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):
December 10, 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 8.01. Other Events.

Syndax Pharmaceuticals, Inc. ("***our***," "***we***," or the "***Company***") issued a press release today announcing that we plan to commence a Phase 2 expansion study of SNDX-6352, our anti-CSF-1R monoclonal antibody, for the treatment of chronic graft versus host disease ("***cGVHD***"). We have also included in this filing a revised corporate presentation containing the update to the cGVHD trial. A copy of the press release is filed herewith as Exhibit 99.1 and a copy of the presentation is filed herewith as Exhibit 99.2. The information contained in each of the press release and presentation is incorporated by reference into this Current Report on Form 8-K.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements," including, but not limited to, statements regarding the Company's development plans for SNDX-6352 for patients with cGVHD. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "could," "expects," "plans," "anticipates," "believes," and similar expressions intended to identify forward-looking statements. These statements reflect the Company's current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Any forward-looking statements set forth in this Current Report speak only as of the date of this Current Report. The Company does not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof other than as required by law. You are cautioned not to place undue reliance on any forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated December 10, 2019.
99.2	Presentation of the Company dated December 10, 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: December 10, 2019

Syndax

Syndax Pharmaceuticals Announces Plans to Commence Phase 2 Expansion Cohort of SNDX-6352 for the Treatment of Chronic Graft Versus Host Disease

- Preliminary Phase 1 results demonstrate inhibition of CSF1R leads to responses in patients with cGvHD -

- Phase 2 expansion expected to commence in 1Q20 -

WALTHAM, Mass., December 10, 2019 -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced that it plans to commence a Phase 2 expansion cohort based on encouraging clinical activity and a well-tolerated safety profile observed to date in the ongoing Phase 1 dose escalation trial of SNDX-6352 in patients with chronic graft versus host disease (cGVHD). SNDX-6352 is the Company's anti-CSF-1R monoclonal antibody.

The ongoing Phase 1, open-label, modified 3+3 dose escalation trial is designed to evaluate the safety and preliminary efficacy of SNDX-6352 in up to 30 patients with cGVHD who have received at least two prior lines of therapy. As of a November 25, 2019 data cutoff date, a total of five patients, all of whom received prior treatment with ibrutinib, steroids, and a calcineurin inhibitor, have been enrolled across three dose cohorts: one patient was treated at 0.15 mg/kg every two weeks (Q2W, Cohort 1), one is receiving a dose of 0.5 mg/kg Q2W (Cohort 2), and three patients are receiving 1.0 mg/kg Q2W (Cohort 3).

Responses have been observed in all evaluable patients as of the data cutoff date, with no dose limiting toxicities (DLTs) reported. Among the three patients dosed in Cohort 3 (1.0 mg/kg Q2W), one patient recently cleared the DLT period and has not yet been evaluated for efficacy, two patients experienced a partial response, and all three patients remain on therapy. The patient in Cohort 2 experienced a partial response and is currently in their ninth month of treatment with SNDX-6352 following prior treatment with ibrutinib and both Jakafi® (ruxolitinib) and KD025, two agents currently being investigated for the treatment of cGVHD. The first patient (Cohort 1) achieved a partial response but discontinued in their third cycle due to elevated LFTs attributed to progression in their liver cGVHD. Cohort 4, which will explore a 3.0 mg/kg Q2W dose, is now open for enrollment.

"The initial results from our Phase 1 trial underscore the potential of SNDX-6352 to serve as an effective therapy for patients with cGVHD who are lacking alternative options," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "We had not anticipated commenting on data from this initial trial until the second half of 2020, so it is quite encouraging to see the early signs of activity in patients with this difficult to treat disease. Based on these results, we have decided to advance into a Phase 2 expansion cohort to evaluate additional patients at the 1.0 mg/kg dose while we continue the dose escalation to 3.0 mg/kg. We continue to expect to present the Phase 1 trial results in the second half of 2020.

"Published preclinical data have demonstrated that CSF-1R blockade can prevent and treat disease in animal models of cGVHD[1]," said Peter Ordentlich, Ph.D., Chief Scientific Officer and Co-founder of Syndax. "The initial data from our trial provide the first clinical evidence that targeting CSF-1R dependent macrophages may benefit patients with cGVHD."

To date, SNDX-6352 has been safe and well-tolerated, with no DLTs observed. Dose escalation is ongoing in the Phase 1 portion of the trial. The Phase 2 expansion cohort is expected to enroll up to 22 patients to further characterize the safety and efficacy at an initial dosing schedule of 1.0 mg/kg of SNDX-6352 administered every two weeks.

About Chronic Graft Versus Host Disease

Chronic graft versus host disease (cGVHD), an immune response of the donor-derived hematopoietic cells against recipient tissues, is a serious, potentially life-threatening complication of allogeneic hematopoietic stem cell transplantation (HSCT) which can last for years. cGVHD is estimated to develop in approximately 40% of transplant recipients, and affect approximately 14,000 patients in the US. [2-4] cGVHD typically manifests across multiple organ systems, with the skin and mucosa being commonly involved, and is characterized by the development of fibrotic tissue.

About SNDX-6352

SNDX-6352 is an investigational monoclonal antibody that targets colony stimulating factor-1 receptor, or CSF-1R, a cell surface protein thought to control the survival and function of monocytes and macrophages. In pre-clinical models, inhibition of signaling through the CSF-1 receptor has been shown to reduce the number of disease-mediating macrophages and the development of cutaneous and pulmonary chronic graft versus host disease (cGVHD), as well as to lead to the depletion of cells known as Tumor Associated Macrophages, or TAMS. SNDX-6352 is currently being evaluated in a Phase 1 multiple ascending dose clinical trial in cGVHD, and a Phase 1 multiple ascending dose clinical trial as monotherapy and in combination with Infinzi® (durvalumab) in solid tumors. SNDX-6352 has the potential to treat a variety of solid tumor and immune-related diseases.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company's lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, is being tested in a Phase 3 combination trial with exemestane for treatment of advanced HR+, HER2- breast cancer and has been evaluated in combination with several approved PD-1/PD-(L)1 antagonists. The Company's pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these

forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for Syndax's product candidates, and the potential use of our product candidates to treat various cancer indications. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical trials, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Syndax's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

References

1. Alexander, KA. et al. J Clin Invest. 2014;124(10):4266–4280.

2.Kantar GVHD Expert Interviews N=8 interviews

3. SmartAnalyst 2017 SmartImmunology Insights chronic GVHD report.

4. Bachier, CR. et al. ASH annual meeting 2019; abstract #2109 Epidemiology and Real-World Treatment of Chronic Graft-Versus-Host Disease Post Allogeneic Hematopoietic Cell Transplantation: A U.S. Claims Analysis.

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SNDX-G

Exhibit 99.2

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

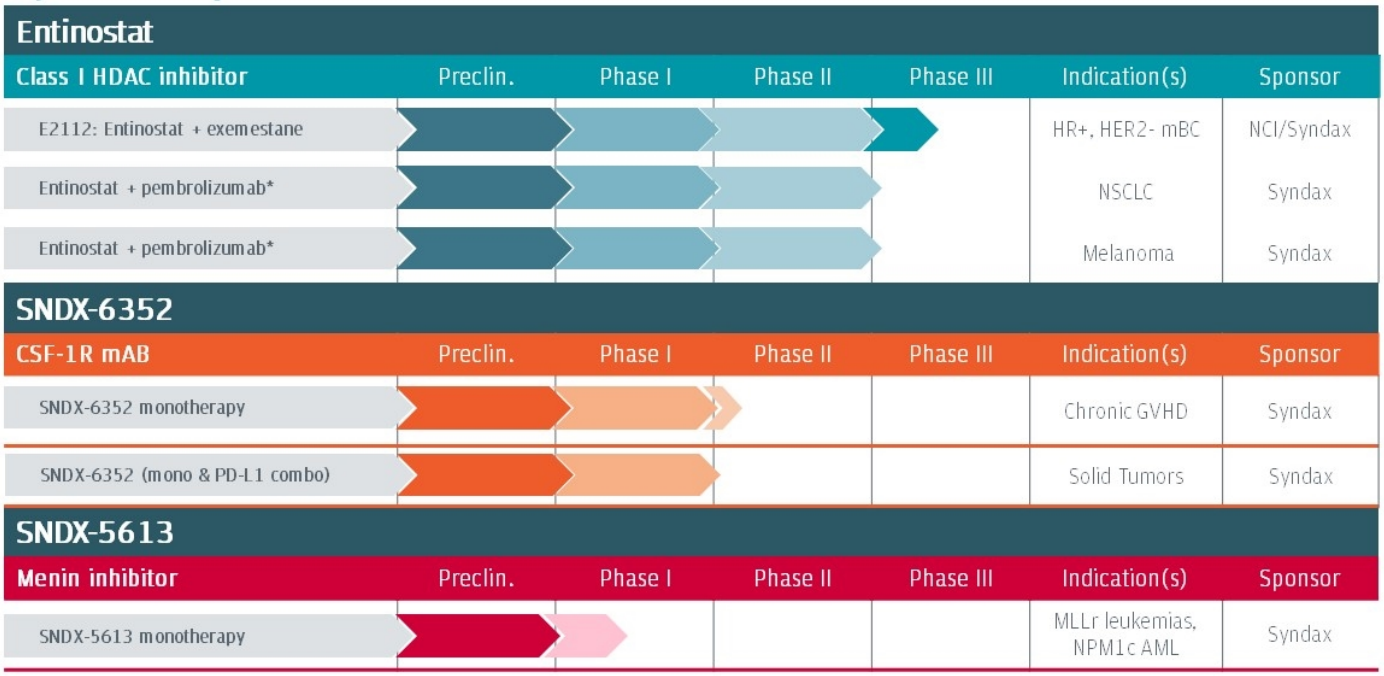
Syndax

CORPORATE PRESENTATION | DECEMBER 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.

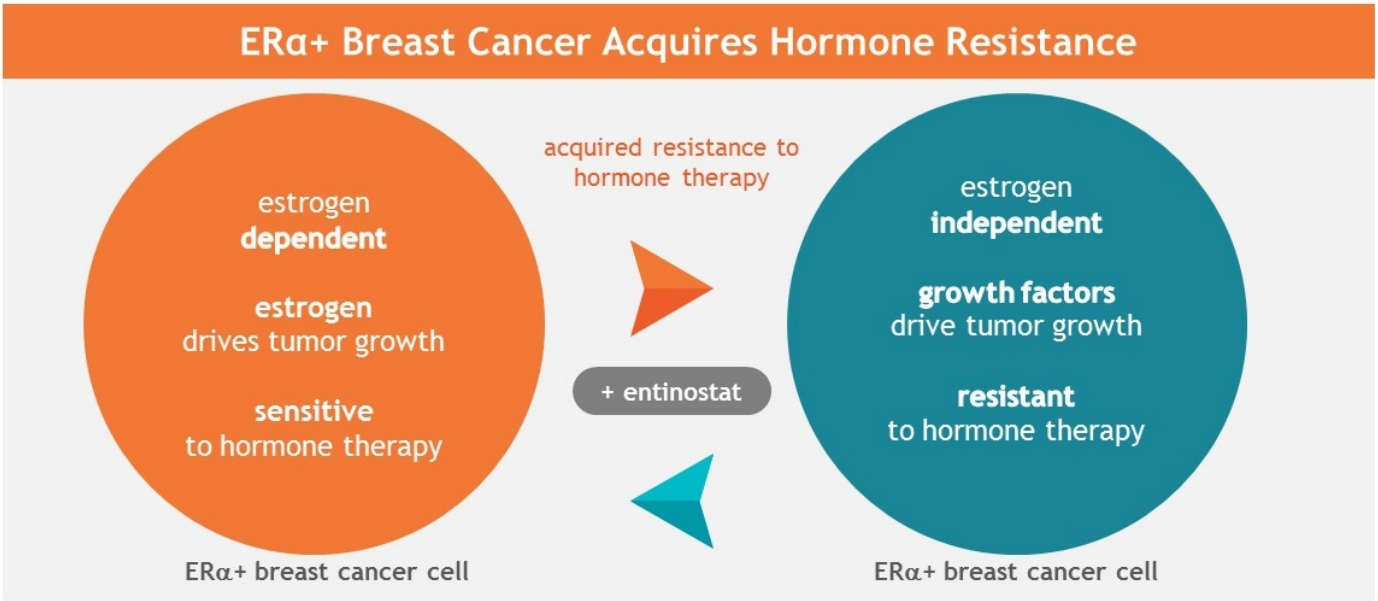
Syndax Pipeline



* Development on hold pending positive E2112 OS trial results

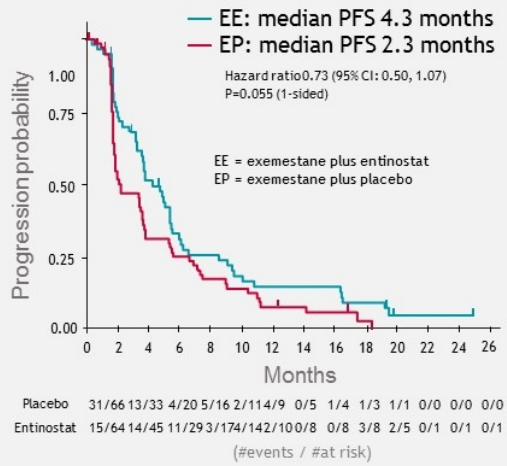

Entinostat
Breast Cancer
SNDX-5613
Menin inhibitor
Leukemias
SNDX-6352
anti-CSF1R Ab
cGVHD

Entinostat re-sensitizes cancer cells

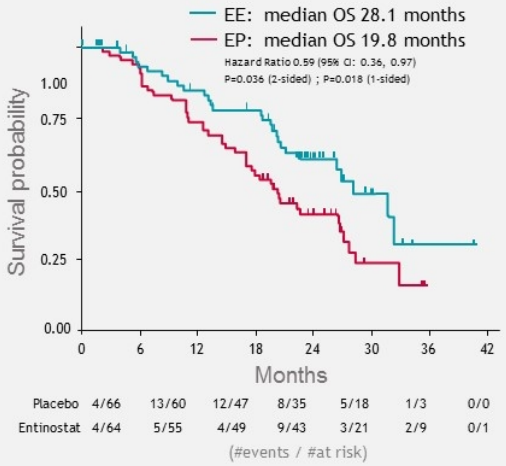


Phase 2 trial resulted in breakthrough therapy designation

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

E2112: Exemestane +/- entinostat

Primary endpoint: OS

FDA BTD

National Cancer Institute

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

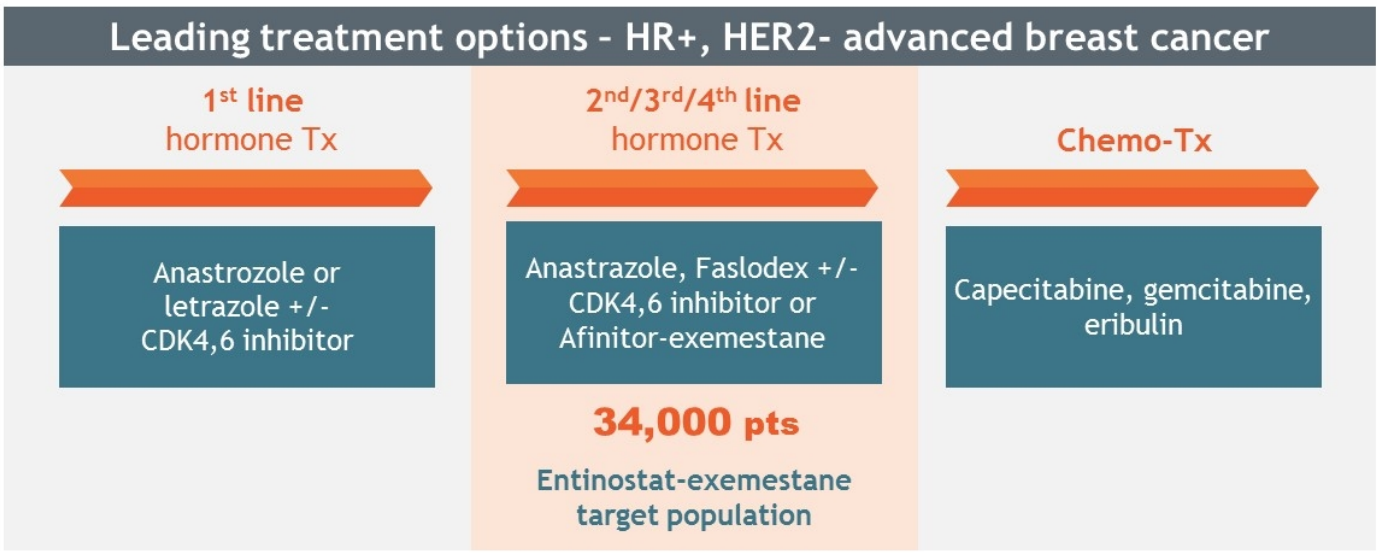
Syndax

E2112 Trial Assumptions

- **80% power** to detect HR = 0.75
- **Minimal** HR detectable = 0.82
  - Equates to a clinically meaningful risk reduction and ~5 mo mOS benefit
- **2Q20:** Final OS analysis anticipated

A positive OS result allows filing for full regulatory approval

Blockbuster potential as 2nd/3rd line agent



US commercial launch preparation underway

Source: DataMonitor 2017 Breast cancer: HR+/HER2- Disease Coverage Report; IQUVIA Monthly treatment report (2018)


Entinostat
Breast Cancer
SNDX-5613
Menin inhibitor
Leukemias
SNDX-6352
anti-CSF1R Ab
cGVHD

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 · XALKORI CRIZOTINIB · ALUNBRIG BRIGATINIB · ALECENSA alectinib

NTRK Fusions

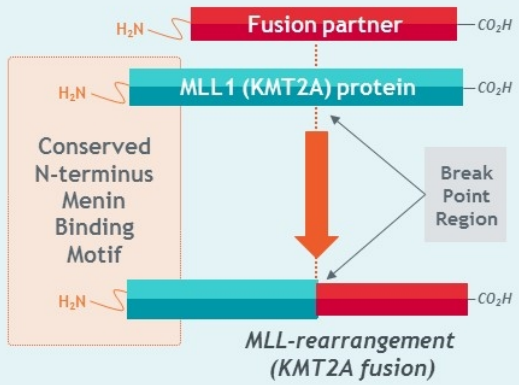
VITRAKVI (larotrectinib) · ROZLYTREK entrectinib 100mg | 200mg capsules

RET Fusions

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

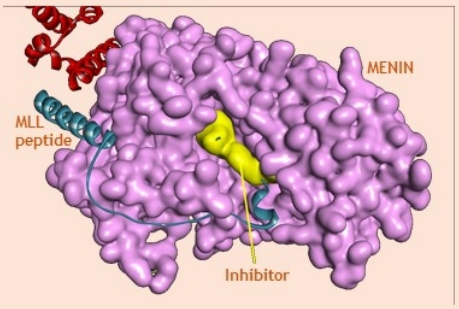
In MLLr, leukemic transformation is highly dependent on the Menin-MLL interaction

MLL1 Transformations



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

Menin

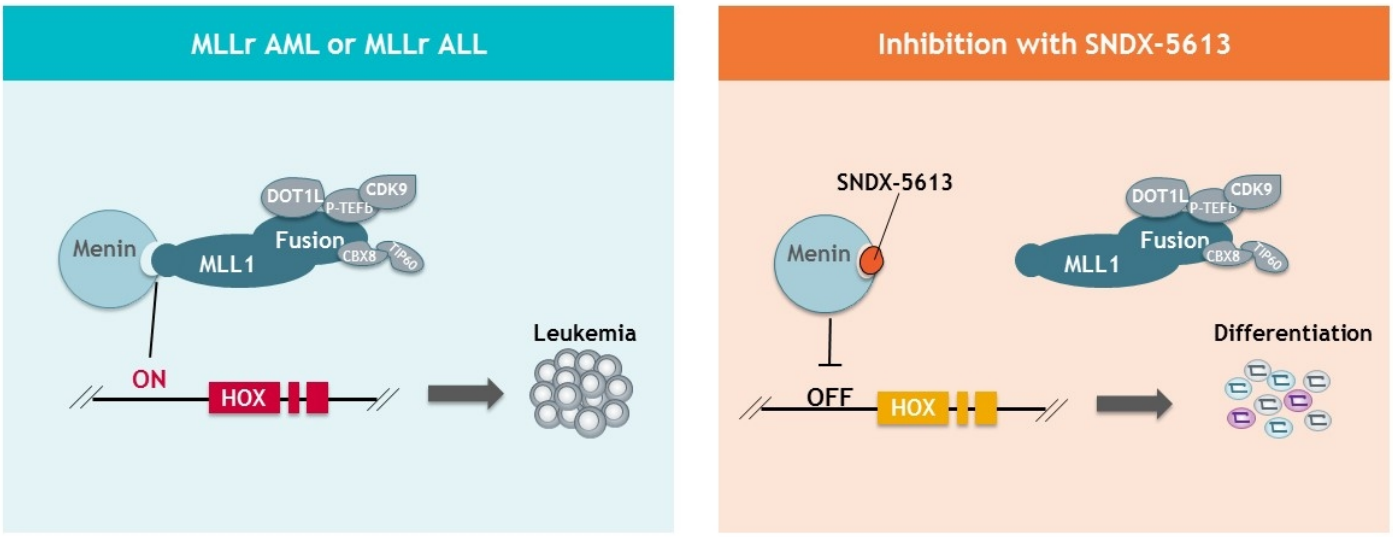


- Menin is a scaffold protein involved in gene transcription
- MLL1 N-terminus binds w/in conserved pocket on Menin

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.

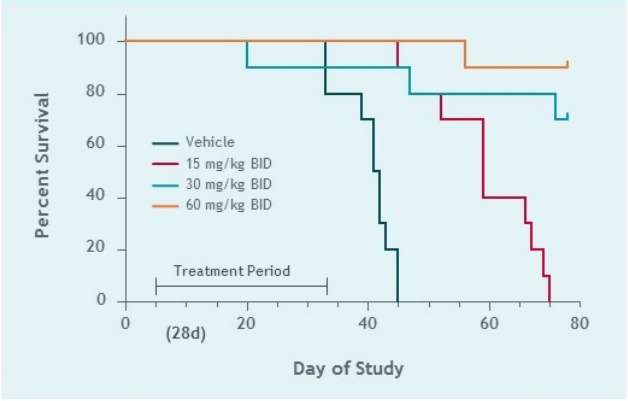
Binding of Menin to MLL1 leads to upregulation of HOX gene transcription and leukemia in MLLr AML and MLLr ALL



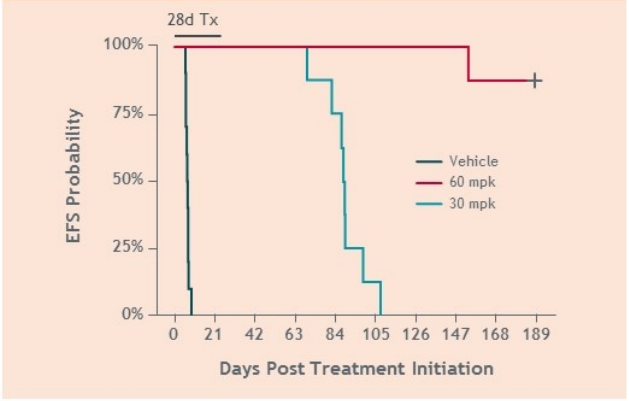
Adopted from: Uckelmann HJ, et al. Presented at ASH Annual Meeting, 2018.

Menin-MLL inhibition significantly prolongs survival in MLLr xenograft models

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



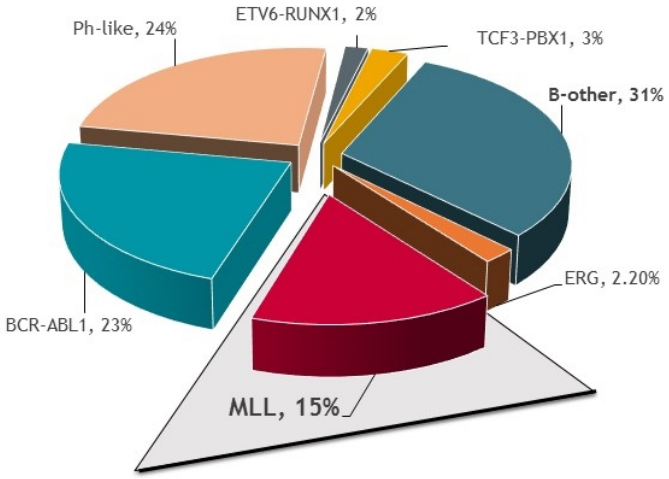
Patient Derived Xenograft (PDX) MLL-AF4 (SNDX-469)



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

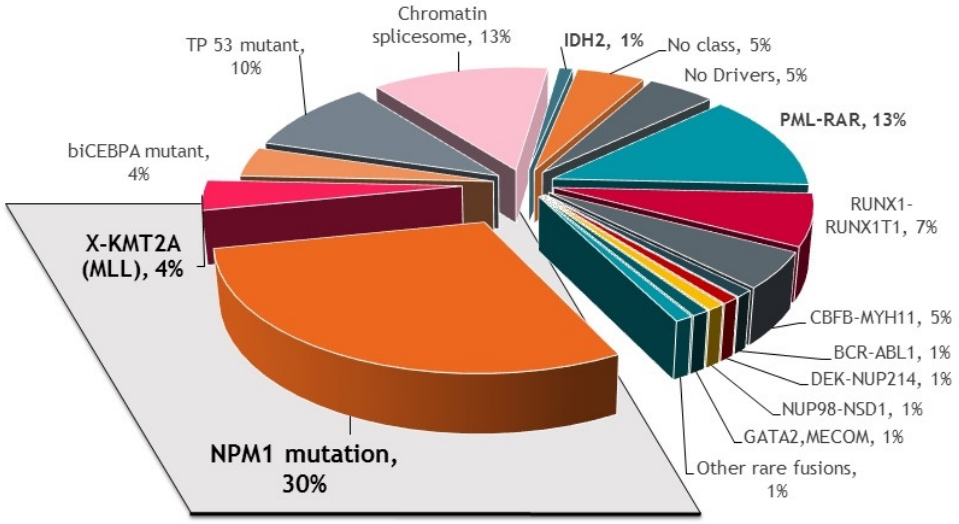
Pediatric ALL: 75%-90%

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

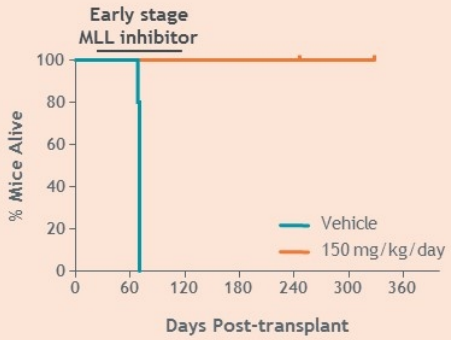
AML 5 yr survival 5% - 55%

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)

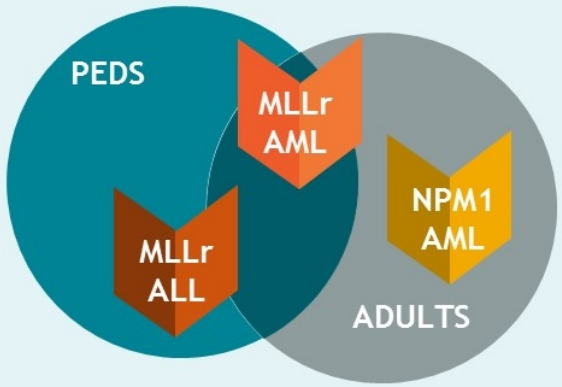


NPM1 transfected mice showed profound single agent survival benefit with SNDX-469 in multiple PDX models

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 AUGMENT-101 population: MLLr adult, MLLr peds, NPM1 mut AML

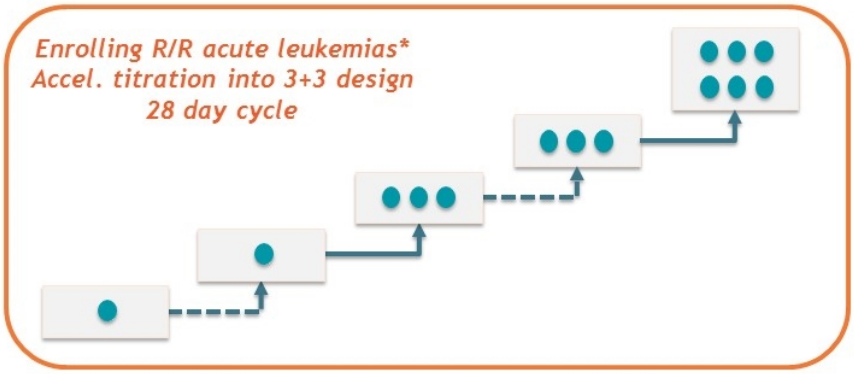


Defined fast to market pathway

- **AUGMENT-101 trial underway**
  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^)

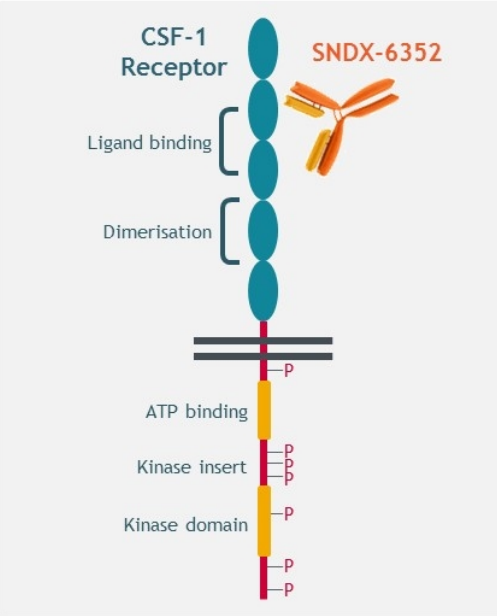
* Unselected population; ^ CR = Complete response, CRh = Complete response with partial hematologic recovery; MLL-r - mixed lineage leukemia rearranged; NPM = nucleophosmin


Entinostat
Breast Cancer
SNDX-5613
Menin inhibitor
Leukemias
SNDX-6352
anti-CSF1R Ab
cGVHD

SNDX-6352: early proof of concept in cGVHD, expanding to phase 2

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

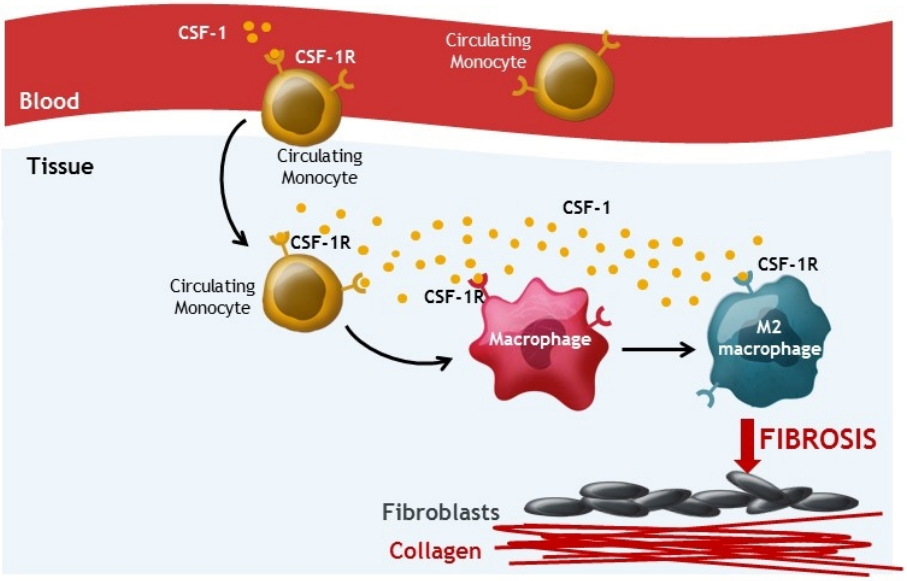
- ✓ Chronic graft versus host disease (cGVHD):
  - 1 mg/kg Q2W cohort expanding into Phase 2
  - Expect phase 1 dose escalation results in 2H20
- ✓ Ascending dose trials in solid tumors:
  - ✓ Identified RP2D in combo with IMFINZI® (durvalumab, AZ)
  - Monotherapy (solid tumors) ongoing



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

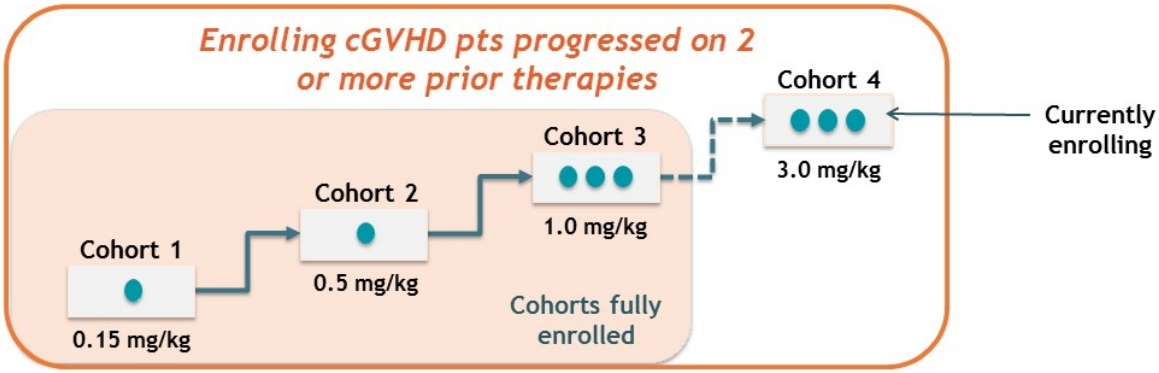
Signaling through CSF-1R may play a meaningful role in cGVHD

- cGVHD develops in 40% of HSCT[1,2]
  - US prevalence ~14,000[2]
- Pre-clinical evidence suggest CSF-1-dependant macrophages mediate cGVHD[3]
- Phase 1 trial ongoing; data 2H20
- Phase 2 expansion to start 1Q20



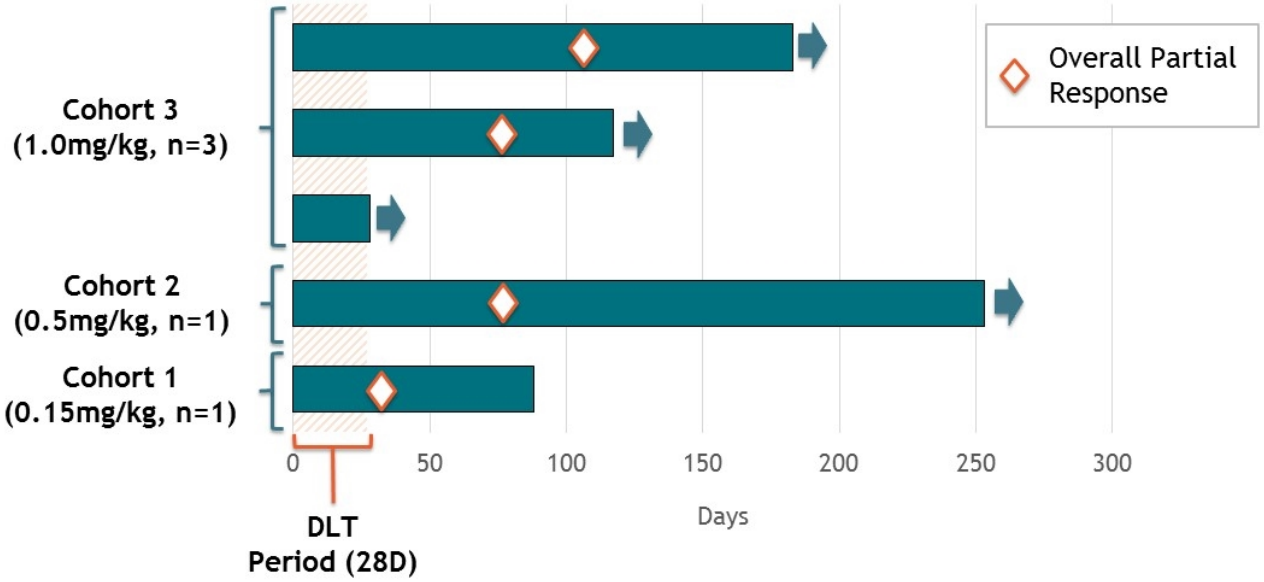
Source: 1. SmartAnalyst 2017 SmartImmunology Insights chronic GVHD report. 2. Bachier, CR. et al. ASH annual meeting 2019; abstract #2109 Epidemiology and Real-World Treatment of cGVHD Post Allogeneic HSCT: A U.S. Claims Analysis.; 3.Alexander, KA et al., J Clin Invest. 2014;124(10):4266-4280.
Figure Adopted from MacDonald, K.P.A. et al., BLOOD, 5 (129) 13-21; HSCT - Hematopoietic stem cell transplantation

SNDX-6352-0503, designed to identify optimal Phase 2 dose



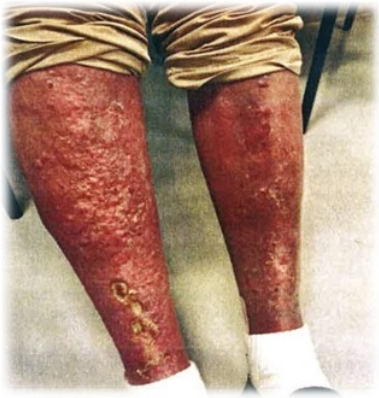
- **Study may enroll up to 30 Patients**
  - Standard "3+3" dose escalation design following 0.15 and 0.5 mg/kg dose
- **Patients continue to receive treatment for up to 12 months or until progressive disease or unacceptable toxicity**
- **Primary endpoint optimal biologic dose and recommended Phase 2 dose**

Responses observed in all evaluable patients as of data cutoff



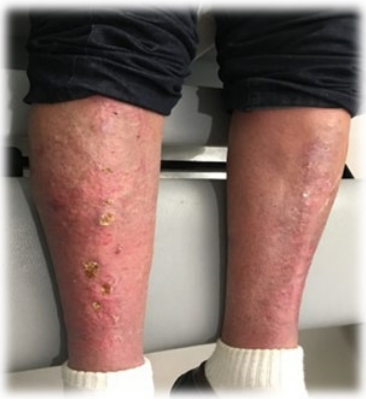
First evidence of CSF-1R inhibition inducing responses in cGVHD

- *Patient experienced chronic condition unresponsive to prior therapies*
- *Treatment with 1mg/kg Q2W SNDX-6352 led to significant improvement in ulceration*



5/15/19

1mg/kg Q2W SNDX-6352
initiated 6/12/19



9/18/19

3Q 2019 financial highlights and 4Q, full-year 2019 guidance

Ticker	SNDX (NASDAQ)	
As of Sept 30, 2019		
Cash and short-term investments	$72.2 million	
Shares Outstanding*	31.6 million	
2019 4Q and full year Operating Expense Guidance		
	4Q 2019	**2019**
Research and Development	$11 - 12 M	$45 - 46 M
Total Operating Expenses^	$15 - 16 M	$60 - 62 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 4Q 2019 and for 2019, respectively

Key upcoming milestones

ENTINOSTAT (Class 1 specific HDAC inhibitor)	4Q19	1Q20	2Q20	2H20
E2112 - Final Overall Survival 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				●


Thank you. Questions?
Syndax