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Syndax: A commercial-stage oncology company with two first-in-class medicines with practice-changing and billion-dollar potential





Revuforj® (revumenib)

- First and only FDA-approved menin inhibitor
- Only targeted therapy for KMT2A translocations
- U.S. launch expected in November 2024
- In development for mNPM1 AML and solid tumors

Niktimvo™ (axatilimab-csfr)

- FDA approved in 3L chronic graft-versus-host disease (GVHD)
- U.S. launch, in partnership with Incyte, expected no later than early first quarter 2025
- In development for patients with newly diagnosed chronic GVHD, and IPF



Delivered on major milestones in 2024, including two FDA approvals and positive pivotal data in R/R mNPM1 AML



Well capitalized to support launch of two new medicines and grow through label expansion and BD opportunities



Integrated commercial-stage organization, with 225+ colleagues across R&D, clinical development, manufacturing, medical, commercial, and corporate

Revuforj (revumenib)

First and Only Menin Inhibitor FDA-Approved to Treat Adult and Pediatric Patients with Relapsed or Refractory Acute Leukemia with a KMT2A Translocation

There is an urgent need to improve treatment for R/R acute leukemia patients with a KMT2A translocation

Disease Background

Rearrangements of the KMT2A gene (KMT2Ar), cause ~10% of acute leukemias¹

>95% of KMT2Ar acute leukemia patients have a KMT2A translocation, a type of rearrangement that occurs when part of one chromosome breaks and fuses to another²

KMT2Ar acute leukemia is associated with a very poor prognosis and high rates of resistance and relapse^{1,3}

historic complete remission (CR) rate 5% after ≥3 lines of therapy³

2.4 median overall survival after ≥3 lines of therapy³

month





Overview of Revuforj U.S. Prescribing Information

Indication:

 Revuforj is a menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients one year and older

Dosage Forms & Strengths:

Tablets: 25 mg, 110 mg, and 160 mg

Dosage & Administration:

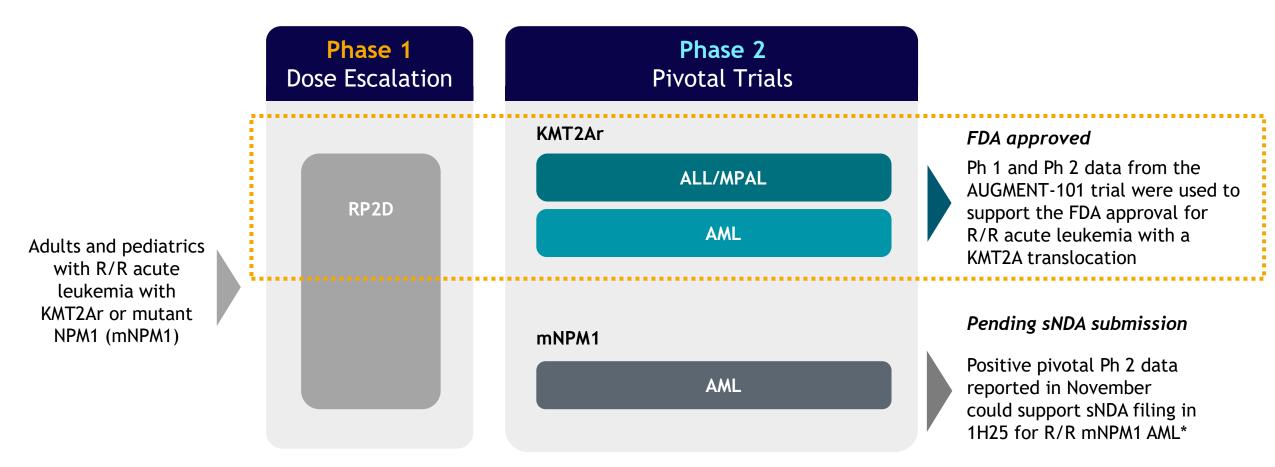
- Administered orally, twice daily
- Recommended dosage varies by patient weight and concomitant use of strong CYP3A4 inhibitors



First and only FDA-approved menin inhibitor



The AUGMENT-101 pivotal trial formed the basis for the approval of Revuforj



- Primary endpoint: CR + CRh rate
- Secondary endpoints included: ORR, CRc, duration of response, time to response, and OS





Baseline demographics/characteristics from Revuforj Prescribing Information

Across the Phase 1/2 AUGMENT-101 trial, Revuforj was studied in R/R acute leukemia patients with a KMT2A translocation

Demographic and Disease Characteristics	Revuforj (N = 104)
Age, median, years (range)	37 (1, 79)
< 17 years old, n (%)	25 (24)
≥ 17 years old, n (%)	79 (76)
Female, n (%)	67 (64)
AML/ALL/MPAL	83%/15%/2%
Disease status, n (%)	
Primary refractory	22 (21)
Untreated relapse	21 (20)
Refractory relapse	61 (59)
Number of previous regimens, median (range)	2 (1, 11)
Prior stem cell transplantation, n (%)	46 (44)

Revuforj was studied in:

- Advanced, heavily pretreated patients
- A broad range of patients, including both adults and children with AML, ALL, or MPAL



Efficacy summary from Revuforj Prescribing Information

Efficacy results from the Phase 1/2 AUGMENT-101 trial formed the basis for the approval of Revuforj

Endpoint	Revuforj N = 104
CR+CRh, n (%) 95% CI	22 (21.2) (13.8, 30.3)
Median duration of CR+CRh (months) 95% CI	6.4 (2.7, NE)
CR, n (%) 95% CI	13 (12.5) (6.8, 20.4)
Median duration of CR (months) 95% CI	4.3 (1.0, NE)
CRh, n (%) 95% CI	9 (8.7) (4.0, 15.8)
Median duration of CRh (months) 95% CI	6.4 (1.9, NE)

1.9 months median time to CR or CRh

23% (24/104) of patients underwent HSCT following treatment with Revuforj



Safety overview from Revuforj Prescribing Information

The label includes safety data from 135 R/R acute leukemia patients (104 adult and 31 pediatric) with a KMT2A translocation who were treated with Revuforj

Boxed warning:

Differentiation syndrome (DS)

Contraindications:

None

Warnings & precautions:

- QTc interval prolongation
- Embryo-fetal toxicity

Revu	forj (N=135)
Adverse reactions leading to dose interruption	42%
Adverse reactions leading to dose reduction	10%
Adverse reactions leading to permanent discontinuation	12%

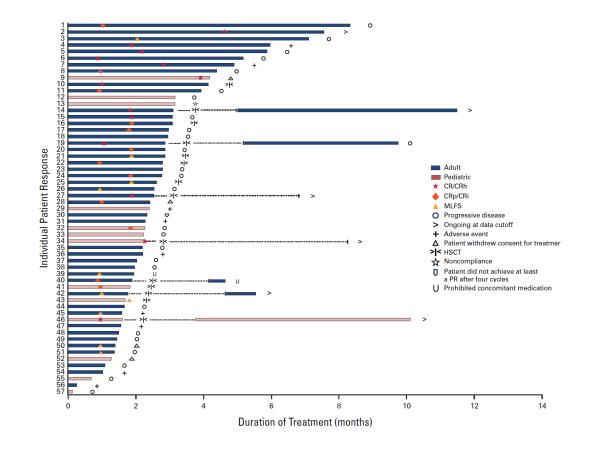
Most common (≥20%) adverse reactions including lab abnormalities: hemorrhage, nausea, phosphate increased, musculoskeletal pain, infection, aspartate aminotransferase increased, febrile neutropenia, alanine aminotransferase increased, parathyroid hormone intact increased, bacterial infection, diarrhea, differentiation syndrome, electrocardiogram QT prolonged, phosphate decreased, triglycerides increased, potassium decreased, decreased appetite, constipation, edema, viral infection, fatigue, and alkaline phosphatase increased.

Drug interactions: Strong CYP3A4 inhibitors, strong or moderate CYP3A4 inducers, or QTc prolonging drugs

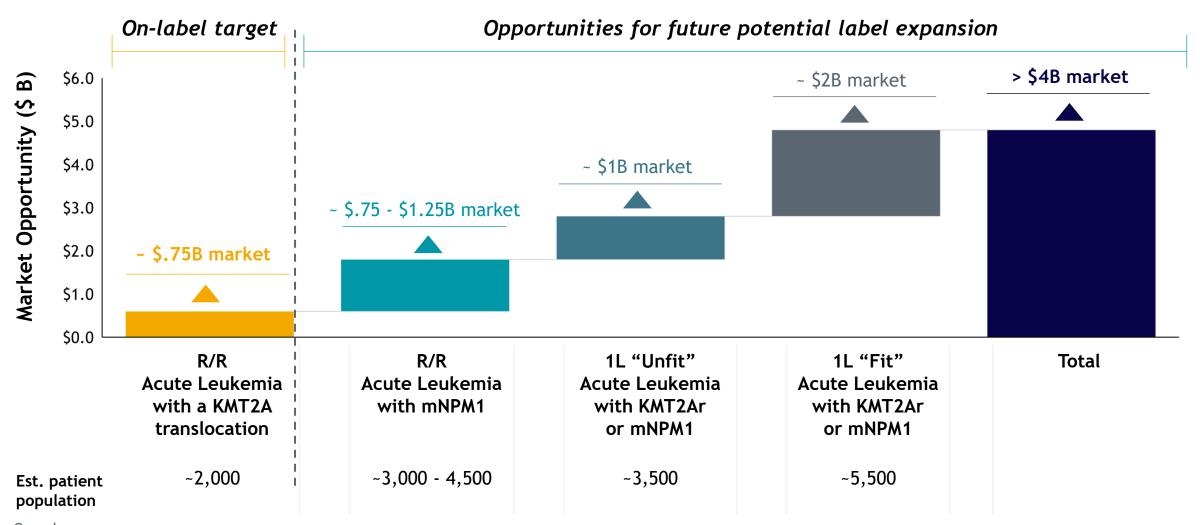
JCO publication highlights rates of ORR, MRD negativity and HSCT in R/R acute leukemia patients with a KMT2A translocation who received Revuforj

Publication includes data from the 57 efficacy evaluable patients in the pre-specified Phase 2 AUGMENT-101 trial interim analysis

Ph 2 Interim Analysis Efficacy Population (n=57)	
Overall response rate (ORR)	36 (63%)
CR + CRh	13 (23%)
CRc	25 (44%)
MRD negative rate within evaluable patients	
Within CR + CRh	7/10 (70%)
Within CRc	15/22 (68%)
Proceeded to HSCT	14/36 (39%)
Resumed revumenib post-HSCT	7/14 (50%)

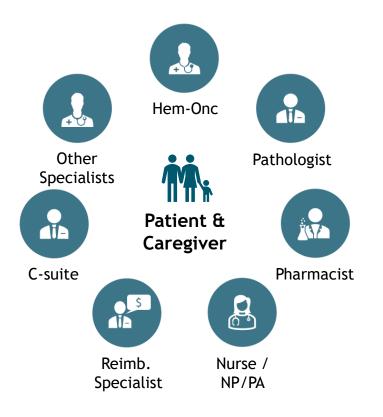


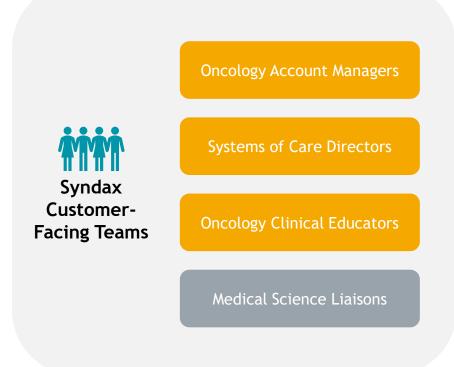
Initial Revuforj indication in R/R acute leukemia with a KMT2A translocation represents a significant market opportunity with potential for label expansion



Syndax >> Source: Data on file; Redbook 2023

Highly-experienced customer facing teams are built to drive best-in-class patient and customer experience





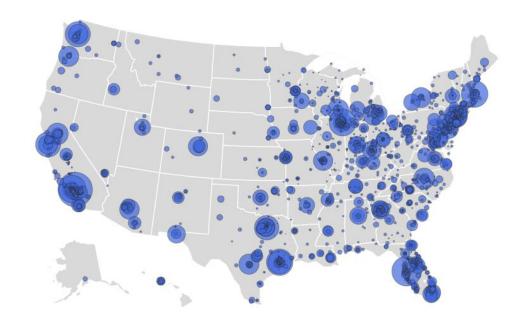
~50 highly experienced professionals will support Revuforj launch

- 22 years of average experience, primarily in hem/onc
- 6 product launches on average
- Strong pre-existing relationships

Multi-disciplinary teams will support key stakeholders across the patient journey with advanced data/analytics leveraged to drive patient identification and HCP targeting

Field teams will target ~2,000 accounts where 98%+ of KMT2Ar patients receive treatment

~200 accounts are estimated to represent 2/3 of the opportunity



Key pre-launch activities have been completed, setting strong foundation for launch



Drive Syndax and disease state/mechanism of disease awareness with target accounts



Profile accounts to understand patient journey and treatment workflows



Identify/validate key stakeholders for future product discussions



Tier/prioritize accounts based on patient volumes

Syndax is uniquely positioned to establish a successful menin franchise



First and only FDA-approved menin inhibitor enables significant first-to-market advantages



Urgent unmet need in R/R KMT2Ar acute leukemia expected to drive rapid uptake

Revuforj is positioned for long-term success



Opportunity to pursue future label expansion, with promising clinical data across the broadest population to date for a menin inhibitor



Opportunity for a unique launch trajectory, with potential for a fast-follow indication in R/R mNPM1 AML leveraging sNDA pathway and established commercial infrastructure



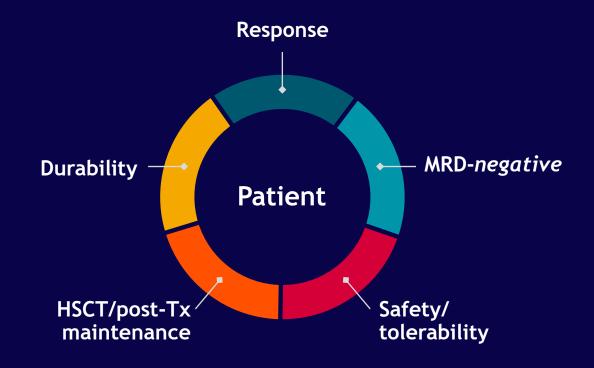
both adults and pediatrics, supporting a broad patient population in first indication

Revumenib - Development Pipeline

Revumenib has practice-changing potential in R/R mNPM1 AML

Met the primary endpoint in pivotal AUGMENT-101 cohort enrolling patients with NPM1 mutations

- Robust remission rates in heavily pre-treated population
- Remissions were notably deep and meaningfully durable
- A number of responders proceeded to HSCT, with the majority resuming revumenib post-transplant
- Favorable safety and tolerability supports continued evaluation of use in maintenance and in combination
- Results highlight consistency of revumenib's compelling clinical profile



Revumenib delivers on key metrics that address the needs of patients and drive physician utilization

There is an urgent need for new treatment options for R/R mNPM1 AML patients

mNPM1 AML DISEASE BACKGROUND

NPM1 mutations are the most common genetic alterations in AML

~30% of AML patients have NPM1 mutations

On average, mNPM1 patients are older, and less fit for HSCT than KMT2Ar patients

R/R mNPM1 AML patients have a poor prognosis and high unmet need





AUGMENT-101 baseline characteristics in Phase 2 cohort of patients with R/R mNPM1 AML

Baseline Characteristics	Adult Efficacy Evaluable Population N = 64	Safety Population N = 84
Age, years, median (range)	65 (19, 84)	63 (11, 84)
≥ 18 to <65, n (%)	31 (48)	42 (50)
≥ 65, n (%)	33 (52)	41 (49)
Female, n (%)	38 (59)	50 (60)
Baseline co-mutations of interest, n (%)		
FLT3-ITD	22 (34)	26 (31)
FLT3-TKD	4 (6)	6 (7)
Disease Status at Baseline, n (%)		
Primary refractory (persistent leukemia following induction chemotherapy)	5 (8)	7 (8)
Refractory relapse (unresponsive to most recent salvage treatment)	35 (55)	41 (49)
Prior lines of therapy, median (range)	2 (1, 7)	2 (1, 7)
≥3 lines, n (%)	23 (36)	29 (35)
Prior venetoclax, n (%)	48 (75)	62 (74)
Prior HSCT, n (%)	14 (22)	20 (24)

Patients were significantly older than R/R KMT2Ar cohort

75% had prior venetoclax exposure in efficacy population

36% received revumenib in the 4L or later in efficacy population



Revumenib demonstrated compelling efficacy in R/R mNPM1 AML patients in Ph 2 portion of AUGMENT-101

Best Response, n (%)	Adult Efficacy Evaluable Population N = 64
CR/CRh (95% Conf. interval); one-sided p-value	15 (23%) (14%, 36%); 0.0014
CR	12 (19%)
CRh	3 (5%)
MRDneg CR/CRh*	9/14 (64%)
Median duration of CR/CRh	4.7 months
Overall Response Rate (ORR)	30 (47%)
Composite complete remission (CRc)	19 (30%)
MRDneg CRc*	10/17 (59%)
Proceeded to HSCT after response	5/30 (17%)
Resumed revumenib post-HSCT	3/5 (60%)

ORR = CR+CRh+CRp+CRi+MLFS+PR; CRc = CR+CRh+CRp+CRi; * Not all patients had MRD status reported. Note: Totals may not sum due to rounding.

~50% of patients achieved an overall response in heavily pre-treated population

Deep, meaningfully durable CR/CRh responses

Consistent with R/R KMT2Ar acute leukemia cohort



Safety results from Phase 2 R/R mNPM1 AML cohort in the AUGMENT-101 trial support favorable revumenib safety and tolerability profile

Grade ≥3 Treatment-Related Adverse Events [TRAEs] (≥5% of patients)	Safety Population N = 84
Patients with Grade ≥3 TRAE	50 (60%)
Electrocardiogram QT prolonged	18 (21%) (Gr 3: 19% Gr 4: 2%)
Anemia	12 (14%)
Febrile neutropenia	11 (13%)
Differentiation syndrome	11 (13%) (Gr 3: 11% Gr 4: 2%)
Platelet count decreased	9 (11%)
Thrombocytopenia	8 (10%)
White blood cell count decreased	7 (8%)
Neutrophil count decreased	6 (7%)

- Safety results in this older, heavily pre-treated population were consistent with previously reported data
- Low rate of treatment-related discontinuations (5%)
- Most common adverse events observed are largely characteristic of symptoms experienced by patients undergoing treatment for AML

Multiple ongoing and planned revumenib clinical trials support potential label expansion and franchise opportunity

KMT2Ar & mNPM1 Relapsed / Maintenance acute leukemia Frontline Refractory treatment paradigm Revumenib clinical development program (acute leukemia with a KMT2Ar or NPM1 mutation) - ongoing trials **Pivotal AUGMENT-101** Rev Monotherapy **BEAT AML INTERCEPT AUGMENT-102** Rev + Chemo Rev + Ven/Aza Rev Monotherapy Tx Phase 1/2 SAVE Rev + Intensive **Rev Maintenance** Rev + Ven + INQOVI® Chemo "7+3"



BEAT AML data show revumenib's potential to enhance ven/aza combo in frontline mNPM1 or KMT2Ar AML

Summary of Enrolled Patients (n=26)	
Genetics, n	KMT2Ar: 9 mNPM1: 17
Summary of Outcomes in Efficacy Evaluable Population (n=24)	
CRc, n (%)	23 (96%)
CR/CRh	20 (83%)
CRi	3 (13%)
Transplant, n (%)	3 (13%)
Relapse, n (%)	3 (13%)
MRD ^{neg} , n (%)	22 (92%)

Safety Highlights

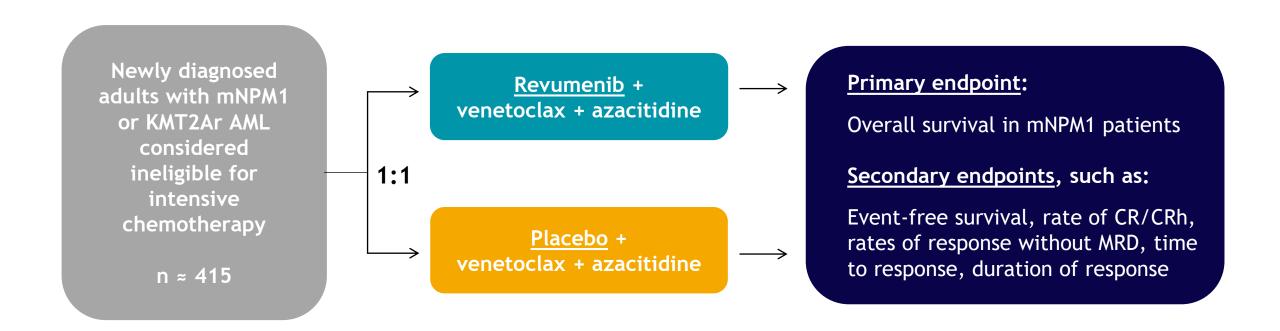
- Overall, no new or increased safety signals observed outside of known reported ven/aza toxicities
- Only 1 DLT (113 mg q12 h) observed
- No increase in cytopenias beyond ven/aza doublet

Expansion cohort is ongoing to establish RP2D

Syndax plans to initiate pivotal trial with this frontline combo by YE24

Pivotal frontline trial of revumenib + ven/aza on track to initiate by YE24

Frontline triplet will be studied in a randomized, double-blind, placebo-controlled, clinical trial in collaboration with the HOVON network



SAVE: Revumenib-ven/HMA combo in R/R AML resulted in high rates of remission, MRD negativity & HSCT

ASH 2024 abstract #216

Patient Characteristics (n=26)	
Years of age, median (range)	35 (12-79)
KMT2Ar/mNPM1/NUP98r enrolled, n	11/10/5
Prior lines of therapy, median (range)	3 (1-5)
Prior venetoclax	17 (65%)
Prior HSCT	11 (42%)

Safety Highlights

- Safety profile with revumenib similar to profile for venetoclax/HMA alone
- TRAEs (any agent) Grade ≥3: thrombocytopenia (12%), neutropenia (8%), QT prolongation (8%), and DS in 1 patient (4%; Grade 3)

Responses (n=26)	
ORR	23 (88%)
CR	12 (46%)
CRh	3 (12%)
CRp	3 (12%)
PR	1 (4%)
MLFS	4 (15%)
MRD ^{neg} all responders	17/23 (74%)
MRD ^{neg} CR/CRh	13/14 (93%)
Median duration of CR/CRh response	Not reached
Proceeded to HSCT	12/26 (46%)
Resumed revumenib post-HSCT	3/12 (25%)

With a median follow-up of 6.6 months, 6-month RFS was 59% and OS was 74%

In addition to the R/R cohort, a frontline cohort is now enrolling



Niktimvo (axatilimab-csfr) - anti-CSF-1R antibody

FDA approved for treatment of certain patients with chronic graft-versus-host disease in 2024 with opportunities for potential label expansion

Niktimvo (axatilimab-csfr) is now FDA approved in the U.S.



- ▼ FDA approved for treatment of chronic GVHD after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg
- ✓ Included in NCCN Guidelines®
- ✓ Preparing for U.S. launch no later than early 1Q25

Syndax and Incyte are co-commercializing Niktimvo in the U.S.

Synda	ax
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SOLVE
ON.

Within U.S.

30% sales effort 50% profit

70% sales effort 50% profit

Outside U.S.

Double-digit royalties and milestones

Exclusive rights to commercialization

Niktimvo clinical development programs

Underway:

- Ph 2 MAXPIRe trial in idiopathic pulmonary fibrosis (IPF)
- Ph 2 frontline combo trial with Jakafi[®] in cGVHD

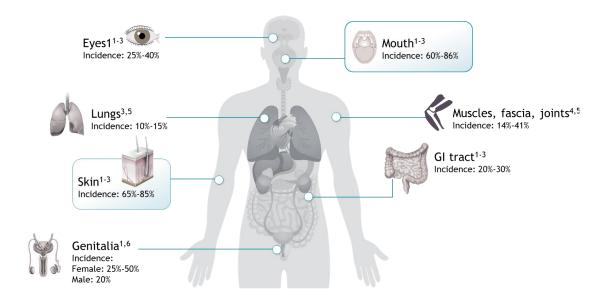
In preparation:

 Ph 3 frontline combo trial with steroids in cGVHD



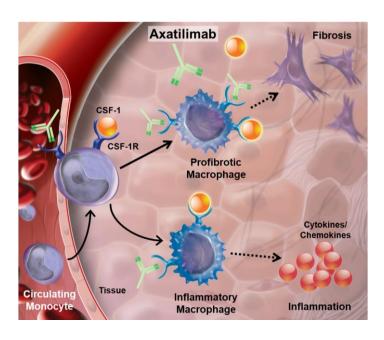
There is a significant need for a new therapeutic approach to cGVHD, a debilitating and difficult to treat disease

cGVHD impacts multiple organ systems, drives significant morbidity and impairs quality of life



Complete responses are rare, and many organs respond poorly to available therapies; nearly 50% of patients progress to third line treatments¹

Niktimvo is the first approved anti-CSF-1R antibody targeting the drivers of inflammation and fibrosis in cGVHD



Blocking CSF-1R with Niktimvo reduces the levels of proinflammatory and profibrotic monocytes and monocyte-derived macrophages

Overview of Niktimvo (axatilimab-csfr) U.S. prescribing info

INDICATION

 Niktimvo is indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg

DOSAGE & ADMINISTRATION

- The recommended dosage of Niktimvo is 0.3 mg/kg (maximum 35 mg) every 2 weeks in adult and pediatric patients weighing at least 40 kg
- Administered as an intravenous infusion over 30 minutes

Niktimvo FDA approval was based on AGAVE-201 trial data



A randomized, open-label, multicenter study (121 study sites, 16 countries)

Key eligibility criteria:

- Adult and pediatric participants with recurrent or refractory active cGVHD whose disease had progressed after ≥2 prior therapies
- Concomitant use of corticosteroids, calcineurin inhibitors, or mTOR inhibitors was allowed; no additional systemic cGVHD therapy was allowed

Primary endpoint:

Overall response rate (ORR) by Cycle 7 (28-day cycles)
Day 1, including complete response or partial response according to the NIH 2014 Consensus Criteria¹

Secondary and exploratory endpoints:

- Improvement in mLSS (≥7 points)
- Organ-specific response rates, DOR, FFS, OS
- Safety

Of the three doses evaluated², 0.3 mg/kg IV every 2 weeks was selected as the recommended therapeutic dose



AGAVE-201 enrolled advanced, heavily pre-treated cGVHD patients

Demographics & Baseline Characteristics of Patients with cGVHD	Niktimvo 0.3 mg/kg every 2 weeks (N=79)
Median age, years (range)	50 (7, 76)
Male, n (%)	46 (58%)
Race - white, n (%)	67 (85%)
Median time (range) from cGVHD diagnosis	47 months (4, 211)
≥ 4 organs involved, n (%)	45 (57%)
Severe cGVHD, n (%)	63 (80%)
Median (range) prior lines of therapy	4 (2, 12)
≥ 4 prior lines of treatment, n (%)	54 (69%)
Prior ruxolitinib, n (%)	57 (72%)
Prior ibrutinib, n (%)	27 (34%)
Prior belumosudil, n (%)	16 (20%)

Compared to the registrational population in the belumosudil trial¹, AGAVE-201 enrolled a population with:

- Significantly longer median time since diagnosis (47 vs. 25 months)
- More severe cGVHD (80% vs 71%)
- More exposure to prior therapies (e.g., 72% vs 31% exposed to ruxolitinib)

Summary from Niktimvo U.S. prescribing information

Efficacy results	Niktimvo 0.3 mg/kg every 2 weeks (N=79)
Overall response rate through 6 months, n (%) 95% CI	59 (75%) 64, 84
Median time to first response (range)	1.5 months (0.9-5.1)
Median duration of treatment (range)	10.3 months (0.5-28.6)

60% of responders maintained a response for at least 12 months¹ (95% CI: 43, 74)

56% of patients reported symptom improvements² (95% CI: 44, 67)



Measured from first response until new systemic therapy for cGHVD or death, based on the Kaplan Meier estimate.
Defined as ≥7-point decrease in modified Lee Symptom Scale score in an exploratory analysis through 6 months.

Safety summary from Niktimvo U.S. prescribing information

Boxed warning:

None

Contraindications:

None

Warnings & precautions:

Infusion-related reactions and embryo-fetal toxicity

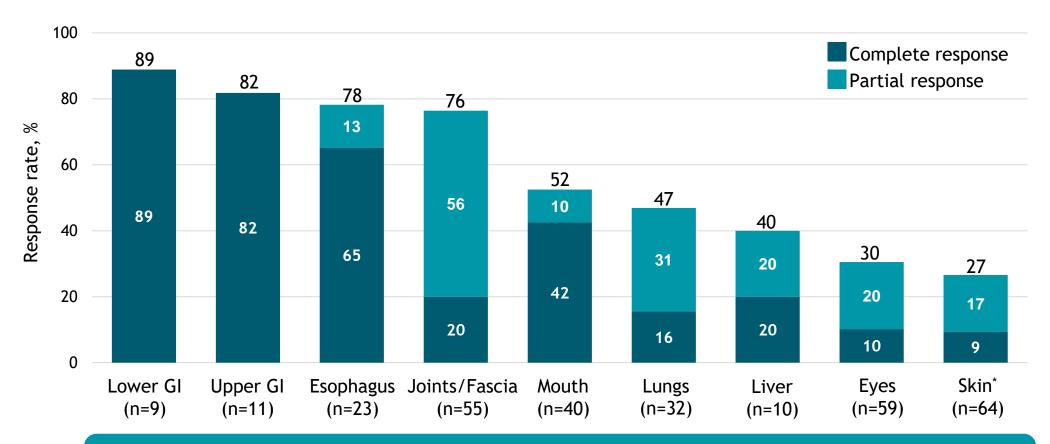
Most common (≥15%) adverse reactions, including lab abnormalities:

Increased AST, infection (pathogen unspecified), increased ALT, decreased phosphate, decreased hemoglobin, viral infection, increased GGT, musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased CPK, increased ALP, nausea, headache, diarrhea, cough, bacterial infection, pyrexia, and dyspnea.

Niktimvo 0.3 mg/kg every 2 weeks (N=79)		
	% of patients	
Serious adverse reactions	44%	
Dose interruptions due to adverse reactions	44%	
Dose reductions due to adverse reactions	8%	
Permanent discontinuation due to adverse reactions	10%	

Niktimvo showed robust responses across all organs studied in the heavily pre-treated population enrolled in AGAVE-201

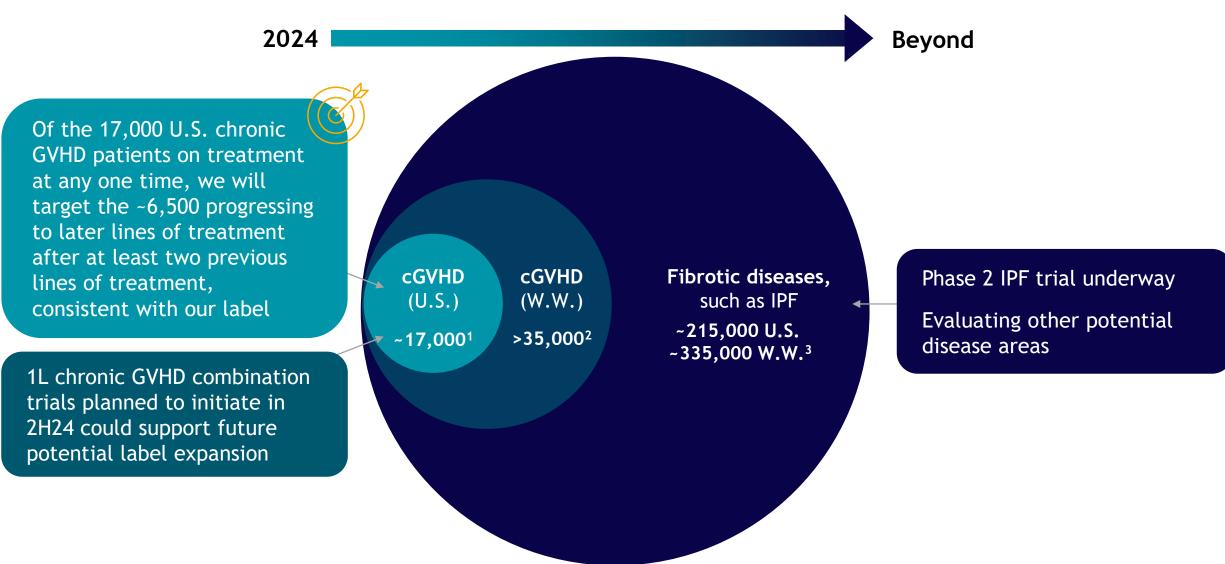
Niktimvo 0.3 mg/kg every two weeks



Responses were notable in fibrosis-dominated organs, including esophagus (78%), joints and fascia (76%), lung (47%), and skin (27%)



Niktimvo has a significant opportunity in 3L cGVHD in the U.S., with opportunities for geographical and label expansion



Targeted Niktimvo launch strategy will be led by highly experienced team from Incyte and Syndax

- Incyte to lead commercialization and contribute 70% of sales effort, leveraging their leadership in GVHD and extensive pre-existing relationships
- Syndax to contribute 30% of sales effort, deploying its own highly experienced field force
 - Average of 22 years of experience, primarily in hematology/oncology, with an average of 6 product launches
 - Overlapping call point with Revuforj targets allows for commercial synergies

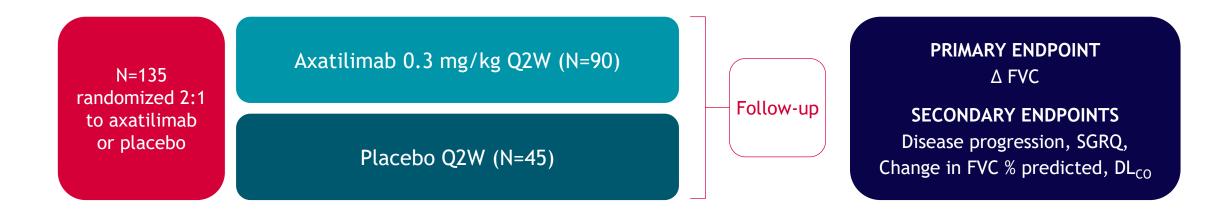
At launch, Incyte & Syndax will prioritize top centers with the highest volumes and greatest opportunity for rapid uptake



Robust stakeholder engagement and education is underway to support successful U.S. launch

Axatilimab Phase 2 trial in IPF trial now enrolling patients

A 26-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety, and Tolerability of Axatilimab in Subjects with Idiopathic Pulmonary Fibrosis (IPF)



Axatilimab's advancement into IPF supported by:

- Published preclinical and clinical rationale for CSF-1 pathway inhibition in IPF
- Clinical results from chronic GVHD trials showing the positive impact on lung fibrosis

Corporate Highlights

Financial highlights and financial guidance

Ticker	SNDX (NASDAQ)
Cash and equivalents ⁺ (30 September 2024)	\$399.6 M
Shares outstanding* (30 September 2024)	85.6 M
2024 Operating Expense Guidance	
	FY24
Research and development	\$245 - \$250 M
Total operating expenses^	\$365 - \$370 M

Syndax expects that its cash, cash equivalents and marketable securities, together with the \$350 M from the sale of a portion of the Niktimvo royalty and anticipated product revenue and interest income, enables the company to reach profitability

^{*} Includes pre-funded warrants to purchase 285,714 common shares (rounded)

[^] Includes an estimated \$41 million in non-cash stock compensation expense for the full year 2024

[→] Includes short- and long-term investments

Expected upcoming milestones Syndax 👺

Revuforj (revumenib)

Menin-KMT2A inhibition

- U.S. launch of Revuforj in November
- Presentation of acute leukemia data at ASH 2024
- Initiation of pivotal combination trial with ven/aza in newly diagnosed mNPM1 or KMT2Ar acute leukemias by YE24
- Publish and present pivotal R/R mNPM1 AML data at a medical conference in 1H25
- sNDA filing in R/R mNPM1 AML in 1H25

Niktimvo (axatilimab-csfr)

CSF-1R inhibition

- Presentation of additional AGAVE-201 data at ASH 2024
- Launch in refractory chronic GVHD no later than early first quarter 2025
- Chronic GVHD frontline combination trial with steroids in preparation
- Topline readout from Phase 2 IPF trial in 2026

