Syndax

Reimagining Cancer Treatment

Revuforj® (revumenib) FDA Approval Conference Call

November 15, 2024

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Agenda

1. **Introduction**
   Michael Metzger, CEO
2. **Revuforj U.S. Prescribing Information**
   Neil Gallagher, MD, PhD, President, Head of R&D
3. ***JCO* Publication & Development Program**
   Neil Gallagher, MD, PhD, President, Head of R&D
4. **Revuforj U.S. Launch Plans**
   Steve Closter, CCO
5. **Financial Considerations**
   Keith Goldan, CFO
6. **Q&A Session**

Revuforj® (revumenib) is now FDA approved!

- First and only FDA-approved menin inhibitor
- Only targeted therapy for KMT2A translocations
- Approved for treatment of relapsed or refractory (R/R) acute leukemia with a KMT2A translocation in patients 1 year and older
- Robust Revuforj clinical development strategy expected to support future label expansion and blockbuster opportunity
- Approval caps a historic year for Syndax, with the approval of two first-in-class medicines with practice-changing potential in 2024

Revuforj® (revumenib) tablets
25 mg • 110 mg • 160 mg

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 leukemias**[1]

>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 another[2]

KMT2Ar acute leukemia is associated with a **very poor prognosis and high rates of resistance and relapse**[1,3]

5% **historic complete remission (CR) rate** after ≥3 lines of therapy[3]

2.4 month **median overall survival** after ≥3 lines of therapy[3]

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1. Issa, GC, et al. Therapeutic implications of menin inhibition in acute leukemias. Leukemia 35, 2482–2495 (2021); 2. Meyer, C, et al. The KMT2A recombinome of acute leukemias in 2023. Leukemia 37, 988–1005 (2023); 3. Issa GC, et al. Predictors of outcomes in adults with acute myeloid leukemia and KMT2A rearrangements. Blood Cancer J. 2021;11:162

Overview of Revuforj (revumenib) U.S. Prescribing Information

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

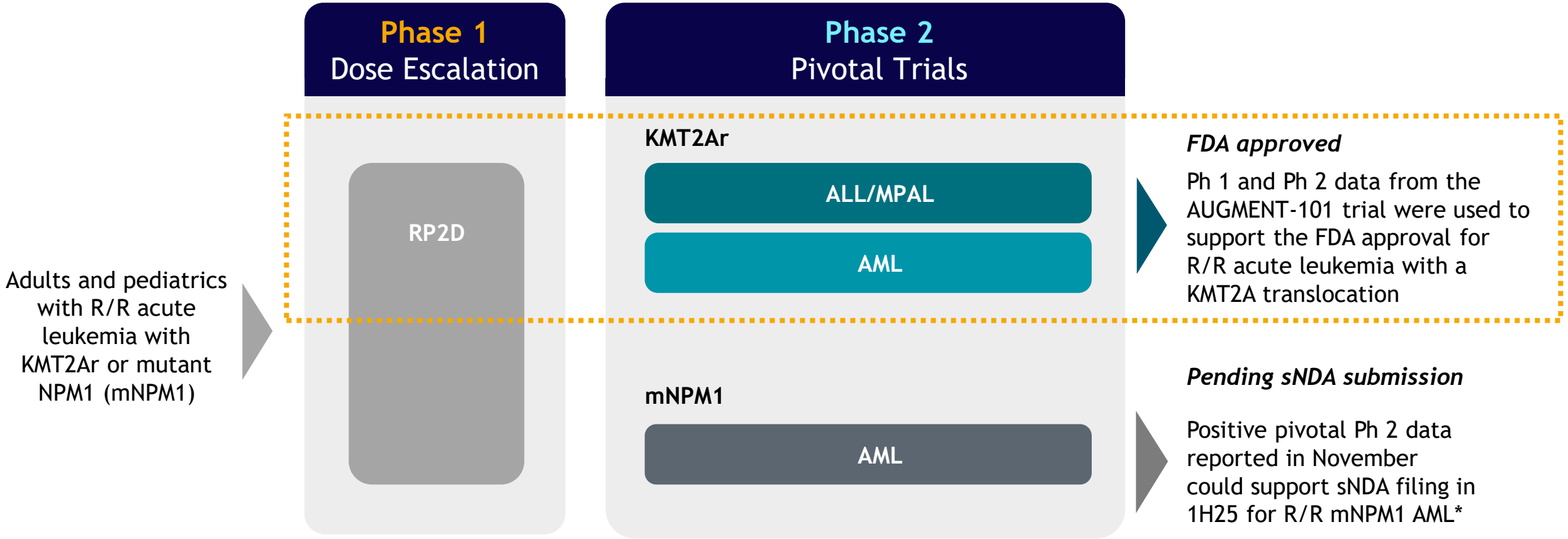
Dosage & Administration:

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

First and only FDA-approved menin inhibitor

Please see full Prescribing Information, including **BOXED WARNING**, for complete details.

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

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*The use of revumenib in R/R mNPM1 AML is still under investigation and has not been approved by the FDA.
ORR, overall response rate; CR, Complete remission; CRh, Complete remission with partial hematological recovery; CRc, Composite complete remission; OS, overall survival; R/R, relapsed or refractory

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

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Duration of CR+CRh is defined as the time from first CR or CRh to the first documented relapse or death, which occurs first.
CI, confidence interval; NE, not estimable; CR, complete remission; CRh, complete remission with partial hematologic recovery; HSCT, hematopoietic stem cell transplantation

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

	Revuforj (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

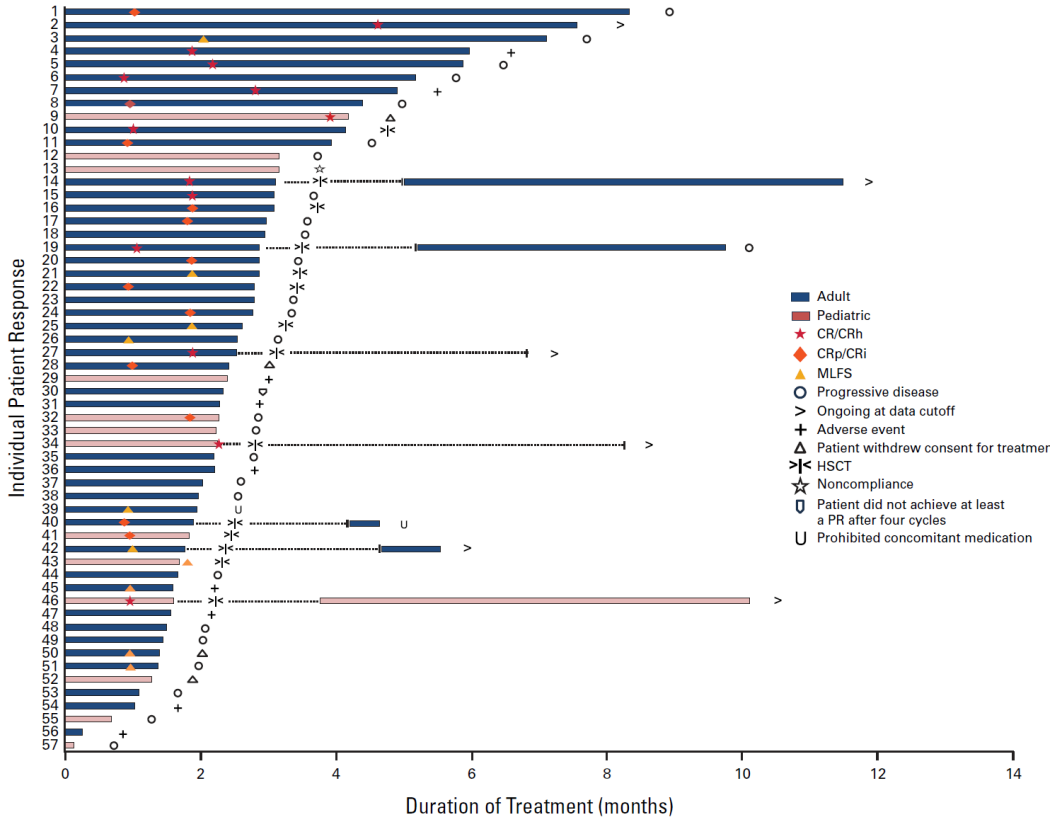
Please see full Prescribing Information, including **BOXED WARNING**, for complete details.

Overview of *Journal of Clinical Oncology (JCO)* Publication & Clinical Development Program

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%)



Issa GC, et al. Menin Inhibition With Revumenib for KMT2A-Rearranged Relapsed or Refractory Acute Leukemia (AUGMENT-101). J Clin Oncol 2024.
The primary Phase 2 endpoints of the AUGMENT-101 trial were the rate of complete remission (CR) plus CR with partial hematologic recovery (CRh) and safety. Other secondary endpoints, such as overall response rate, and exploratory endpoints, such as MRD negativity rates, should be interpreted with caution due to the lack of statistical power.

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

KMT2Ar & mNPM1 acute leukemia treatment paradigm

Revumenib clinical development program (acute leukemia with a KMT2Ar or NPM1 mutation) - ongoing trials

Pivotal

AUGMENT-101
Rev Monotherapy

Phase 1/2

BEAT AML
Rev + Ven/Aza

INTERCEPT
Rev Monotherapy Tx

AUGMENT-102
Rev + Chemo

Rev + Intensive Chemo "7+3"

Rev Maintenance

SAVE
Rev + Ven + INQOVI®

Revuforj (revumenib) U.S. Launch Plans

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**

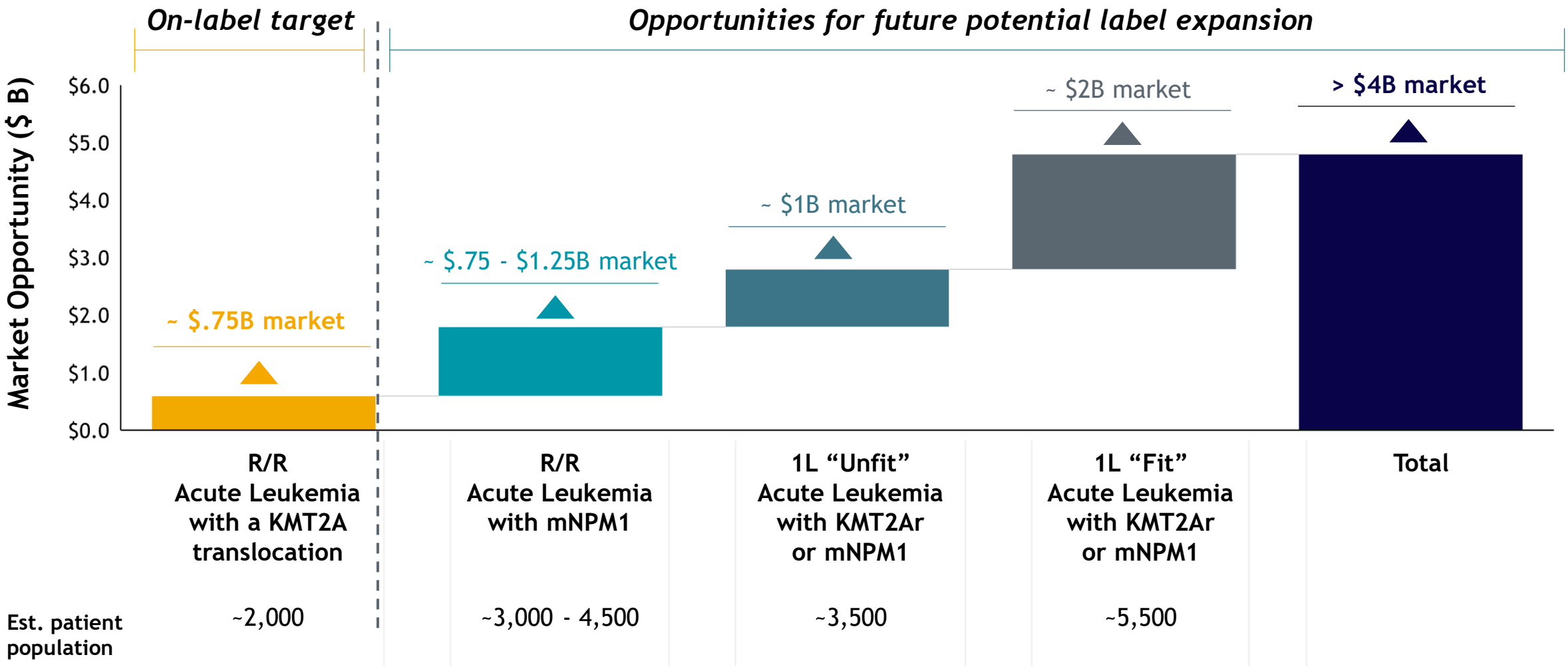
Revuforj is positioned for long-term success

Development program included **both adults and pediatrics,** supporting a broad patient population in first indication

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

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

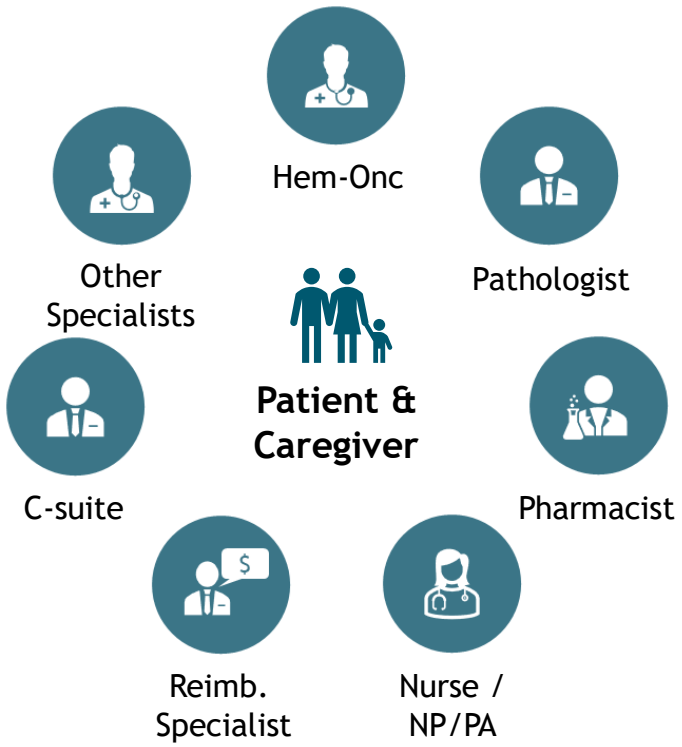


Source: Data on file; Redbook 2023

We will focus on three strategic imperatives to drive a successful launch and secure first-to-market advantages

	1	2	3
Strategic imperatives	**Leave no patient behind**	**Engage all key stakeholders**	**Deliver premium experience**
Key insights driving strategy	High-risk patients require rapid identification of treatment opportunities	Complex patient journey makes it crucial to engage all decision makers	Critically ill patients need rapid access without major barriers
Tactics to achieve strategy	Leverage advanced data and analytics to enable targeted HCP engagement	Achieve >95% full account coverage with a highly-experienced team	Expedite formulary review and provide robust support to patients and HCPs

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



Syndax Customer-Facing Teams

- Oncology Account Managers
- Systems of Care Directors
- Oncology Clinical Educators
- Medical Science Liaisons

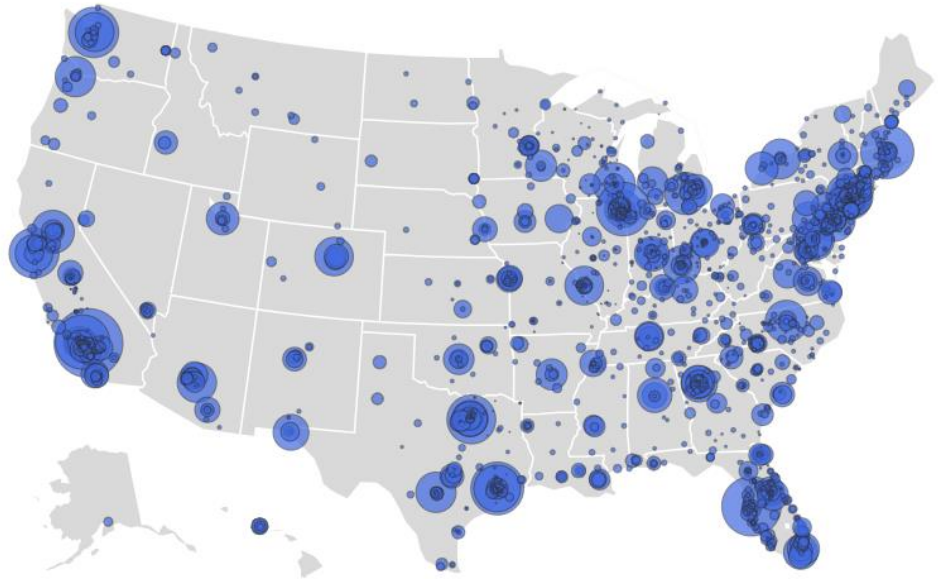
~50 highly experienced professionals will support Revuforj launch

- 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



Note: Bubble size corresponds to prevalent AML+ALL patients

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

Robust payor engagement prior to launch is anticipated to expedite formulary review and coverage decisions

Key pre-approval activities completed:

- Educated payors on burden of disease and provided scientific information about revumenib
- Conducted payor research to inform our strategy and pricing decisions
- Reached plans covering >90% of all covered lives

Payors recognize urgent unmet need in R/R KMT2Ar acute leukemia

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Wholesale acquisition cost (WAC) reflects clinical and economic value and is anticipated to support broad payor coverage

Robust U.S. patient support program is in place for Revuforj launch

SyndAccess™ Patient Support Program

How the SyndAccess Patient Support Team Can Help*

ACCESS

Support with understanding insurance coverage, benefit verifications, prior authorizations, and patient financial responsibility

AFFORDABILITY

A Patient Assistance Program and copay support to help provide financial assistance to patients who cannot afford their medication

ADHERENCE

Oncology-certified nurses may answer questions about Syndax medication and provide ongoing patient support

Dedicated patient support program will supplement the support provided by our industry-leading specialty pharmacy partners

*All programs subject to eligibility criteria and terms and conditions for enrollment

Expected upcoming milestones

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