(3)

अ० भा० आ० सं० अस्पताल/A.I.I.M.S. HOSPITAL
बहिरंग रोगी विभाग /Out Patient Department
अस्पताल के अन्दर धूम्रपान मना है।/SMOKING IS PROHIBITED IN HOSPITAL PREMISES

OPR-6

एकक/Unit _____
विभाग/Dept. _____
नाम/Name _____

प्रवासी विभाग UHID: 108427313
Dept No. 20250100018338
कमरा / Room 3
Queue / संख्या N16
Unit-I, Obs. and Gynae.

/O.P.D. Regn. No. _____

प्रीती प्रीती / PREETI PREETI
W/O SUNIL SINGH
28Y 2M 0D / F(महिला)
AINAGAR NO.3 POST CHATTARPUR
UDHAM SINGH NAGAR RUDARPUR.
Ph: 7351583023 General Rs. 0
New Patient

(10)
रोगज सूत्र.
Reporting: 05 03:15
01/07/2025

पता/Address

निदान/Diagnosis

दिनांक/Date

उपचार/Treatment

c/o lower abdominal pain
x 3 months

MH
LMP - 12/6/25
Regular cycle, avg. flow

OH
P_2L_2
both FTNVD
LCB - 2019

PH
k/c/o SAH Subacute Intestinal Obstruction. in 2019 → Underwent laparotomy + Adhesiolysis ⇒ diagnosed ē ABdTB, took ATT for 6 months
k/c/o (L) tubal ectopic ruptured → underwent laparotomy in ~~2017~~ 2019.

CLEAN AND GREEN AIIMS / एम्स का यही संकल्प, स्वच्छता से किया कल्प
अंगदान-जीवन का बहुमूल्य उपहार/ORGAN DONATION - A GIFT OF LIFE
O.R.B.O., AIIMS, 26588360, 26593444, www.orbo.org Helpline - 1060 (24 hrs service)

मेरा अस्पताल My Hospital meraaspatal.nhp.gov.in

अखिल भारतीय आयुर्विज्ञान संस्थान, नई दिल्ली-110029 (99) (REVISIT)

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI-110029

आपातकालीन विभाग

(DEPT. OF EMERGENCY MEDICINE)

UHID No:107782829

आपातकालीन नं.(Emergency No): 2025/030/0096592 दिनांक DATE: 22/08/2025 समय TIME: 02:45:00 PM

NON-MLC

1077,82829

नाम NAME: MISS SURBHI SINGH आयु AGE: 6 years 6 months 15 days लिंग /SEX: F

D/O: SUNEEL SINGH

पता ADDRESS:

मकान संख्या H.NO: JAINAGAR NO 3 CHATTARPUR RUDRAPUR UDHAM SINGH NAGAR गली / मुहल्ला STREET/MOH:

शहर/प्रखंड CITY/BLOCK:

राज्य STATE: UTTRAKHAND

मोबाइल MOBILE NO: 7351583023

पिन PIN: 263153

दूरभाष सं. PHONE NO: 7351583023

स्थान Location: Paediatrics Emergency

द्वारा BROUGHT BY: Relative:

Criticality: Red / Yellow / Green

Triage: Responsive/ Unresponsive HR 160/min BP mmHg RR /min spO2 %

AML Relapse

Shifted to Paeds/ Main/ New Emergency

Presenting Complaints

Med onco

Fever × 1day.

C/O - loose stools 2 episode.
vomiting 2 episode.

last chemo. today and yesterday.

Primary Assessment (ABCDE) : Assessment Pentagon (Received

Airway	Circulation	Disability
Open & stable: Yes/No If No..... **Breathing**: RR 22 /min **Efforts**: Normal/Poor/increased **Auscultation**: Air entry: Normal/poor/Differential Added sounds: None/Stridor/Wheeze/Crackles SpO2 on Room air 99 %. Wt = 19 kg.	HR 153/min CFT <3sec BP 108/70 mmHg Peripheral pulse: Poor/Good Central pulse: Poor/Good Skin temp: Warm/cool Others imp: AML relapse c FN.	GCS 15/15 Pupil size...../min Pupillary Reactions: BL reactive **Motor activity**: Normal & Symmetrical/ Asymetrical/ Posturing/Flacidity/Seizure Blood Sugar.....mg/dl **Exposure**: Temp 103°F Colour: Normal/pallor/cyanosis/ mottled Any other skin lesions.....

Diagnosis

Advise

- inj IVF. DNS @ 58 ml/hr
- inj pcm. 200 mg IV SOS
- inj Emset 3 mg IV SOS
- inj Pantop 20 mg IV stat

3pm

- CBC
- LFT/KFT
- USG.

PTO.

डॉ. बी. आर. अम्बेडकर संस्थान रोटरी कैंसर अस्पताल
Dr. B.R. Ambedkar Institute Rotary Cancer Hospital

OPR-6

Clinic Paediatric Medical Oncology Clinic | Clinic No. 7780/2024
Deptt. MEDICAL ONCOLOGY
General

नाम IRCH - 327833

UHID-107782829

Name SURBHI SINGH
D/O- SUNEEL SINGH
Phone No. 7351583023 | Sex/Age F /5Y
Address JAINAGAR NO 3 CHATTARPUR RUDRAPUR UDHAM SINGH NAGAR, UTTRAKHAND, Pin:263153, INDIA
Room Board Room (Shift Morning)

एकक/Unit Dr SB/DP
विभाग/Dept. MO

नाम/Name
Surbhi Singh

Date of Birth

DR. B.R.A. IRCH,AIIMS,NEW DELHI

निदान/Diagnosis
Δ AML – 4p 3+7 (14/9 — 20/9)

दिनांक/Date	उपचार/Treatment
21/9/24.	D3 (M) (E) 23/9/24 (R-15)
	Rx
	① Inj Magnex 2g BD x 3 days — R-15
	② T voriconazole 200mg BD to continue (ओ/आर)
	③ T Lanzol DR 20mg OD to continue (ओ/आर खाली पेट)
	④ T Emeset- 2mg SOS (उल्टी)
	⑤ plenty of oral fluids ~(2-2.5-4/day) (ज्यादा पानी)
	⑥ (Headache) CHMW/SF/SB TDS (उल्टी)
	⑦ PICC line care — (Room 15) (ओ/आर-15)
	⑧ SDP Transfusion on 23/9/24 — daycare (2 U/Room Apharesis Lab) Daycare
	F/U — MO OPD — 23/9/24 : CBC/LFT/KFT
	Review SOS in emergency
	if fever / loose stools / oral ulcers

Dr ANAND BHAHI
Senior Resident
Dept. of Medical Oncology

अ.भा.आ.संस्थान अस्पताल

A.I.I.M.S. HOSPITAL

प्रवेश-पत्र / Entry Pass

(केवल एक व्यक्ति के लिए / For One Person only)

रोगी का नाम
Name of the Patient Surbhi

वार्ड/शैय्या सं.
Ward/Bed No. C6-36

पास जारी किया
PASS ISSUED

अवधि दिनांक 20.08.25 तक 09.09.25
Period from ... to ...

कृते चिकित्सा अधीक्षक
For Medical Superintendent

Name	: Baby SURBHI SINGH		
Lab No.	: 183808840	**Age**	: 5 Years
Ref By	: dr sameer bakshi	**Gender**	: Female
Collected	: 10/9/2024 1:15:00PM	**Reported**	: 3/10/2024 4:02:04PM
A/c Status	: P	**Report Status**	: Final
Collected at	: Yusuf Sarai – Lab C.L HOUSE, UPPER GROUND FLOOR, 4/1-3 AUROBINDO MARG, YUSUF SARAI(NEAR AIIMS GATE NO.3) New Delhi - 110016	**Processed at**	: LPL-NATIONAL REFERENCE LAB National Reference laboratory, Block E, Sector 18, Rohini, New Delhi -110085

Test Report

Test Name	Results	Units	Bio. Ref. Interval
ONCOPRO COMPREHENSIVE LEUKAEMIA PANEL: DNA MUTATIONS & RNA FUSIONS	Result Attached		

Dr Vamshi Krishna Thamtam
MCI - 17-25915
MBBS, MD Pathology
DipRCPath UK, Molecular Genetics
Fellowship, Tata Medical Center
Head - Genomics & Clinical Cytogenomics
NRL - Dr Lal PathLabs Ltd

----------End of report ----------

IMPORTANT INSTRUCTIONS

•Test results released pertain to the specimen submitted.•All test results are dependent on the quality of the sample received by the Laboratory.•Laboratory investigations are only a tool to facilitate in arriving at a diagnosis and should be clinically correlated by the Referring Physician .•Report delivery may be delayed due to unforeseen circumstances. Inconvenience is regretted.•Certain tests may require further testing at additional cost for derivation of exact value. Kindly submit request within 72 hours post reporting.•Test results may show interlaboratory variations.•The Courts/Forum at Delhi shall have exclusive jurisdiction in all disputes/claims concerning the test(s) & or results of test(s).•Test results are not valid for medico legal purposes.•This is computer generated medical diagnostic report that has been validated by Authorized Medical Practitioner /Doctor.•The report does not need physical signature.

(#) Sample drawn from outside source.

If Test results are alarming or unexpected, client is advised to contact the Customer Care immediately for possible remedial action.

Tel: +91-11-49885050,Fax: - +91-11-2788-2134, E-mail: lalpathlabs@lalpathlabs.com

National Reference lab, Delhi, a CAP (7171001) Accredited, ISO 9001:2015 (FS60411) & ISO 27001:2013 (616691) Certified laboratory.

GENEVOLVE Dr Lal PathLabs

Dr Lal PathLabs OncoPro Comprehensive Oncology Diagnostics

DEMOGRAPHICS		
	NAME	Baby SURBHI SINGH
	AGE/SEX	5 YEARS / FEMALE
	LAB NUMBER	183808840
	REFERRED BY	DR SAMEER BAKSHI
	REPORTING CENTRE	YUSUF SARAI – LAB
	RECEIVING DATE	10 / SEPTEMBER / 2024
	REPORTING DATE	03 / OCTOBER / 2024

TEST NAME	ONCOPRO COMPREHENSIVE LEUKAEMIA PANEL – DNA MUTATIONS & RNA FUSIONS

CLINICAL INDICATION	A 5 years old Female with Acute Leukemia under evaluation
GENE MUTATION	*NRAS*(NM_002524.5):c.34G>T;p.Gly12Cys
GENE FUSION	*KMT2A::MLLT10 Fusion* Detected

DNA MUTATIONS

GENE (EXON)	VARIANT INFORMATION				CLASSIFICATION (AMP/ASCO/CAP)
	Coding DNA Alteration	Amino Acid Alteration	Variant Allele Frequency	Coverage	
NRAS (Exon2)	c.34G>T	p.G12C	~25%	1998x	Tier IIC

RNA FUSIONS

Gene Fusion Detected	Read Counts	Read Counts (per million)
KMT2A(9)::MLLT10(9) Fusion	523	1098

GENEVOLVE
Dr Lal PathLabs

Dr Lal PathLabs
OncoPro
Comprehensive Oncology Diagnostics

HOTSPOT GENES COVERED (23)

ABL1	BRAF	CBL	CSF3R	DNMT3A	FLT3	GATA2
HRAS	IDH1	IDH2	JAK2	KIT	KRAS	MPL
MYD88	NPM1	NRAS	PTPN11	SETBP1	SF3B1	SRSF2
U2AF1	WT1					

FULL GENES COVERED (17)

ASXL1	BCOR	CALR	CEBPA	ETV6	EZH2	IKZF1
NF1	PHF6	PRPF8	RB1	RUNX1	SH2B3	STAG2
TET2	TP53	ZRSR2				

FUSION DRIVER GENES COVERED (29)

ABL1	ALK	BCL2	BRAF	CCND1	CREBBP	EGFR
ETV6	FGFR1	FGFR2	FUS	HMGA2	JAK2	KMT2A
TFE3	MECOM	MET	MLLT10	MLLT3	MYBL1	MYH11
NTRK3	NUP214	PDGFRA	PDGFRB	RARA	RBM15	RUNX1
TCF3						

EXPRESSION GENES (5)

BAALC	MECOM	MYC	SMC1A	WT1

GENEVOLVE Dr Lal PathLabs

Dr Lal PathLabs OncoPro Comprehensive Oncology Diagnostics

Tier Classification (AMP/ASCO/CAP)

Tier I: Variants of Strong Clinical Significance Therapeutic, Prognostic & Diagnostic Relevance	Tier II: Variants of Potential Clinical Significance Therapeutic, Prognostic & Diagnostic Relevance	Tier III: Variants of Unknown Clinical Significance	Tier IV: Benign or Likely Benign Variants
Level A Evidence FDA-approved therapy included in professional guidelines	Level C Evidence FDA-approved therapies for different tumor types or investigational therapies Multiple small published studies with some consensus	Not observed at a significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases No convincing published evidence of cancer association	Observed at significant allele frequency in the general or specific subpopulation databases No existing published evidence of cancer association
Level B Evidence Well-powered studies with consensus from experts in the field	Level D Evidence Preclinical trials or a few case reports without consensus		

Lab ID : 183808840

Clinical Indication : A 5 years old Female with Acute Leukemia under evaluation ?AML

Sample Type : Peripheral Blood

Sample Cancer Type: Acute Lymphoblastic Leukemia

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Relevant Therapy Details	5
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Clinical Trials Summary	18
Clinical Trials	23

Report Highlights
2 Relevant Biomarkers
16 Therapies Available
19 Clinical Trials

Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
KMT2A::MLLT10 fusion **Prognostic significance:** NCCN: Poor	None	allogeneic stem cells azacitidine cladribine + cytarabine + daunorubicin cytarabine cytarabine + daunorubicin cytarabine + daunorubicin + etoposide cytarabine + daunorubicin + fludarabine cytarabine + etoposide + idarubicin cytarabine + fludarabine + idarubicin + filgrastim cytarabine + idarubicin cytarabine + mitoxantrone decitabine gemtuzumab ozogamicin glasdegib + chemotherapy liposomal cytarabine-daunorubicin CPX-351 venetoclax + chemotherapy	17
NRAS p.(G12C) c.34G>T Allele Frequency: 25.33%	None	None	2

Public data sources included in relevant therapies: FDA[1], NCCN, **EMA**[2], ESMO
Public data sources included in prognostic and diagnostic significance: NCCN, ESMO

Relevant Biomarkers (continued)

Alerts informed by public data sources: Contraindicated, Resistance, Breakthrough, Fast Track

KMT2A::MLLT10 fusion **revumenib** [1]

Public data sources included in alerts: FDA[1], NCCN, **EMA**[2], ESMO

Biomarker Descriptions

NRAS p.(G12C) c.34G>T

NRAS proto-oncogene, GTPase

Background: The NRAS proto-oncogene encodes a GTPase that functions in signal transduction and is a member of the RAS superfamily which also includes KRAS and HRAS. RAS proteins mediate the transmission of growth signals from the cell surface to the nucleus via the PI3K/AKT/MTOR and RAS/RAF/MEK/ERK pathways, which regulate cell division, differentiation, and survival[1,2,3].

Alterations and prevalence: Recurrent mutations in RAS oncogenes cause constitutive activation and are found in 20-30% of cancers. NRAS mutations are particularly common in melanomas (up to 25%) and are observed at frequencies of 5-10% in acute myeloid leukemia, colorectal, and thyroid cancers[4,5]. The majority of NRAS mutations consist of point mutations at G12, G13, and Q61[4,6]. Mutations at A59, K117, and A146 have also been observed but are less frequent[7,8].

Potential relevance: Currently, no therapies are approved for NRAS aberrations. The EGFR antagonists, cetuximab[9] and panitumumab[10], are contraindicated for treatment of colorectal cancer patients with NRAS mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146)[8]. In 2022, the FDA has granted fast track designation to the pan-RAF inhibitor, KIN-2787[11], for the treatment of NRAS-mutant metastatic or unresectable melanoma. In 2023, the FDA has granted fast track designation to the pan-RAF inhibitor, naporafenib, in combination with trametinib[12] for NRAS-mutated unresectable or metastatic melanoma. NRAS mutations are associated with poor prognosis in patients with low-risk myelodysplastic syndrome[13] as well as melanoma[14]. In a phase III clinical trial in patients with advanced NRAS-mutant melanoma, binimetinib improved progression free survival (PFS) relative to dacarbazine with median PFS of 2.8 and 1.5 months, respectively[15].

Variant Details

DNA Sequence Variants

Gene	Amino Acid Change	Coding	Variant ID	Locus	Allele Frequency	Transcript	Variant Effect
NRAS	p.(G12C)	c.34G>T	COSM562	chr1:115258748	25.33%	NM_002524.5	missense

Gene Fusions

Genes	Variant ID	Locus
KMT2A::MLLT10	KMT2A-MLLT10.K9M9	chr11:118355029 - chr10:21940602

Relevant Therapy Summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ✖ No evidence

KMT2A::MLLT10 fusion

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
Allogeneic hematopoietic stem cell transplantation	✖	○	✖	○	✖
cytarabine + daunorubicin	✖	○	✖	○	✖
azacitidine	✖	○	✖	✖	✖
cytarabine	✖	○	✖	✖	✖
cytarabine + daunorubicin + etoposide	✖	○	✖	✖	✖
cytarabine + etoposide + idarubicin	✖	○	✖	✖	✖
cytarabine + fludarabine + idarubicin + filgrastim	✖	○	✖	✖	✖
cytarabine + idarubicin	✖	○	✖	✖	✖
cytarabine + mitoxantrone	✖	○	✖	✖	✖
decitabine	✖	○	✖	✖	✖
gemtuzumab ozogamicin	✖	○	✖	✖	✖
glasdegib + cytarabine	✖	○	✖	✖	✖
liposomal cytarabine-daunorubicin CPX-351	✖	○	✖	✖	✖
venetoclax + azacitidine	✖	○	✖	✖	✖
venetoclax + cytarabine	✖	○	✖	✖	✖
venetoclax + decitabine	✖	○	✖	✖	✖
cladribine + cytarabine + daunorubicin	✖	✖	✖	○	✖
cytarabine + daunorubicin + fludarabine	✖	✖	✖	○	✖
allogeneic stem cells, chemotherapy, radiation therapy	✖	✖	✖	✖	● (II)
allopurinol, chemotherapy, sirolimus, radiation therapy, mycophenolate mofetil	✖	✖	✖	✖	● (II)
CART-CD19	✖	✖	✖	✖	● (II)
α/β CD3+ T-cell and CD19+ B-cells	✖	✖	✖	✖	● (II)
blinatumomab, bortezomib, vorinostat, ziftomenib, steroid, chemotherapy	✖	✖	✖	✖	● (I/II)
BN-104	✖	✖	✖	✖	● (I/II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Relevant Therapy Summary (continued)

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ✖ No evidence

KMT2A::MLLT10 fusion (continued)

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
stem cell therapy	✖	✖	✖	✖	● (I/II)
bleximenib	✖	✖	✖	✖	● (I)
BMF-219	✖	✖	✖	✖	● (I)
BMF-500	✖	✖	✖	✖	● (I)
CART cell therapy	✖	✖	✖	✖	● (I)
CART-CD19/CD22, stem cell engraftment therapy (Orca Biosystems)	✖	✖	✖	✖	● (I)
CART-CD19A, chemotherapy	✖	✖	✖	✖	● (I)
HMPL-506	✖	✖	✖	✖	● (I)
radiation therapy, chemotherapy, stem cell engraftment therapy (Orca Biosystems), tacrolimus	✖	✖	✖	✖	● (I)
venetoclax, chemotherapy	✖	✖	✖	✖	● (I)

NRAS p.(G12C) c.34G>T

Relevant Therapy	FDA	NCCN	EMA	ESMO	Clinical Trials*
trametinib, steroid, chemotherapy	✖	✖	✖	✖	● (I/II)
JZP-815	✖	✖	✖	✖	● (I)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available.

Relevant Therapy Details

Current NCCN Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types

NCCN information is current as of 2024-08-01. To view the most recent and complete version of the guideline, go online to NCCN.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/what-we-do/international-adaptations.

Some variant specific evidence in this report may be associated with a broader set of alterations from the NCCN Guidelines. Specific variants listed in this report were sourced from approved therapies or scientific literature. These therapeutic options are appropriate for certain population segments with cancer. Refer to the NCCN Guidelines® for full recommendation.

KMT2A::MLLT10 fusion

○ Allogeneic hematopoietic stem cell transplantation

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy); Preferred intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

○ azacitidine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

cytarabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + daunorubicin + etoposide

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

cytarabine + daunorubicin + etoposide

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + etoposide + idarubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + etoposide + idarubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + fludarabine + idarubicin + filgrastim

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

cytarabine + idarubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

cytarabine + idarubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

---

decitabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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gemtuzumab ozogamicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: CD33 positive, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

glasdegib + cytarabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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liposomal cytarabine-daunorubicin CPX-351

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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venetoclax + azacitidine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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venetoclax + azacitidine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

venetoclax + azacitidine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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venetoclax + cytarabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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venetoclax + decitabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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venetoclax + decitabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

venetoclax + decitabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2A

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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azacitidine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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azacitidine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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cytarabine + daunorubicin + etoposide

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

cytarabine + daunorubicin + etoposide

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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cytarabine + etoposide + idarubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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cytarabine + etoposide + idarubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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cytarabine + fludarabine + idarubicin + filgrastim

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

cytarabine + fludarabine + idarubicin + filgrastim

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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cytarabine + mitoxantrone

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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cytarabine + mitoxantrone

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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decitabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

decitabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Useful in certain circumstances

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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liposomal cytarabine-daunorubicin CPX-351

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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liposomal cytarabine-daunorubicin CPX-351

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

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venetoclax + cytarabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: Deletion 17p negative, KMT2A PTD negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

KMT2A::MLLT10 fusion (continued)

venetoclax + cytarabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

Other criteria: KMT2A PTD negative, TP53 mutation negative

NCCN Recommendation category: 2B

Population segment (Line of therapy):
- (Induction therapy); Other recommended intervention

Reference: NCCN Guidelines® - NCCN-Acute Myeloid Leukemia [Version 3.2024]

Current ESMO Information

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types

ESMO information is current as of 2024-08-01. For the most up-to-date information, search www.esmo.org.

KMT2A::MLLT10 fusion

○ Allogeneic hematopoietic stem cell transplantation

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

ESMO Level of Evidence/Grade of Recommendation: II / A

Population segment (Line of therapy):
- (Consolidation therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

○ cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

ESMO Level of Evidence/Grade of Recommendation: II / A

Population segment (Line of therapy):
- (Induction therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

○ cladribine + cytarabine + daunorubicin

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

ESMO Level of Evidence/Grade of Recommendation: II / C

Population segment (Line of therapy):
- (Induction therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

KMT2A::MLLT10 fusion (continued)

cytarabine + daunorubicin + fludarabine

Cancer type: Acute Myeloid Leukemia **Variant class:** KMT2A fusion

ESMO Level of Evidence/Grade of Recommendation: II / C

Population segment (Line of therapy):
- (Induction therapy)

Reference: ESMO Clinical Practice Guidelines - ESMO-Acute Myeloblastic Leukaemia in Adult Patients [Ann Oncol (2020); 31(6): 697-712.]

Prognostic Details

Current NCCN Information

NCCN information is current as of 2024-08-01. To view the most recent and complete version of the guideline, go online to NCCN.org.
For NCCN International Adaptations & Translations, search www.nccn.org/global/what-we-do/international-adaptations.

Some variant specific evidence in this report may be associated with a broader set of alterations from the NCCN Guidelines. Specific variants listed in this report were sourced from approved therapies or scientific literature. These therapeutic options are appropriate for certain population segments with cancer. Refer to the NCCN Guidelines® for full recommendation.

KMT2A::MLLT10 fusion

Prognostic significance: NCCN: Poor

Cancer type: Acute Lymphoblastic Leukemia **Variant class:** KMT2A fusion

NCCN Recommendation category: 2A

Summary:
- Cytogenetics risk groups for B-ALL

Reference: NCCN Guidelines® - NCCN-Acute Lymphoblastic Leukemia [Version 2.2024]

Clinical Trials Summary

KMT2A::MLLT10 fusion

NCT ID	Title	Phase
NCT06013423	Optimized Cord Blood Transplantation for the Treatment of High-Risk Hematologic Malignancies in Adults and Pediatrics	II
NCT05805605	Allogeneic Hematopoietic Stem Cell Transplantation Using Reduced Intensity Conditioning (RIC) With Post-Transplant Cytoxan (PTCy) for the Treatment of Hematological Diseases	II
NCT04276870	CD19-Directed Chimeric Antigen Receptor CD19 Redirected Autologous T Cells (CART19) for Orphan Indications of Pediatric B Cell Acute Lymphoblastic Leukemia (B ALL)	II
NCT05800210	Alpha/Beta T Cell and CD19+ B Cell Depletion in Allogeneic Stem Cell Transplantation in Patients With Malignant Diseases	II
NCT05848687	TINI 2: Total Therapy for Infants With Acute Lymphoblastic Leukemia II	I/II
NCT06052813	A Phasel/II, Multicenter, Open-label Clinical Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of the Menin Inhibitor BN104 in the Treatment of Patients With Relapsed/Refractory Acute Leukemia	I/II
NCT04787263	Phase I/II Study of Anti-CD19 Chimeric Antigen Receptor-Expressing T Cells in Pediatric Patients Affected by Relapsed/Refractory CD19+ Acute Lymphoblastic Leukemia and Diffuse Large B Cell Lymphoma (DLBCL) or Primary Mediastinal B Cell Lymphoma (PML)	I/II

Clinical Trials Summary (continued)

KMT2A::MLLT10 fusion (continued)

NCT ID	Title	Phase
NCT01203722	Reduced Intensity, Partially HLA Mismatched Allogeneic BMT for Hematologic Malignancies Using Donors Other Than First-degree Relatives	I/II
NCT05153330	A Phase I First-in-human Dose-escalation and Dose-expansion Study of BMF-219, an Oral Irreversible Menin Inhibitor, in Adult Patients With Acute Leukemia (AL), Diffuse Large B-cell Lymphoma (DLBCL), and Multiple Myeloma (MM).	I
NCT05918692	A Phase 1, Open-label, Dose-escalation, and Dose-expansion Study of BMF-500, an Oral Covalent FLT3 Inhibitor, in Adults With Acute Leukemia	I
NCT05038696	Chimeric-Antigen Receptor (CAR) T-Cell Therapy Using Multiple CARs and Cell Marker Profiling in High Risk and Relapsed/ Refractory B-Lineage Acute Lymphoblastic Leukaemia	I
NCT05507827	Phase I Trial Evaluating the Safety of Myeloablative Conditioning, Orca-T, and Allogeneic, Donor-Derived CD19/CD22-CAR (Chimeric Antigen Receptor) T Cells in Adults With B-Cell Acute Lymphoblastic Leukemia (ALL)	I
NCT05350787	To Evaluate the Safety, Efficacy and Pharmacokinetics of ThisCART19A in Patients With Relapsed and Refractory Acute B-cell Leukemia	I
NCT06387082	A Multicenter, Open-Label Phase I Clinical Study to Evaluate the Safety, Pharmacokinetics and Efficacy of HMPL-506 in Patients With Hematological Malignancies	I
NCT06195891	A Single Center, Non-Randomized, Phase 1b Study of Orca-T Following Escalated Dose of Total Marrow and Lymphoid Irradiation in Patients With Acute Leukemias and MDS	I
NCT03826992	A Phase I Study of Venetoclax Combined With Vyxeos (CPX-351) for Children, Adolescents and Young Adults With Relapsed or Refractory Acute Leukemia	I
NCT04811560	A First in Human Study of the Menin-KMT2A (MLL1) Inhibitor JNJ-75276617 in Participants With Acute Leukemia	I

NRAS p.(G12C) c.34G>T

NCT ID	Title	Phase
NCT05658640	International Proof of Concept Therapeutic Stratification Trial of Molecular Anomalies in Relapsed or Refractory HEMatological Malignancies in Children, Subprotocol D: Trametinib + Dexamethasone + Cyclophosphamide and Cytarabine in Pediatric Patients With Relapsed or Refractory Hematological Malignancies	I/II
NCT05557045	Phase I, FIH, Open-label, Nonrandomized, Multicenter Study of JZP815 in Participants With Advanced or Metastatic Solid Tumors Harboring Alterations in the MAPK Pathway	I

Evidence Summary by Variant Class

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

KMT2A::MLLT10 fusion

Variant Class	Evidence Items
KMT2A aberration	1
↳ KMT2A fusion	62
↳ KMT2A::MLLT10 fusion	0
t(10;11)	0
↳ t(10;11)(p12;q23)	0
↳ KMT2A::MLLT10 fusion	0

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Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

NRAS p.(G12C) c.34G>T

Variant Class	Evidence Items
RAS/RAF/MEK/ERK pathway status	0
↳ RAS status	0
↳ RAS aberration	0
↳ NRAS status	0
↳ NRAS aberration	0
↳ NRAS positive	0
↳ NRAS mutation status	0
↳ NRAS mutation	1
↳ NRAS exon 2 mutation	0
↳ NRAS G12 mutation	0
↳ RAS/RAF/MEK/ERK pathway	0
↳ RAS aberration	0
↳ NRAS status	0
↳ NRAS aberration	0
↳ NRAS positive	0
↳ NRAS mutation status	0
↳ NRAS mutation	1
↳ NRAS exon 2 mutation	0
↳ NRAS G12 mutation	0
↳ RAS/RAF/MEK/ERK mutation	1
↳ RAS mutation status	0
↳ RAS mutation	0
↳ NRAS mutation status	0
↳ NRAS mutation	1
↳ NRAS exon 2 mutation	0

Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

NRAS p.(G12C) c.34G>T (continued)

Variant Class	Evidence Items
↳ NRAS G12 mutation	0
RAS/RAF/MEK/ERK pathway status	0
↳ RAS status	0
↳ RAS aberration	0
↳ NRAS status	0
↳ NRAS aberration	0
↳ NRAS positive	0
↳ NRAS mutation status	0
↳ NRAS mutation	1
↳ NRAS activating mutation	0
↳ RAS activating aberration	0
↳ RAS activating mutation	0
↳ NRAS activating mutation	0
↳ RAS/RAF/MEK/ERK pathway	0
↳ RAS aberration	0
↳ NRAS status	0
↳ NRAS aberration	0
↳ NRAS positive	0
↳ NRAS mutation status	0
↳ NRAS mutation	1
↳ NRAS activating mutation	0
↳ RAS activating aberration	0
↳ RAS activating mutation	0
↳ NRAS activating mutation	0
↳ RAS/RAF/MEK/ERK mutation	1

Evidence Summary by Variant Class (continued)

A variant class hierarchy was created to summarize gene variants with associated clinical evidence. Evidence items refers to citations across the different global data sources.

NRAS p.(G12C) c.34G>T (continued)

Variant Class	Evidence Items
↳ RAS mutation status	0
↳ RAS mutation	0
↳ NRAS mutation status	0
↳ NRAS mutation	1
↳ NRAS activating mutation	0
↳ RAS activating mutation	0
↳ NRAS activating mutation	0

Current Clinical Trials Information

Clinical Trials information is current as of 2024-08-01. For the most up-to-date information regarding a particular trial, search www.clinicaltrials.gov by NCT ID or search local clinical trials authority website by local identifier listed in 'Other identifiers'.

KMT2A::MLLT10 fusion

NCT06013423
Optimized Cord Blood Transplantation for the Treatment of High-Risk Hematologic Malignancies in Adults and Pediatrics

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: NCI-2023-05598, RG1123652

Population segments: (N/A), Aggressive, Blast phase, Diffuse large B-cell lymphoma (DLBCL), Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), High risk, Indolent, Mantle cell lymphoma (MCL), Remission, Second line, Small lymphocytic lymphoma (SLL)

Phase: II

Therapies: allogeneic stem cells, chemotherapy, radiation therapy

Location: United States

US State: WA

Contact: Ann Dahlberg [206-667-1959; adahlber@fredhutch.org]

KMT2A::MLLT10 fusion (continued)

NCT05805605
Allogeneic Hematopoietic Stem Cell Transplantation Using Reduced Intensity Conditioning (RIC) With Post-Transplant Cytoxan (PTCy) for the Treatment of Hematological Diseases

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifier: 2022LS146

Population segments: (N/A), Accelerated phase, Aggressive, Chronic phase, Extranodal marginal zone B-cell lymphoma (MALT), Follicular lymphoma (FL), High risk, Indolent, Int-2 risk, Other subtype, Primary Myelofibrosis, Remission, Second line

Phase: II

Therapies: allopurinol, chemotherapy, sirolimus, radiation therapy, mycophenolate mofetil

Location: United States

US State: MN

Contact: Mark Juckett [612-625-5469; juck0001@umn.edu]

NCT04276870
CD19-Directed Chimeric Antigen Receptor CD19 Redirected Autologous T Cells (CART19) for Orphan Indications of Pediatric B Cell Acute Lymphoblastic Leukemia (B ALL)

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other inclusion criteria: CD19 positive

Other identifiers: 19-016979, 19CT023, 834653, NCI-2020-02051

Population segments: B-cell, First line, High risk, Pediatric or Adolescent, Second line, Untreated

Phase: II

Therapy: CART-CD19

Location: United States

US State: PA

Contact: Dr. Amanda DiNofia [215-590-5476; DiNofiaA@chop.edu]

NCT05800210
Alpha/Beta T Cell and CD19+ B Cell Depletion in Allogeneic Stem Cell Transplantation in Patients With Malignant Diseases

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifier: UF-PED-004

Population segments: (N/A), Aggressive, Classical, Graft-versus-host disease, High risk, Indolent, Line of therapy N/A, Nodular lymphocyte-predominant, Remission, Second line, Stem cell transplant

Phase: II

Therapy: α/β CD3+ T-cell and CD19+ B-cells

Location: United States

US State: FL

Contact: Priya Gurjar [352-273-6772; PMO@cancer.ufl.edu]

KMT2A::MLLT10 fusion (continued)

NCT05848687
TINI 2: Total Therapy for Infants With Acute Lymphoblastic Leukemia II

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other inclusion criteria: CD19 positive

Other identifiers: PEDSHEMALL0015, TINI 2

Population segments: (N/A), First line, Maintenance/Consolidation, Pediatric or Adolescent, Untreated

Phase: I/II

Therapies: blinatumomab, bortezomib, vorinostat, ziftomenib, steroid, chemotherapy

Location: United States

US State: CA

Contact: Dr. Tanja A. Gruber [650-723-5535; tagruber@stanford.edu]

NCT06052813
A Phase I/II, Multicenter, Open-label Clinical Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of the Menin Inhibitor BN104 in the Treatment of Patients With Relapsed/Refractory Acute Leukemia

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: BN104-101, CTR20232750

Population segments: (N/A), Second line

Phase: I/II

Therapy: BN-104

Location: China

NCT04787263
Phase I/II Study of Anti-CD19 Chimeric Antigen Receptor-Expressing T Cells in Pediatric Patients Affected by Relapsed/Refractory CD19+ Acute Lymphoblastic Leukemia and Diffuse Large B Cell Lymphoma (DLBCL) or Primary Mediastinal B Cell Lymphoma (PML)

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: CD19-CAR_Lenti, EudraCT Number: 2020-003452-32

Population segments: (N/A), Aggressive, B-cell, Diffuse large B-cell lymphoma (DLBCL), High risk, Other subtype, Pediatric or Adolescent, Second line

Phase: I/II

Therapy: CART-CD19

Location: Italy

KMT2A::MLLT10 fusion (continued)

NCT01203722
Reduced Intensity, Partially HLA Mismatched Allogeneic BMT for Hematologic Malignancies Using Donors Other Than First-degree Relatives

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: CRMS-33771, J1055, NCI-2011-00377

Population segments: (N/A), Aggressive, B-cell, Chronic phase, Classical, Diffuse large B-cell lymphoma (DLBCL), Follicular lymphoma (FL), Graft-versus-host disease, Indolent, Mantle cell lymphoma (MCL), Nodular lymphocyte-predominant, Pediatric, Pediatric or Adolescent, Peripheral T-cell lymphoma (PTCL), Poor-risk, Second line, Small lymphocytic lymphoma (SLL), Stem cell transplant, T-cell, Third line

Phase: I/II

Therapy: stem cell therapy

Location: United States

US State: MD

Contact: Dr. Richard Ambinder [410-955-8839; rambind1@jhmi.edu]

NCT05153330
A Phase I First-in-human Dose-escalation and Dose-expansion Study of BMF-219, an Oral Irreversible Menin Inhibitor, in Adult Patients With Acute Leukemia (AL), Diffuse Large B-cell Lymphoma (DLBCL), and Multiple Myeloma (MM).

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: BF-MNN-101, COVALENT-101, NCI-2021-14401

Population segments: (N/A), Aggressive, Diffuse large B-cell lymphoma (DLBCL), Line of therapy N/A, Second line

Phase: I

Therapy: BMF-219

Locations: Greece, Italy, Netherlands, Spain, United States

US States: CA, FL, GA, IL, OH, TN, TX, VA

Contact: Mona Vimal [844-245-0490; clinicaltrials@biomeafusion.com]

NCT05918692
A Phase 1, Open-label, Dose-escalation, and Dose-expansion Study of BMF-500, an Oral Covalent FLT3 Inhibitor, in Adults With Acute Leukemia

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: 3559023, COVALENT-103

Population segments: (N/A), Second line

Phase: I

Therapy: BMF-500

Location: United States

US States: CA, CO, IL, KY, NY, OH, OK, TX, VA, WA

Contact: Mona Vimal [844-245-0490; clinicaltrials@biomeafusion.com]

KMT2A::MLLT10 fusion (continued)

NCT05038696
Chimeric-Antigen Receptor (CAR) T-Cell Therapy Using Multiple CARs and Cell Marker Profiling in High Risk and Relapsed/ Refractory B-Lineage Acute Lymphoblastic Leukaemia

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: 2020/00865, ALaCART, ALaCART-B

Population segments: (N/A), Aggressive, B-cell, Cutaneous T-cell lymphoma (CTCL), High risk, Lymphoblastic lymphoma (LBL), Second line

Phase: I

Therapy: CART cell therapy

Location: Singapore

NCT05507827
Phase I Trial Evaluating the Safety of Myeloablative Conditioning, Orca-T, and Allogeneic, Donor-Derived CD19/CD22-CAR (Chimeric Antigen Receptor) T Cells in Adults With B-Cell Acute Lymphoblastic Leukemia (ALL)

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other inclusion criteria: CD19 positive

Other identifiers: BMT378, NCI-2022-07232

Population segments: (N/A), B-cell, Remission, Second line

Phase: I

Therapies: CART-CD19/CD22, stem cell engraftment therapy (Orca Biosystems)

Location: United States

US State: CA

Contact: Lindsay Danley [650-721-2372; lindsmd@stanford.edu]

NCT05350787
To Evaluate the Safety, Efficacy and Pharmacokinetics of ThisCART19A in Patients With Relapsed and Refractory Acute B-cell Leukemia

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifier: FT400-004

Population segments: (N/A), B-cell, Fourth line or greater, Third line

Phase: I

Therapies: CART-CD19A, chemotherapy

Location: China

NCT06387082
A Multicenter, Open-Label Phase I Clinical Study to Evaluate the Safety, Pharmacokinetics and Efficacy of HMPL-506 in Patients With Hematological Malignancies

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: 2023-506-00CH1, CTR20241210

Population segments: (N/A), Second line

Phase: I

Therapy: HMPL-506

Location: China

KMT2A::MLLT10 fusion (continued)

NCT06195891
A Single Center, Non-Randomized, Phase 1b Study of Orca-T Following Escalated Dose of Total Marrow and Lymphoid Irradiation in Patients With Acute Leukemias and MDS

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifiers: 23343, NCI-2023-08816, P30CA033572

Population segments: (N/A), Int-2 risk, Line of therapy N/A

Phase: I

Therapies: radiation therapy, chemotherapy, stem cell engraftment therapy (Orca Biosystems), tacrolimus

Location: United States

US State: CA

Contact: Amandeep Salhotra [626-218-2405; asalhotra@coh.org]

NCT03826992
A Phase I Study of Venetoclax Combined With Vyxeos (CPX-351) for Children, Adolescents and Young Adults With Relapsed or Refractory Acute Leukemia

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A fusion

Other identifier: V2-MA-1801

Population segments: (N/A), Pediatric or Adolescent, Second line, T-cell

Exclusion criteria variant class: BCR::ABL1 fusion

Phase: I

Therapies: venetoclax, chemotherapy

Location: United States

US State: OH

Contact: Site Pulblic Contact [513-636-2799; cancer@cchmc.org]

NCT04811560
A First in Human Study of the Menin-KMT2A (MLL1) Inhibitor JNJ-75276617 in Participants With Acute Leukemia

Cancer type: Acute Lymphoblastic Leukemia

Variant class: KMT2A aberration

Other identifiers: 2021-0319, 21202, 75276617ALE1001, CR108998, EUCT number: 2023-506581-31-00, EudraCT Number: 2020-005967-30, IRAS ID: 297789, JNJ-75276617ALE1001, NCI-2021-05696, S21-00051

Population segments: (N/A), Fourth line or greater, Second line, Third line

Phase: I

Therapy: bleximenib

Locations: Australia, France, Spain, United Kingdom, United States

US States: CA, MA, NY, TX, WI

Contact: Study Contact [844-434-4210; Participate-In-This-Study@its.jnj.com]

NRAS p.(G12C) c.34G>T

NCT05658640

International Proof of Concept Therapeutic Stratification Trial of Molecular Anomalies in Relapsed or Refractory HEMatological Malignancies in Children, Subprotocol D: Trametinib + Dexamethasone + Cyclophosphamide and Cytarabine in Pediatric Patients With Relapsed or Refractory Hematological Malignancies

Cancer type: Acute Lymphoblastic Leukemia

Variant class: NRAS mutation

Other identifiers: EudraCT Number: 2021-003398-79, HEM-iSMART D, MH21HEM

Population segments: (N/A), Aggressive, Lymphoblastic lymphoma (LBL), Pediatric or Adolescent, Second line

Phase: I/II

Therapies: trametinib, steroid, chemotherapy

Location: Netherlands

NCT05557045

Phase I, FIH, Open-label, Nonrandomized, Multicenter Study of JZP815 in Participants With Advanced or Metastatic Solid Tumors Harboring Alterations in the MAPK Pathway

Cancer type: Unspecified Hematological Cancer

Variant class: RAS/RAF/MEK/ERK mutation

Other identifiers: JZP815-101, NCI-2022-10167

Population segments: (N/A), Line of therapy N/A, Stage III, Stage IV

Phase: I

Therapy: JZP-815

Location: United States

US States: CO, FL, IL, NY, OK, PA, TN

Contact: Clinical Trial Disclosure & Transparency [215-832-3750; ClinicalTrialDisclosure@JazzPharma.com]

METHODOLOGY: This panel targets 40 key genes, 29 fusion driver genes and uses Next generation sequencing methodology. The kits used is Oncomine myeloid assay. These genes have been selected on the basis of their known impact as actionable targets of existing and emerging anti-cancer therapies, and the prognostic features in specific tumor types. The sensitivity of the assays depends on the quality of the sample and the percentage of blasts. In validation studies using control materials and a variety of cell lines, the minimum analytic detection limit for each of the assays is 5%. The Genomic positions are given in reference to the GRCh37 (hg19) assembly of the human genome.

LIMITATIONS: The accuracy and completeness of this information may vary due to variable information available in different databases. Variants with variant allele frequency at nearly 50% or 100% may be considered Germline mutations. Synonymous mutations were not considered while preparing this report. UDG treatment has not been done. The mutations are usually not confirmed using Sanger sequencing and/or alternate technologies and additional testing might be required if clinically indicated. False negative results may be due to sampling error/errors in sample handling as well as clonal density below the limit of detection.

DISCLAIMER: This report provides information about the patient's mutations that may aid the physician's decision making process, but this test should not be the sole source of information for making decisions on patient care and treatment. These tests should be interpreted in the context of standard clinical, laboratory, and pathological findings. Identification of a mutation in one or more of these genes does not guarantee activity of the drug in a given indication. Insertions and deletions greater than 10bp in size may not be reported by this assay. Benign mutations and mutations in the intronic regions have not been included in this report. The information provided in this report was collected from various sources that we believe to be reliable and quality control procedures have been put in place to ensure the information provided is as accurate, comprehensive, and current as possible. The information provided should only be utilized as a guide or aid and the decision to select any therapy option based on the information reported here resides

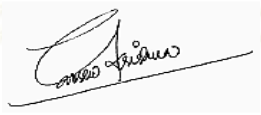
solely with the discretion of the treating physician. Patient care and treatment decisions should only be made by the physician after taking into account all relevant information available including but not limited to the patient's condition, family history, findings upon examination, results of other diagnostic tests, and the current standards of care. This report should only be used as an aid and the physician should employ clinical judgment in arriving at any decision for patient care or treatment.

Report Signed By

Name	Role	Date	Comments
Lalpath Labs	National Head - Genomics & Clinical Cytogenomics	01 Oct 2024 04:50 PM	Kindly correlate with clinical history, treatment history including blood transfusion history, Complete Blood Picture, BMA/BMBx findings, Flow cytometry, Cytogenetics and other relevant laboratory parameters.

References

1. Pylayeva-Gupta et al. RAS oncogenes: weaving a tumorigenic web. Nat. Rev. Cancer. 2011 Oct 13;11(11):761-74. PMID: 21993244
2. Karnoub et al. Ras oncogenes: split personalities. Nat. Rev. Mol. Cell Biol. 2008 Jul;9(7):517-31. PMID: 18568040
3. Scott et al. Therapeutic Approaches to RAS Mutation. Cancer J. 2016 May-Jun;22(3):165-74. doi: 10.1097/PPO.0000000000000187. PMID: 27341593
4. Weinstein et al. The Cancer Genome Atlas Pan-Cancer analysis project. Nat. Genet. 2013 Oct;45(10):1113-20. PMID: 24071849
5. Janku et al. PIK3CA mutations frequently coexist with RAS and BRAF mutations in patients with advanced cancers. PLoS ONE. 2011;6(7):e22769. PMID: 21829508
6. Ohashi et al. Characteristics of lung cancers harboring NRAS mutations. Clin. Cancer Res. 2013 May 1;19(9):2584-91. PMID: 23515407
7. Cerami et al. The cBio cancer genomics portal: an open platform for exploring multidimensional cancer genomics data. Cancer Discov. 2012 May;2(5):401-4. PMID: 22588877
8. Allegra et al. Extended RAS Gene Mutation Testing in Metastatic Colorectal Carcinoma to Predict Response to Anti-Epidermal Growth Factor Receptor Monoclonal Antibody Therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. J. Clin. Oncol. 2016 Jan 10;34(2):179-85. PMID: 26438111
9. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125084s279lbl.pdf
10. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125147s210lbl.pdf
11. https://investors.kinnate.com/news-releases/news-release-details/kinnate-biopharma-inc-receives-fast-track-designation-us-food
12. https://investors.erasca.com/node/7891/pdf
13. NCCN Guidelines® - NCCN-Myelodysplastic Syndromes [Version 3.2024]
14. Johnson et al. Treatment of NRAS-Mutant Melanoma. Curr Treat Options Oncol. 2015 Apr;16(4):15. doi: 10.1007/s11864-015-0330-z. PMID: 25796376
15. Dummer et al. Binimetinib versus dacarbazine in patients with advanced NRAS-mutant melanoma (NEMO): a multicentre, open-label, randomised, phase 3 trial. Lancet Oncol. 2017 Apr;18(4):435-445. PMID: 28284557



Dr. Vamshi Krishna Thamtam
MCI-I7-25915
MBBS, MD Pathology
DipRCPath, UK (Molecular Genetics)
Fellowship, Tata Medical Center
National Head – Genomics & Clinical Cytogenomics
National Reference Laboratory
Dr Lal PathLabs Ltd

--- END OF REPORT ---

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•Test results released pertain to the specimen submitted.•All test results are dependent on the quality of the sample received by the Laboratory.•Laboratory investigations are only a tool to facilitate in arriving at a diagnosis and should be clinically correlated by the Referring Physician .•Report delivery may be delayed due to unforeseen circumstances. Inconvenience is regretted.•Certain tests may require further testing at additional cost for derivation of exact value. Kindly submit request within 72 hours post reporting.•Test results may show interlaboratory variations.•The Courts/Forum at Delhi shall have exclusive jurisdiction in all disputes/claims concerning the test(s) & or results of test(s).•Test results are not valid for medico legal purposes.•This is computer generated medical diagnostic report that has been validated by Authorized Medical Practitioner /Doctor.•The report does not need physical signature.

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Tel: +91-11-49885050,Fax: - +91-11-2788-2134, E-mail: lalpathlabs@lalpathlabs.com

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