NOW RECRUITING

AUGMENT-101

Patients with relapsed/refractory *MLLr* (*KMT2Ar*) or *NPM1c* acute leukemias

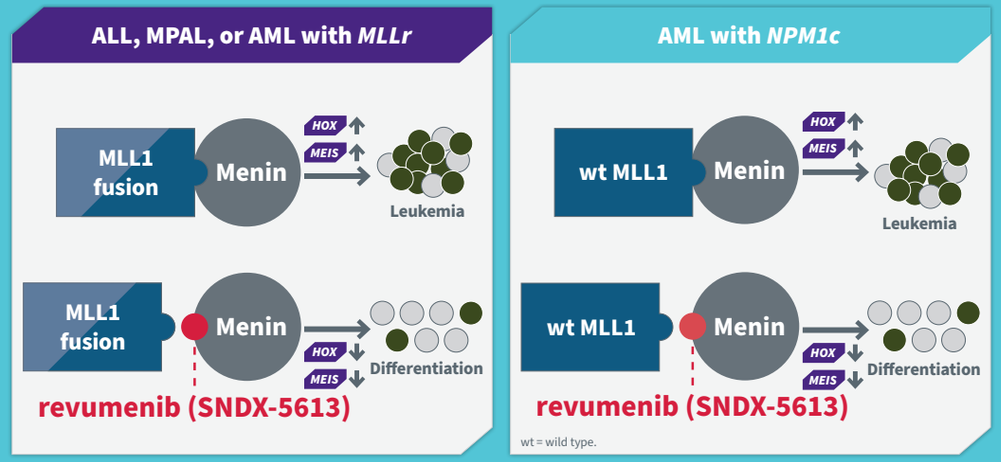
AUGMENT-101 (NCT04065399) is a pivotal, open-label, multicenter study to evaluate the efficacy, safety, and tolerability of revumenib (SNDX-5613), an inhibitor of the MLL1 (KMT2A)-Menin interaction, in R/R adult and pediatric patients with *MLLr* ALL/MPAL/AML or *NPM1c* AML.

ALL = acute lymphoblastic leukemia, AML = acute myeloid leukemia, *KMT2Ar* = lysine (K) methyltransferase 2A rearranged, *MLLr* = mixed-lineage leukemia rearranged, MPAL = mixed phenotype acute leukemia, *NPM1c* = nucleophosmin 1 mutation, R/R = relapsed/refractory.

Syndax

Overview: revumenib (SNDX-5613) for *MLLr* (*KMT2Ar*) and *NPM1c* acute leukemias

The interaction between MLL1 (KMT2A) and Menin has been shown to be a contributor to leukemogenesis for certain acute leukemias, such as *MLLr* or *NPM1c* acute leukemias. Revumenib (SNDX-5613) is a potent, orally available, small molecule inhibitor of the MLL1-Menin interaction.



In the Phase 1 portion of AUGMENT-101, revumenib (SNDX-5613) has demonstrated a manageable safety profile and deep, durable single-agent responses have been observed.

Syndax Pharmaceuticals has initiated Phase 2 of AUGMENT-101 (NCT04065399) to further evaluate the efficacy, safety, and tolerability of revumenib (SNDX-5613).

Revumenib (SNDX-5613) is an investigational agent that has not been approved for use in any country.

Criteria for enrollment

SELECT INCLUSION CRITERIA

- ≥30 days of age
- R/R active acute leukemia harboring *MLLr* (*KMT2Ar*) or *NPM1c**†
- Eastern Cooperative Oncology Group (ECOG) performance status score 0-2 (if ≥18 years old); Karnofsky Performance Score of ≥50 (if ≥16 years and <18 years old); Lansky Performance Score of ≥50 (if <16 years old)
- Any prior treatment-related toxicities resolved to ≤Grade 1 prior to enrollment, with the exception of ≤Grade 2 neuropathy or alopecia

SELECT EXCLUSION CRITERIA

- Isolated extramedullary relapse
- Known CNS involvement (cytologic or radiographic)
- Signs or symptoms of acute or chronic GVHD
- Within 60 days from HSCT

CNS = central nervous system, GVHD = graft-versus-host disease, HSCT = hematopoietic stem cell transplantation.

*Active acute leukemia as defined by the National Comprehensive Cancer Network (NCCN) in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia (V.1.2022) and Acute Myeloid Leukemia (V.2.2022).

†R/R AML/ALL or MPAL as defined by standardized criteria (eg, European LeukemiaNet criteria: International Working Group criteria) after standard-of-care therapy.

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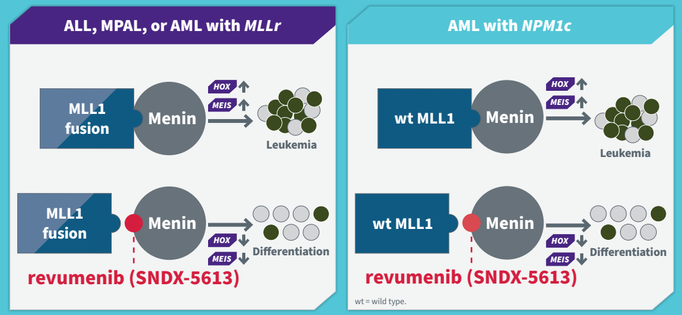

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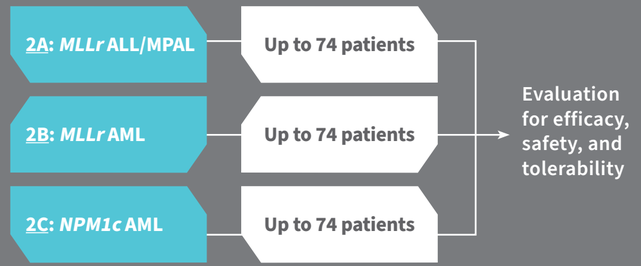
Patient population

PATIENTS WHO

- Are ≥30 days of age
- Have relapsed/refractory acute leukemias harboring *MLLr* (*KMT2Ar*) or *NPM1c*

Study design

AUGMENT-101



- Patients taken to HSCT can restart treatment with revumenib (SNDX-5613) post-transplant

The ASH/CAP guideline recommends testing for *MLL* and *NPM1* mutations as part of the diagnostic workup of acute leukemia.*

*The guideline is presented in Arber DA, Borowitz MJ, Cessna M, et al. Initial diagnostic workup of acute leukemia: Guideline from the College of American Pathologists and the American Society of Hematology. *Arch Pathol Lab Med.* 2017;141(10):1342-1393.

ASH/CAP = American Society of Hematology/College of American Pathologists.

Select study objectives

1 PRIMARY

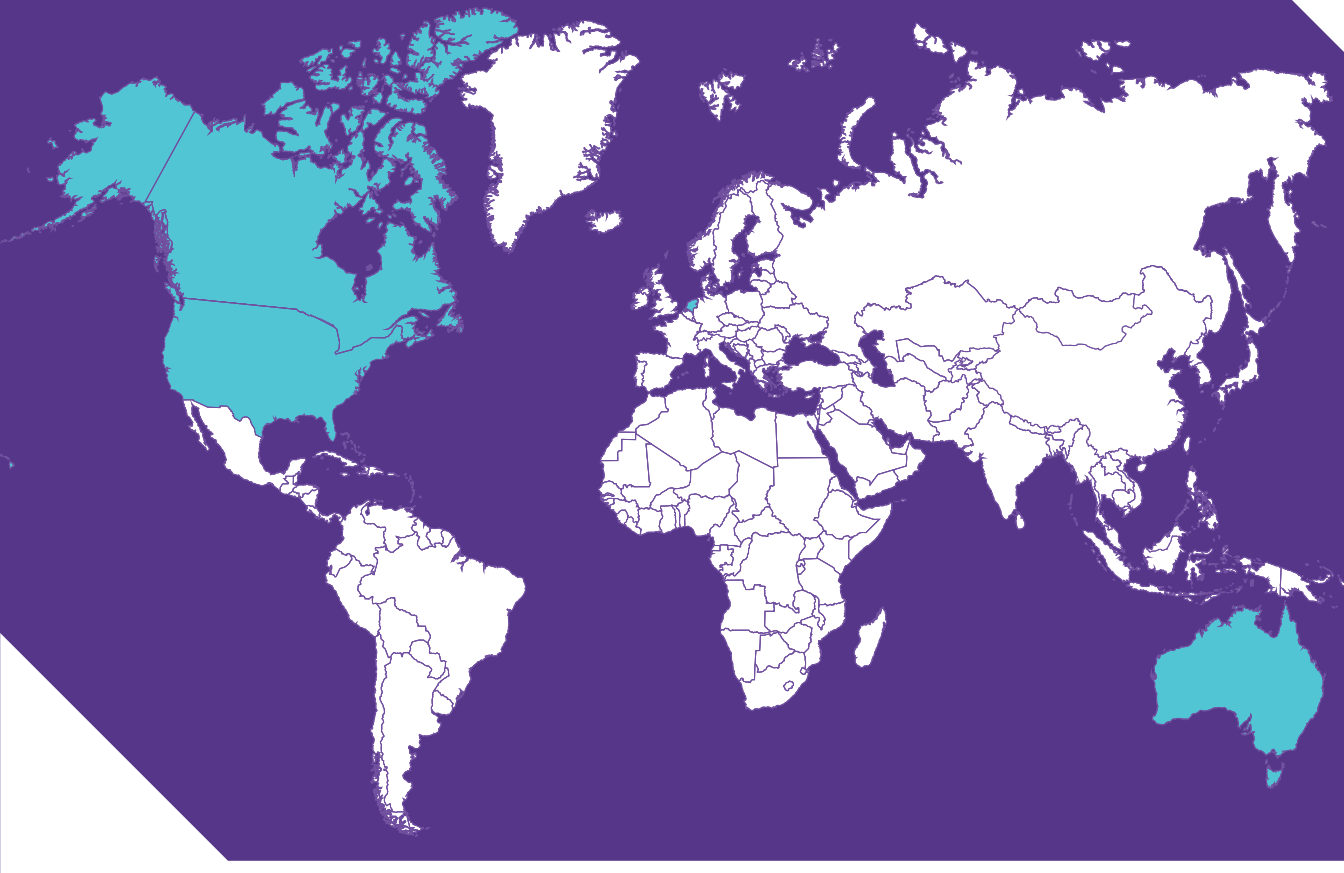
- **Efficacy** as measured by complete remission (CR+CRh) in adult patients
- **Safety and tolerability** as measured by frequency, duration, and severity of TEAEs, TRAEs, and SAEs

2 SECONDARY

- CR rate (CR+CRh) in adult and pediatric patients combined
- CRc rate (CR+CRh+CRp+CRi)
- Time to response (TTR)
- Duration of response (DOR)
- Overall survival (OS)
- Event-free survival (EFS)
- Transfusion independence

CR = complete remission, CRc = composite definition of complete remission (CR+CRh+CRp+CRi), CRh = complete remission with partial hematologic recovery, CRi = complete remission with incomplete hematologic recovery, CRp = complete remission with incomplete platelet recovery, SAE = serious adverse event, TEAE = treatment-emergent adverse event, TRAE = treatment-related adverse event.

Global study sites



For more information about the AUGMENT-101 clinical trial, including full eligibility criteria and study sites, please visit **www.clinicaltrials.gov (NCT04065399)** or **www.syndax.com/clinical-trials/revumenib/augment-101**.

Contact Syndax directly at **clinicaltrials@syndax.com**

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