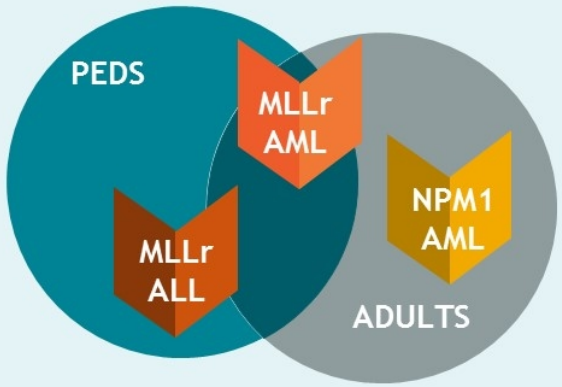


NPM1 transfected mice showed profound single agent survival benefit with SNDX-469 in multiple PDX models

Source: Kühn MW, *Cancer Discov.* 2016 Oct;6(10):1166-1181; Kristov, A., 2018 American Association for Cancer Research annual meeting

SNDX-5613: potential best-in-class, targeted, oral agent with single agent activity and fast to market potential

Phase 1/2 trial population:
MLLr adult, MLLr peds, NPM1 mut AML

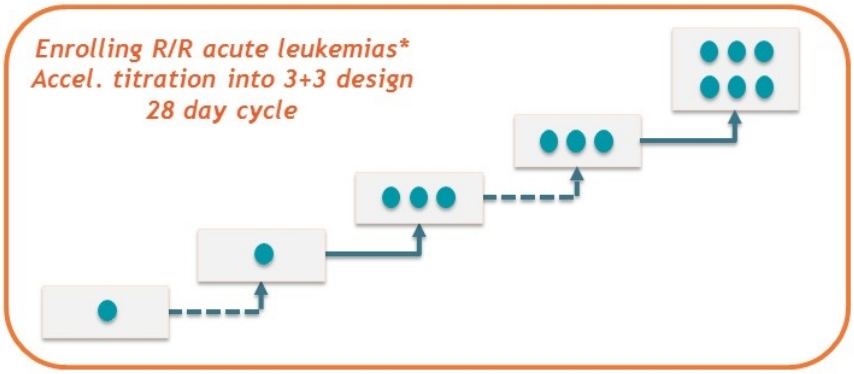


Defined fast to market pathway

- **IND cleared; AUGMENT program init.**
  - Initial data expected in 2020
- **MLLr and NPM1 identified today with standard screening protocols**
- **No approved therapies targeting MLLr or NPM1 acute leukemias**
  - $$B commercial opportunity

AUGMENT clinical program: testing oral Menin inhibitor, SNDX-5613, in patients with acute leukemia

Phase 1:
Dose escalation



Endpoints: Safety, PK, RP2D

Phase 2:
Expansion

- Adult MLL-r ALL
- Adult MLL-r AML
- Adult NPM1 mut AML

Primary endpoint:
CR Rate (CR + CRh^)

* Unselected population; ^ CR = Complete response, CRh = Complete response with partial hematologic recovery; MLL-r - mixed lineage leukemia rearranged; NPM = nucleophosmin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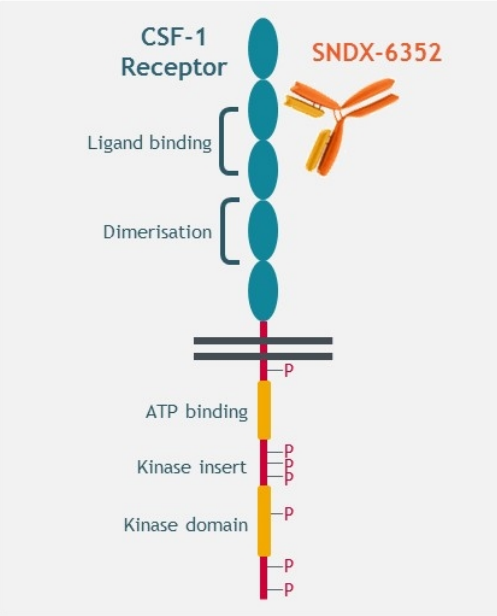
Update on SNDX-6352: pursuing novel indication

High affinity, IgG4 (K_D = 4-8 pM)

- ✓ Chronic graft versus host disease (cGVHD) study initiated
  - Expect phase 1 dose escalation results in 2H20
- ✓ Ascending dose trials:
  - ✓ Identified RP2D in combo with IMFINZI® (durvalumab, AZ)
  - Monotherapy (solid tumors) ongoing



CSF-1R - colony stimulating factor -1 receptor; RP2D recommended Phase 2 dose.
Source : Ordentlich, P. et al SITC 2016.

2Q 2019 financial highlights and 3Q, full-year 2019 guidance

Ticker	SNDX (NASDAQ)	
As of June 30, 2019		
Cash and short-term investments	$80.5 million	
Shares Outstanding*	31.6 million	
2019 3Q and full year Operating Expense Guidance		
	3Q 2019	**2019**
Research and Development	$11 - 12 M	$45 - 47 M
Total Operating Expenses^	$15 - 16 M	$60 - 63 M

** Includes 27.1 million common shares and pre-funded warrants to purchase 4.5 million common shares*

^ Includes $1.5 and $6 million non-cash stock compensation expense for 3Q 2019 and for 2019, respectively

Key upcoming milestones

ENTINOSTAT (Class 1 specific HDAC inhibitor)	4Q19	1Q20	2Q20	2H20
E2112 - Final OS analysis expected			●	

SNDX-5613 (Menin inhibitor)	4Q19	1Q20	2Q20	2H20
Results from phase 1 portion of AUGMENT (in R/R acute leukemias)		▬	▬	▬

SNDX-6352 (anti-CSF-1R mAB)	4Q19	1Q20	2Q20	2H20
Results from Phase 1 chronic GVHD trial				●

2019: Portfolio prioritization to drive value

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Thank you. Questions?
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