

Ziftomenib Combined With Intensive Induction (7+3) for Newly Diagnosed *NPM1*-m or *KMT2A*-r Acute Myeloid Leukemia (AML): Long-Term Results From the KOMET-007 Trial

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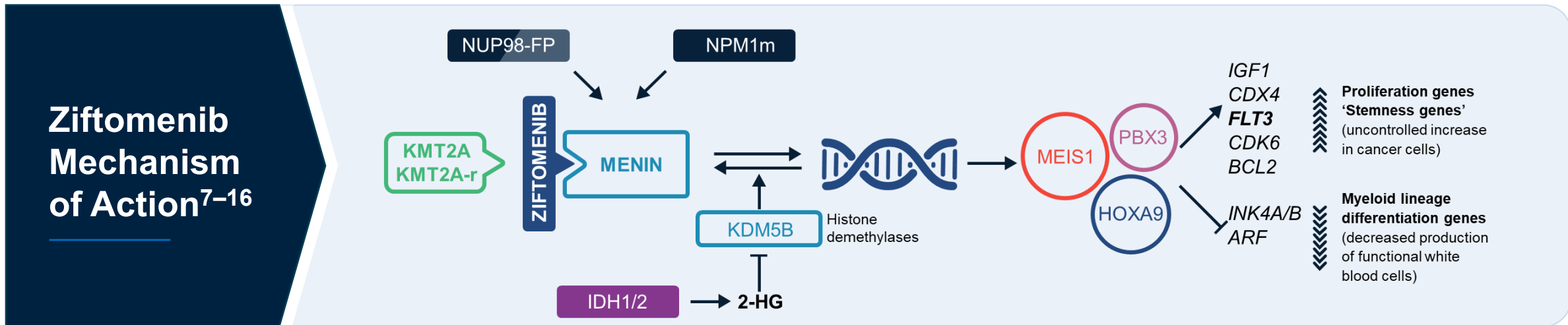
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Ziftomenib Targets the Menin Pathway, a Foundational Target in AML

- *NPM1* mutations and *KMT2A* rearrangements drive leukemogenesis in ~35–40% of AML^{1,2}
- **Ziftomenib** – a potent, selective, once-daily oral menin inhibitor – is approved by the U.S. FDA as monotherapy for adults with R/R *NPM1*-m AML. It has also shown clinically meaningful activity and tolerability in combination for newly diagnosed *NPM1*-m or *KMT2A*-r AML³⁻⁶
- **KOMET-007** ([NCT05735184](https://clinicaltrials.gov/ct2/show/study/NCT05735184)) is an ongoing, multi-cohort, open-label, dose-escalation (phase 1a) and expansion (phase 1b) study of ziftomenib in combination with standard therapies in adults with newly diagnosed or R/R *NPM1*-m or *KMT2A*-r AML



AML, acute myeloid leukemia; *KMT2A*-r, *KMT2A*-rearranged; *NPM1*-m, *NPM1*-mutated; R/R, relapsed/refractory; U.S. FDA, U.S. Food and Drug Administration

1. Papaemmanuil et al. *N Engl J Med.* 2016; 375:900-1; 2. Issa et al. *Leukemia.* 2021; 3:2482-95; 3. Issa et al. *Blood.* 2025; 146(Suppl 1):764; 4. Erba et al. *Hemasphere.* 2025; 9(Suppl 1):S136; 5. Zeidan et al. *Blood.* 2024; 144(Suppl_1):214; 6. Kura Oncology Inc. 2025; KOMZIFTI™ (ziftomenib) prescribing information; 7. Collins and Hess. *Curr Opin Hematol.* 2016; 23(4):354-61; 8. Lu et al. *Cancer Cell.* 2016; 30(1):92-107; 9. Ferreira et al. *Oncogene.* 2016; 35(23):3079-82; 10. Jeong et al. *Nat Genet.* 2014; 46(1):17-23; 11. Wang et al. *Blood.* 2005; 106(1):254-64; 12. Chowdhury et al. *EMBO Rep.* 2011; 12(5):463-9; 13. Schmidt et al. *Leukemia.* 2019; 33(7):1608-19; 14. Xu et al. *Cancer Cell.* 2016; 30(6):863-78; 15. Brunetti et al. *Cancer Cell.* 2018; 34(3):499-512; 16. Wang et al. *Cancer Discov.* 2023; 13(3):724-45.

KOMET-007: Ongoing Combination Trial of Ziftomenib in Newly Diagnosed AML

Ziftomenib / 7+3 Combination

PHASE 1a: HIGH-RISK^a AML Dose Escalation

Induction: Ziftomenib / 7+3
Consolidation: Ziftomenib / HiDAC/IDAC^b or HSCT if clinically indicated^c
Maintenance: Ziftomenib Monotherapy^d

Dose level 3: 600 mg QD

Selected RP2D

Dose level 2: 400 mg QD

Dose level 1: 200 mg QD

Dose level -1: 100 mg QD

PHASE 1b: ALL IC-ELIGIBLE AML Dose Expansion / RP2D Determination

Induction: Ziftomenib / 7+3
Consolidation: Ziftomenib / HiDAC/IDAC^b or HSCT if clinically indicated^c
Maintenance: Ziftomenib Monotherapy^d

Ziftomenib / 7+3
 Selected dose from Phase 1a
 (600 mg QD)

Validated RP2D
 (600 mg QD)

Endpoints:

Primary	Secondary
AEs	CR ^c
DLTs (Phase 1a)	ORR ^g
CR ^e	DoR

Adults with ***NPM1-m*** or ***KMT2A-r*** AML enroll independently

Newly Diagnosed AML
 (N=99)

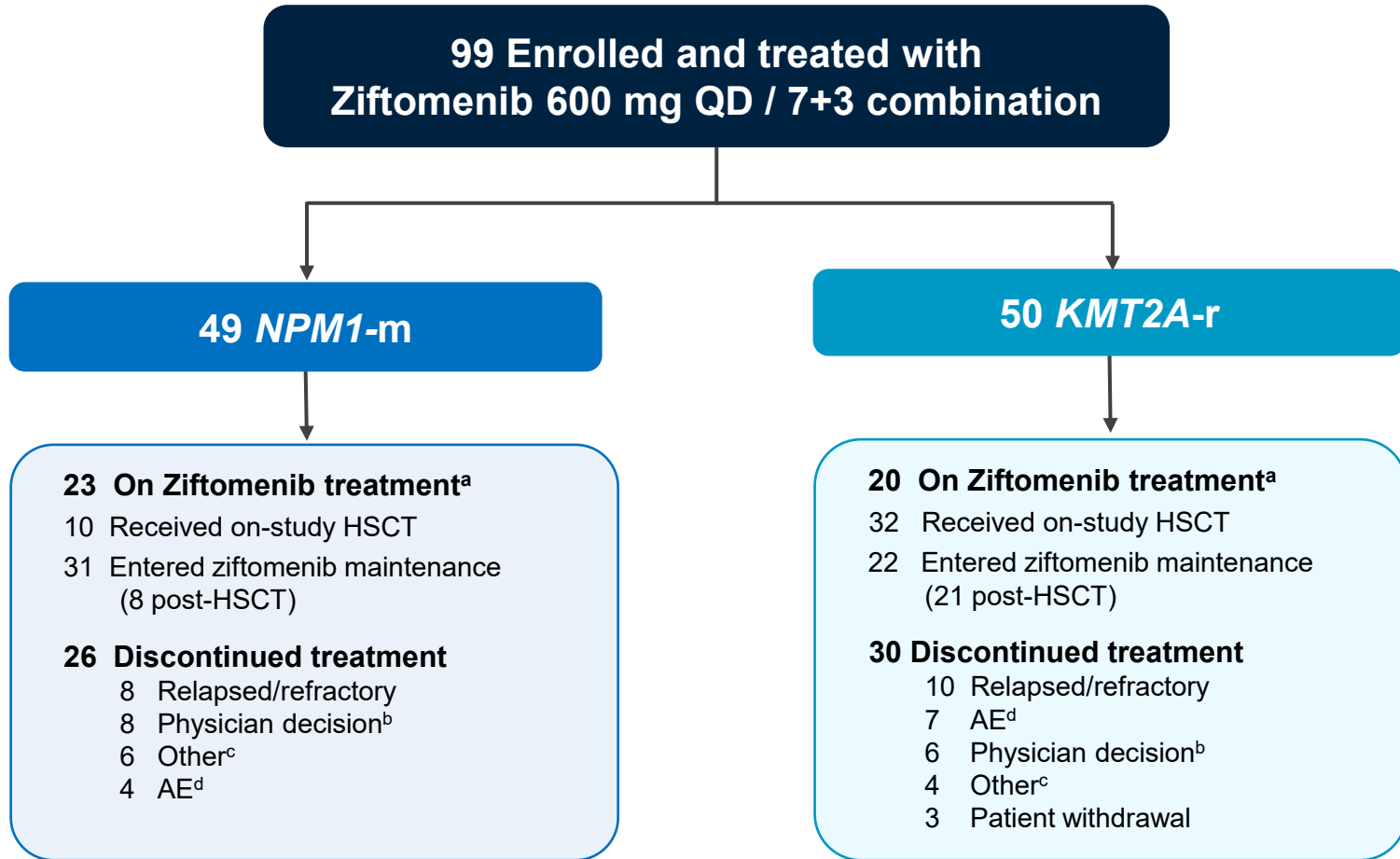
- Ziftomenib started on Cycle 1 Day 8 and administered continuously thereafter; cytarabine was administered on Cycle 1 Days 1–7 and daunorubicin on Cycle 1 Days 1–3; re-induction cycles allowed based on bone marrow biopsy results

Here, we present updated safety and clinical activity in all patients with newly diagnosed AML treated at the ziftomenib RP2D of 600 mg QD in combination with standard doses of 7+3 across phase 1a/b

^aHigh-risk defined as *KMT2A-r* AML, or *NPM1-m* AML with adverse-risk cytogenetics per ELN criteria, age ≥60 years, and/or treatment-related AML regardless of age; ^bHiDAC, IDAC or VYXEOS[®] were permitted; ^cFor HSCT, ziftomenib was held; ^dZiftomenib 600 mg monotherapy for up to 2 years; ^eper ELN 2022 criteria; ^fCR, CRh, or CRi; ^gCRc or MLFS

7+3, cytarabine/daunorubicin; AE, adverse event; CR / CRh / CRi, complete remission with full / partial / incomplete hematologic recovery; CRc, composite complete remission; DLT, dose-limiting toxicity; DoR, duration of remission; HiDAC, high-dose cytarabine; HSCT, hematopoietic stem cell transplantation; IC, intensive chemotherapy; IDAC, intermediate-dose cytarabine; MLFS, morphologic leukemia-free state; ORR, objective response rate; RP2D, recommended phase 2 dose

KOMET-007 Patient Populations: Newly Diagnosed AML



- As of Apr 10, 2026, **99 patients** (49 *NPM1-m*, 50 *KMT2A-r*) with newly diagnosed AML were enrolled and treated with ziftomenib 600 mg orally once daily and 7+3
- Median follow-up was **17.6 months** for *NPM1-m* and **11.0 months** for *KMT2A-r*
- 90% (44/49) of *NPM1-m* and 62% (31/50) of *KMT2A-r* patients were still on-study

^aPatients who had not discontinued ziftomenib as of the data cutoff date; ^bPhysician decisions included: *NPM1-m*: decision to withdraw patient from study (n=1), myocarditis of uncertain etiology (n=1), patient graft-versus-host disease status (n=1), patient commencing alternative treatment (n=5); *KMT2A-r*: patient unable to return to site for treatment (n=1), patient started cranio-spinal irradiation (n=1), nonspecific symptoms (predominantly pruritus) (n=1), failure to meet eligibility criteria for post-HSCT maintenance therapy (n=1), commencing alternative treatment (n=2); ^cOther reasons included: *NPM1-m*: patient refusal to continue study treatment (n=1), maintenance off trial (n=1), patient declined to adhere to birth control requirements (n=1), patient proceeded to off-study transplant (n=3); *KMT2A-r*: patient proceeded with chemotherapy+donor lymphocyte infusion (n=1), patient decided not to continue with ziftomenib (n=1), patient proceeded to transplant (n=2); ^dAdverse events included: *NPM1-m*: arthralgia, ischemic enteritis, cerebral hemorrhage, drug-induced liver injury (all n=1); *KMT2A-r*: multiple organ dysfunction syndrome (n=1), sepsis (n=1), staphylococcal sepsis (n=1), clostridial sepsis (n=1), disseminated mucormycosis (n=1), cardiac arrest (n=1), differentiation syndrome (n=1)

Baseline Characteristics

n (%)	<i>NPM1</i> -m (N=49)	<i>KMT2A</i> -r (N=50)	All Patients (N=99)
Median age, years (range)	60 (30–71)	43 (18–70)	53 (18–71)
Female	25 (51)	31 (62)	56 (57)
Race			
White	36 (73)	32 (64)	68 (69)
Non-White	3 (6)	7 (14)	10 (10)
Unknown ^a	10 (20)	11 (22)	21 (21)
ECOG PS 0–1	44 (90)	48 (96)	92 (93)
Select co-mutations			
<i>FLT3</i> ^b	7 (14)	7 (14)	14 (14)
<i>IDH1/2</i>	18 (37)	2 (4)	20 (20)
Therapy-related AML	2 (4)	10 (20)	12 (12)

^aIncludes unknown and not reported categories; ^b*FLT3*-ITD allelic ratio <0.05 (4 *NPM1*-m) or considered ineligible for *FLT3* inhibitor (3 *NPM1*-m, 7 *KMT2A*-r); ^cPatients on treatment or in long-term follow-up
Data cutoff: Apr 10, 2026. ECOG PS, Eastern Cooperative Oncology Group performance status; ITD, internal tandem duplication

Safety and Tolerability of Ziftomenib with 7+3

TEAEs in ≥30% of All Patients

n (%)	<i>NPM1</i> -m (N=49)	<i>KMT2A</i> -r (N=50)	All Patients (N=99)	Ziftomenib-related (N=99)
Any grade	49 (100)	50 (100)	99 (100)	85 (86)
Febrile neutropenia	30 (61)	37 (74)	67 (68)	16 (16)
Diarrhea	33 (67)	33 (66)	66 (67)	22 (22)
Thrombocytopenia ^a	33 (67)	30 (60)	63 (64)	23 (23)
Pruritus	28 (57)	26 (52)	54 (55)	36 (36)
Nausea	24 (49)	26 (52)	50 (51)	17 (17)
Hypokalemia	21 (43)	24 (48)	45 (45)	5 (5)
Stomatitis	18 (37)	25 (50)	43 (43)	5 (5)
Anemia ^b	22 (45)	20 (40)	42 (42)	16 (16)
Fatigue	20 (41)	20 (40)	40 (40)	13 (13)
ALT increased	20 (41)	19 (38)	39 (39)	13 (13)
Headache	17 (35)	18 (36)	35 (35)	7 (7)
Constipation	20 (41)	13 (26)	33 (33)	3 (3)
Neutropenia ^c	16 (33)	16 (32)	32 (32)	15 (15)
Rash maculo-papular	14 (29)	18 (36)	32 (32)	8 (8)
Vomiting	15 (31)	16 (32)	31 (31)	11 (11)
Edema peripheral	16 (33)	14 (28)	30 (30)	3 (3)
Dizziness	17 (35)	13 (26)	30 (30)	6 (6)

- Ziftomenib safety profile in combination with intensive chemotherapy was consistent with that reported for 7+3 alone¹
- No new or unexpected AEs with long-term follow-up

^aIncludes PTs platelet count decreased and thrombocytopenia; ^bIncludes PTs hemoglobin decreased, red blood cell count decreased and anemia; ^cIncludes PTs neutrophil count decreased and neutropenia

Data cutoff: Apr 10, 2026. ALT, alanine aminotransferase; PT, preferred term; TEAE, treatment-emergent adverse event

1. Lin et al. *Blood Adv.* 2021; 5(6):1719-28.

Safety and Tolerability of Ziftomenib with 7+3

Grade ≥3 TEAEs in ≥10% of All Patients

n (%)	<i>NPM1</i> -m (N=49)	<i>KMT2A</i> -r (N=50)	All Patients (N=99)	Grade ≥3 Ziftomenib-related (N=99)
Any grade ≥3	46 (94)	49 (98)	95 (96)	52 (53)
Febrile neutropenia	29 (59)	33 (66)	62 (63)	13 (13)
Thrombocytopenia ^a	31 (63)	28 (56)	59 (60)	21 (21)
Anemia ^b	20 (41)	17 (34)	37 (37)	15 (15)
Neutropenia ^c	16 (33)	15 (30)	31 (31)	13 (13)
Leukopenia ^d	12 (24)	16 (32)	28 (28)	9 (9)
Hypokalemia	5 (10)	10 (20)	15 (15)	1 (1)
Sepsis	6 (12)	7 (14)	13 (13)	4 (4)
Lymphopenia ^e	5 (10)	9 (18)	14 (14)	4 (4)
ALT increased	6 (12)	5 (10)	11 (11)	4 (4)
Pruritus	6 (12)	4 (8)	10 (10)	10 (10) ^f

Grade ≥3 AEs of Interest

Differentiation syndrome (DS):

- 4 Gr3 DS cases (4%; 1 *NPM1*-m, 3 *KMT2A*-r); no Gr4
- All DS events successfully resolved with protocol-specified mitigation and 3 continued ziftomenib treatment

QTc prolongation:

- 3 Gr3 investigator-assessed QTc prolongation cases^g (3%; 1 *NPM1*-m, 2 *KMT2A*-r; none ziftomenib-related); no Gr4
- All QTc events successfully resolved and continued ziftomenib treatment

^aIncludes PTs platelet count decreased and thrombocytopenia; ^bIncludes PTs hemoglobin decreased, red blood cell count decreased and anemia; ^cIncludes neutrophil count decreased and neutropenia; ^dIncludes white blood cell count decreased and leukopenia; ^eIncludes lymphocyte count decreased and lymphopenia; ^fPruritus was generally managed with gabapentin-based (n=8) or antihistamine-based (n=2) therapy; ^gAll 3 patients were on other medications at time of QT assessment (posaconazole, ciprofloxacin, levofloxacin, hydroxyzine, metronidazole); 1 patient had ongoing hypokalemia and hypomagnesemia

Clinical Activity of Ziftomenib with 7+3

n (%)	<i>NPM1</i> -m (N=49)	<i>KMT2A</i> -r (N=50)	All Patients (N=99)
CRc	47 (96)	45 (90)	92 (93)
ORR	48 (98)	46 (92)	94 (95)
CR	46 (94)	41 (82)	87 (88)
CRh	1 (2)	1 (2)	2 (2)
CRi	0	3 (6)	3 (3)
MLFS	1 (2)	1 (2)	2 (2)
PR	0	0	0
NR	1 (2)	3 (6)	4 (4)
NE	0	1 (2)	1 (1)
CR MRD negativity (local), n/m (%)^a	39/46 (85)	30/35 (86)	69/81 (85)
CRc MRD negativity (local), n/m (%)^a	40/47 (85)	32/39 (82)	72/86 (84)
Median time to CR MRD negativity, months (range)	1.5 (0.5–12.2)	0.9 (0.5–2.8)	1.2 (0.5–12.2)
Median time to CRc MRD negativity, months (range)	1.5 (0.5–12.2)	0.9 (0.5–2.8)	1.1 (0.5–12.2)

^aAmong evaluable responders tested for MRD per local assay (NGS, RT-qPCR, flow cytometry, or FISH [*KMT2A*-r only])

Data cutoff: Apr 10, 2026. FISH, fluorescence in situ hybridization; MRD, measurable residual disease; NE, not estimable; NGS, next-generation sequencing; NR, no response; PR, partial remission; RT-qPCR, quantitative reverse transcription polymerase chain reaction

Central Molecular MRD Negativity: Newly Diagnosed *NPM1*-m AML

n/N (%)	Central MRD (Threshold <0.1%)	Central MRD (Threshold <0.01%)
CRc MRD negativity rate^a	31/39 (79)	22/39 (56)
Median time to MRD negativity, months (range)	2.2 (0.7–2.6)	2.3 (0.8–3.1)
Timing of MRD negativity^b:		
By Cycle 1	10/31 (32)	6/22 (27)
By Cycle 2	31/31 (100)	22/22 (100)
By Cycle 3	31/31 (100)	22/22 (100)

^a*NPM1* MRD was performed among CRc responders by central next-generation sequencing (sensitivity of 0.0025%; protocol-defined threshold <0.01%); ^bAmong CRc responders who achieved MRD negativity
Data cutoff: Apr 10, 2026

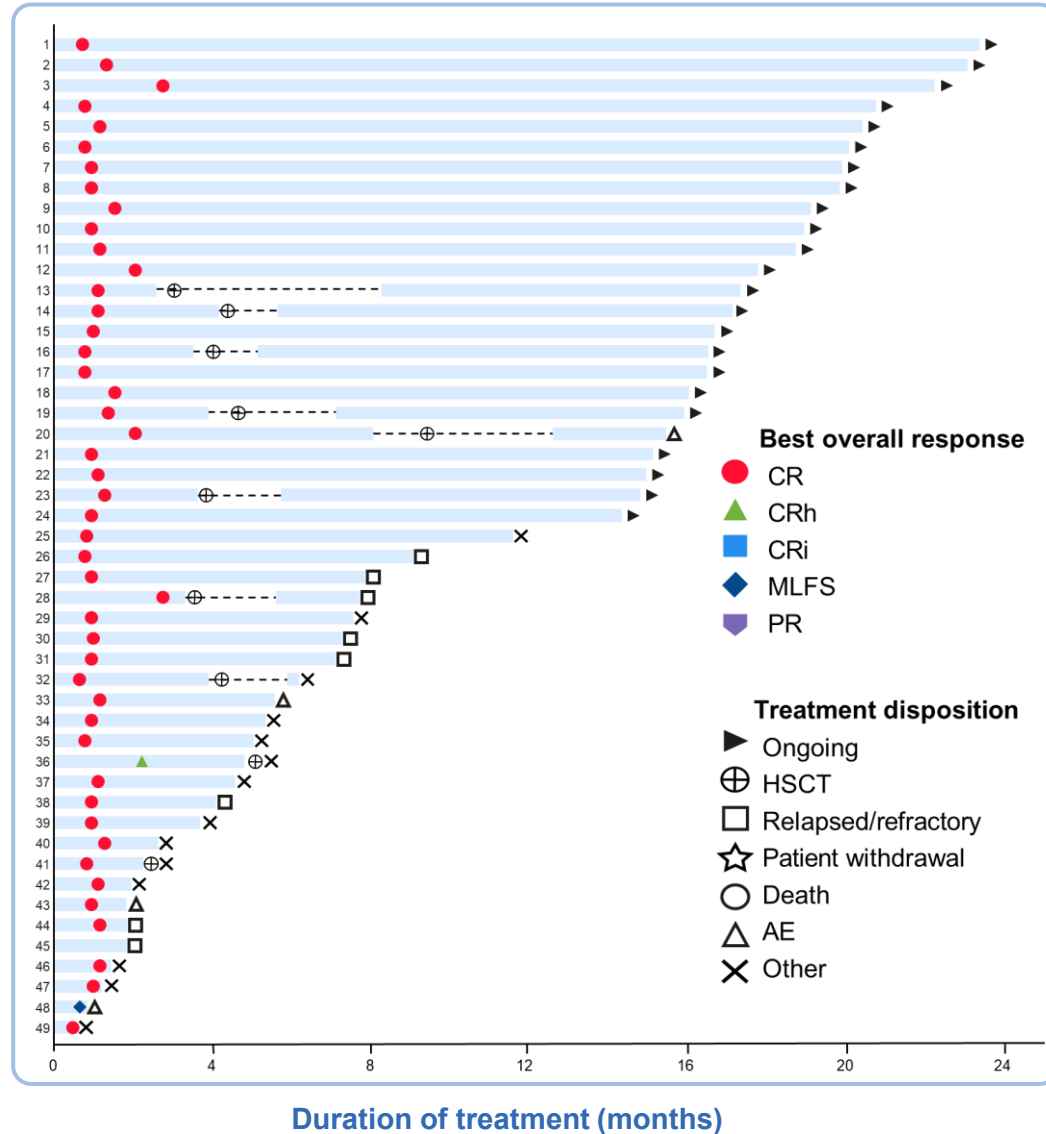
ANC and Platelet Recovery in CRc Responders

Median days (IQR), Cycle 1	<i>NPM1</i> -m (N=47)	<i>KMT2A</i> -r (N=45)	All Patients (N=92)
ANC $\geq 0.5 \times 10^9/L$	28 (21–32)	27 (25–29)	27 (23–30)
ANC $\geq 1.0 \times 10^9/L$	28 (27–35)	28 (26–35)	28 (26–35)
Platelets $\geq 50 \times 10^9/L$	23 (21–29)	26 (22–29)	25 (21–29)
Platelets $\geq 100 \times 10^9/L$	28 (24–33)	28 (26–30)	28 (25–33)

- Time to neutrophil and platelet recovery was comparable to that for intensive chemotherapy regimens^{1,2}

Duration of Treatment and Clinical Outcomes

NPM1-m



After a median follow-up of 17.6 months (range 1.0–23.5):

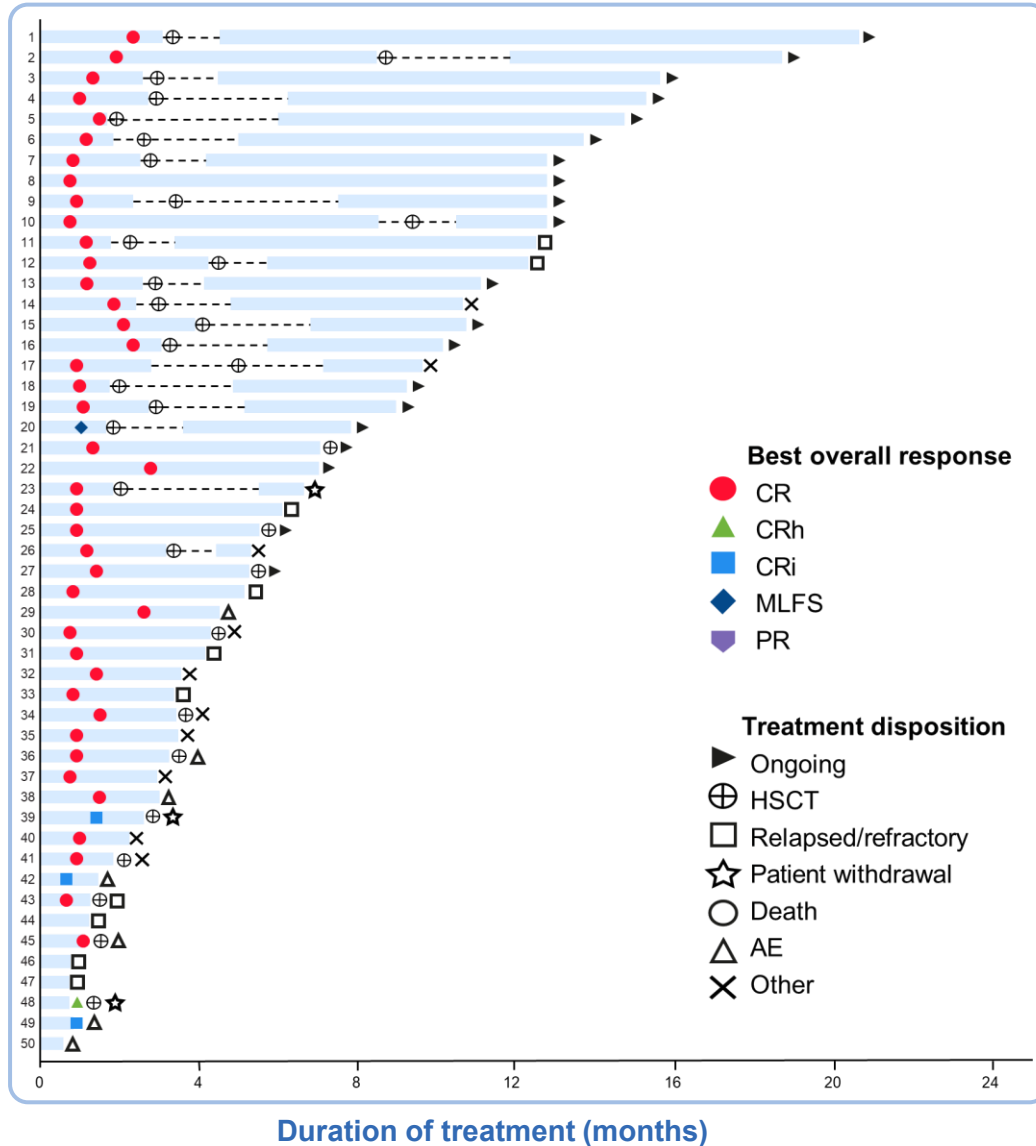
- Median duration of CR was **not reached**
 - 80% duration of CR at 12 months
- 10 *NPM1-m* patients received HSCT
- 31 *NPM1-m* patients entered maintenance treatment
 - 8 after on-study HSCT
 - 23 without on-study HSCT
- 8 discontinued due to relapse/refractory
- 4 discontinued due to AEs (1 ziftomenib-related)

Data cutoff: Apr 10, 2026

AE, adverse event; CR / CRh / CRi, complete remission with full / partial / incomplete hematologic recovery; HSCT, hematopoietic stem cell transplantation; MLFS, morphologic leukemia-free state; PR, partial response

Duration of Treatment and Clinical Outcomes

KMT2A-r



After a median follow-up of 11.0 months (range 0.9–21.9):

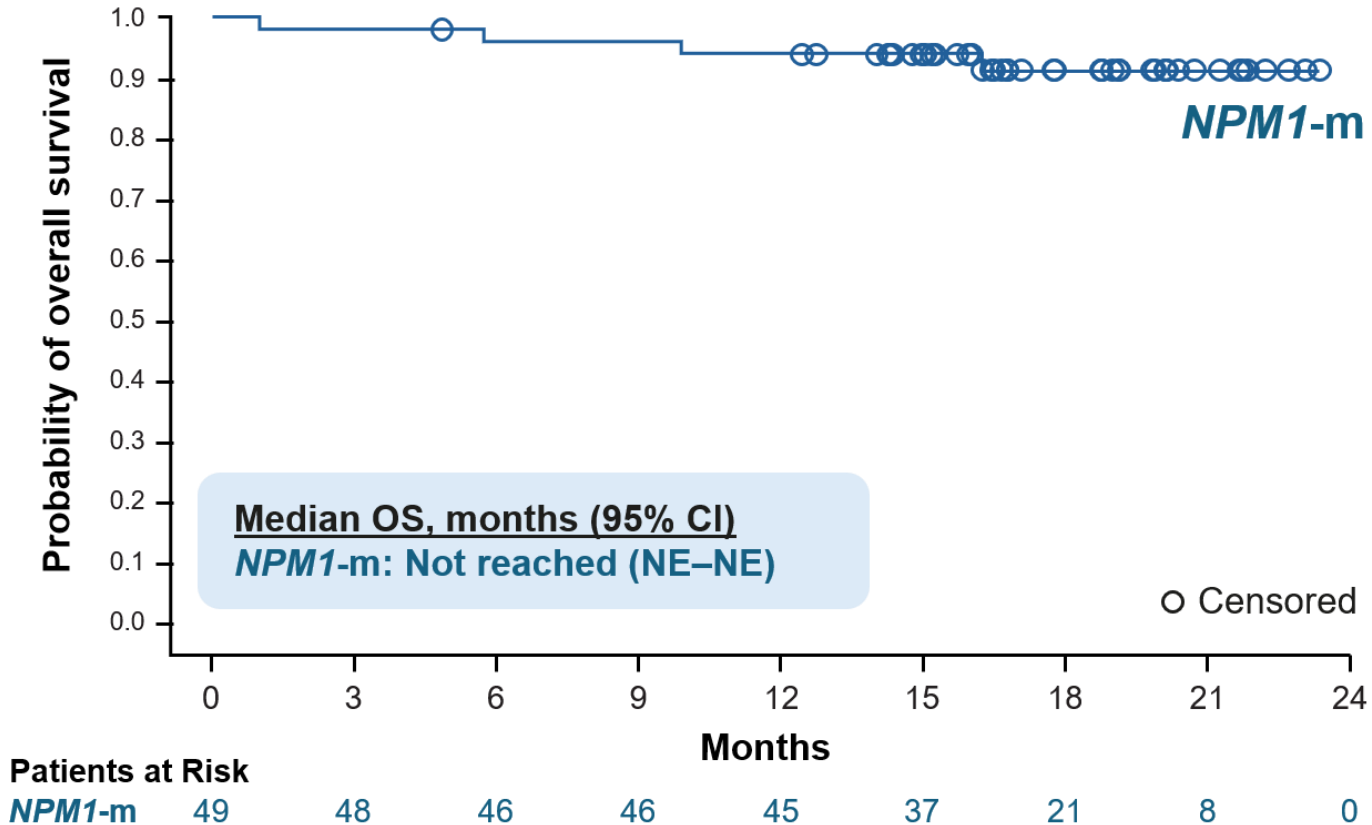
- Median duration of CR was **12.0 months** (95% CI 6.0–NE) and follow-up continues
- 32 *KMT2A-r* patients received HSCT
- 22 *KMT2A-r* patients entered ziftomenib maintenance
 - 21 after on-study HSCT
 - 1 without on-study HSCT
- 10 discontinued due to relapse/refractory
- 7 discontinued due to AEs (2 ziftomenib-related)

Data cutoff: Apr 10, 2026

AE, adverse event; CR / CRh / CRi, complete remission with full / partial / incomplete hematologic recovery; HSCT, hematopoietic stem cell transplantation; MLFS, morphologic leukemia-free state; NE, not estimable; PR, partial response

Overall Survival

NPM1-m



After a median follow-up of 17.6 months (range 1.0–23.5):

- Median OS was **not reached**
 - *NPM1-m*: 94% OS rate at 12 months
- Median age was 60 years
- 90% (44/49) of *NPM1-m* patients remained alive and continued on study^a
 - 60-day mortality: 2% (1/49)
- 12-month OS with intensive chemotherapy-based regimens varied from ~70–80% in younger/fit patients to ~45–55% in older adults¹⁻⁵

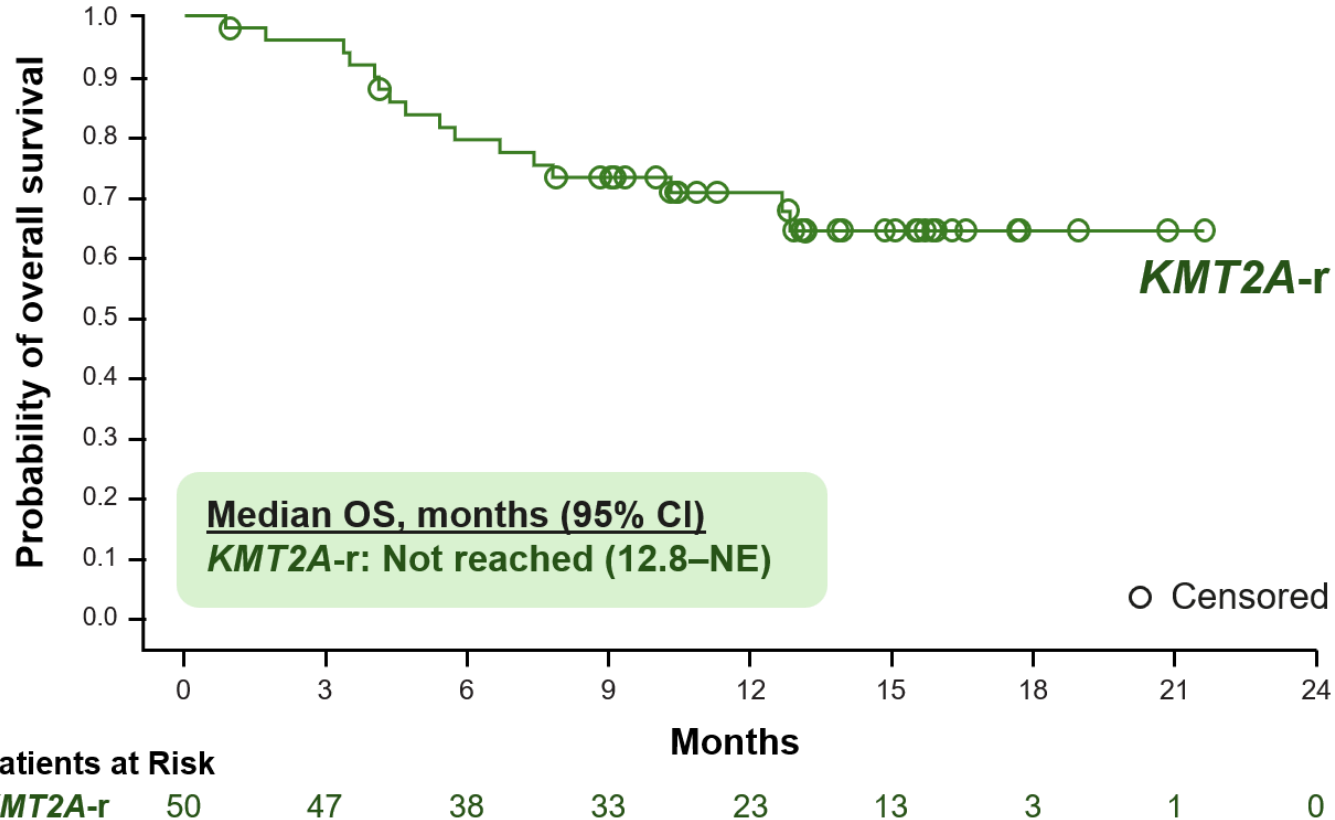
^aPatients on treatment or in long-term follow-up

Data cutoff: Apr 10, 2026. OS, overall survival

1. Othus et al. *Leukemia*. 2019; 33(2):371-378. 2. Othman et al. *Blood*. 2024; 144(7):714-728; 3. Lachowicz et al. *Blood Adv*. 2020; 4(7):1311–1320. 4. Hernández-Sánchez et al., *Leukemia*. 2026; 40(2):418-428. 5. Recher et al. *Leukemia*. 2022; 36(4):913-922.

Overall Survival

KMT2A-r



After a median follow-up of 11.0 months (range 0.9–21.9):

- Median OS was **not reached**
 - KMT2A-r: 71% OS rate at 12 months
- Median age was 43 years
- 62% (31/50) of KMT2A-r patients remained alive and continued on study^a
 - 60-day mortality: 4% (2/50)

^aPatients on treatment or in long-term follow-up
Data cutoff: Apr 10, 2026. OS, overall survival

Conclusions

SAFETY

In KOMET-007, ziftomenib 600 mg QD combined with 7+3 was well tolerated with a safety profile consistent with previous reports

- 4 cases (4%) of Gr3 differentiation syndrome (1 *NPM1*-m, 3 *KMT2A*-r; no Gr4); all successfully resolved with protocol-specified mitigation and 3 continued on treatment
- Low rates of ziftomenib-related cytopenias and minimal additive myelosuppression observed with this combination
 - Ziftomenib 600 mg QD did not delay neutrophil and platelet count recovery

CLINICAL ACTIVITY

Robust clinical activity with deep and durable responses in newly diagnosed *NPM1*-m and *KMT2A*-r AML

- CRc: **96%** for *NPM1*-m, **90%** for *KMT2A*-r
 - CRc MRD negativity (local): **85%** for *NPM1*-m, **82%** for *KMT2A*-r
- Median duration of CR was **not reached** for *NPM1*-m and **12.0 months** for *KMT2A*-r
- Median OS was **not reached**: OS rates of 94% for *NPM1*-m and 71% for *KMT2A*-r at 12 months

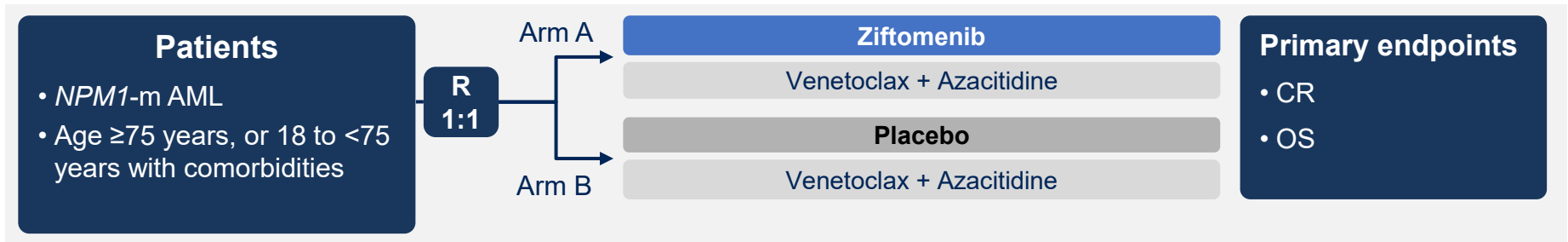
NEXT STEPS

Taken together, these data support the ongoing phase 3 registrational trial of ziftomenib in combination with intensive chemotherapy in newly diagnosed AML (KOMET-017; [NCT07007312](#))

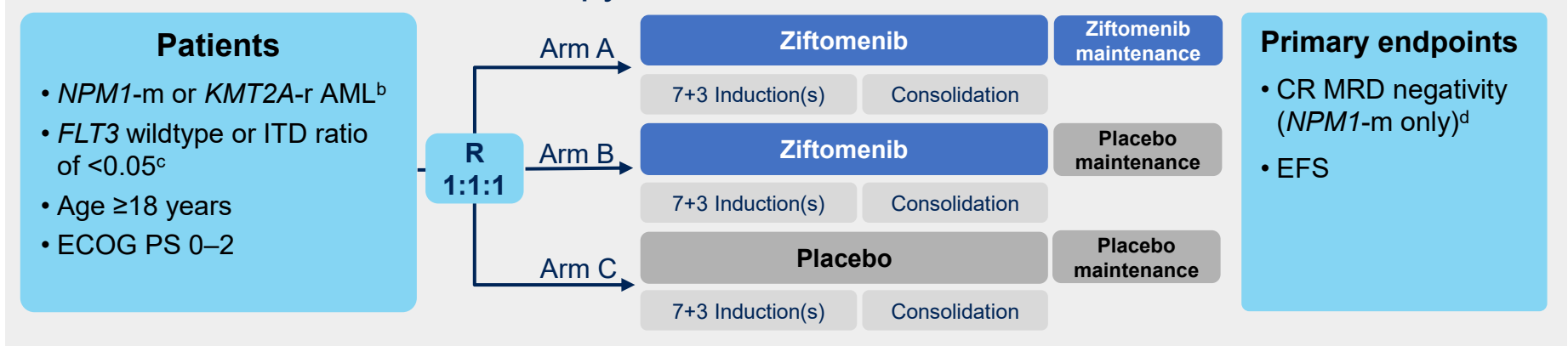
KOMET-017: Phase 3 Ziftomenib Pivotal Newly Diagnosed Combination Studies

Two independently powered, registration-enabling, randomized phase 3 studies in fit and unfit newly diagnosed AML (N=1300)

KOMET-017-NIC: Non-intensive therapy^a – Ziftomenib + venetoclax/azacitidine combo



KOMET-017-IC: Intensive therapy^a – Ziftomenib and 7+3 combo



Study is open and enrolling ([NCT07007312](https://clinicaltrials.gov/ct2/show/study/NCT07007312))

^aHSCT allowed on both studies; ^bExcluding partial tandem duplication; ^cUnless ineligible for *FLT3*-targeted therapy; ^d*NPM1* central MRD by NGS at <0.01% threshold
EFS, event-free survival; IC, intensive chemotherapy; NIC, non-intensive chemotherapy; R, randomized

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