

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 11, 2023

KURA ONCOLOGY, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37620
(Commission
File Number)

61-1547851
(IRS Employer
Identification No.)

12730 High Bluff Drive, Suite 400, San Diego, CA
(Address of Principal Executive Offices)

92130
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 500-8800

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	KURA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On June 11, 2023, Kura Oncology, Inc. (the “Company”) announced updated clinical data from KOMET-001, a Phase 1/2 clinical trial of the Company’s potent and selective menin inhibitor, ziftomenib, that were presented during a late-breaking oral session at the 2023 European Hematology Association Annual Congress in Frankfurt, Germany.

As of the data cutoff on April 12, 2023, seven of the 20 patients (35%) with nucleophosmin 1- (“NPM1-”) mutant acute myeloid leukemia (“AML”) treated at the recommended Phase 2 dose (“RP2D”) of 600 mg achieved a complete remission (“CR”) with full count recovery. Notably, 33% (2/6) of patients with FLT3 co-mutations and 50% (4/8) of patients with IDH co-mutations achieved a CR on ziftomenib. Two patients underwent a stem cell transplant (“SCT”) and remain in remission as of the data cutoff, including one on post-SCT ziftomenib maintenance therapy. An eighth patient who had a CR with incomplete recovery (“CRi”) at the time of transplant subsequently evolved to a CR and remains on study.

The median duration of response for all NPM1-mutant patients was 8.2 months (95% CI: 1.0 to NE), with a median follow-up of 8.8 months. The median duration of response for patients censored at SCT was 5.6 months (95% CI: 1.0 to NE). As of the cutoff date, three patients treated at 600 mg remain on study and in CR; an additional NPM1-mutant patient treated at 200 mg remained on ziftomenib for 36 cycles.

As part of an ongoing analysis, the resistance mutation MEN1-M3271 has been detected in three patients treated with ziftomenib: in two patients, the mutation was detected at study entry after the patients had progressed on a prior menin inhibitor, and in the third patient, the mutation was detected after four cycles of ziftomenib therapy and, despite the mutation, the patient was maintained in a condition of stable disease through cycle 7. These data show that MEN1 mutations developed in just 3% (1/29) of patients analyzed following treatment with ziftomenib and suggest that resistance mutations are less likely to evolve after prolonged exposure to ziftomenib monotherapy. A key new biochemical finding, confirmed by crystal structure, demonstrates that ziftomenib retains full activity against the MEN1-T349M mutation, detected in two-thirds of patients who acquired menin resistance mutations on another recent menin inhibitor trial.

Continuous daily dosing of ziftomenib was well tolerated and the safety profile remains consistent with features of underlying disease. The on-target effect of differentiation syndrome was manageable, with 15% of patients experiencing Grade 1 or 2 events and 5% experiencing a Grade 3 event.

Enrollment in a Phase 2 registration-directed study of ziftomenib in patients with relapsed/refractory NPM1-mutant AML continues to outperform projections. The study is expected to enroll a total of 85 patients at 62 U.S. and European sites. The Company is also preparing to initiate a series of studies to evaluate ziftomenib in combination with current standards of care in earlier lines of therapy and across multiple patient populations, including NPM1-mutant and KMT2A-rearranged AML. The Company has begun site activation in the first of these studies, KOMET-007, and is on track to dose the first patients this quarter.

On June 12, 2023, the Company will host a virtual investor event and present certain materials related to the Company (the “Presentation”). A copy of the Presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding, among other things, the efficacy, safety and therapeutic potential of ziftomenib, potential benefits of combining ziftomenib with appropriate standards of care, progress and expected timing of the ziftomenib program, and plans regarding future clinical trials.

Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the risk that compounds that appeared promising in early research or clinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that the Company may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings, applications and other interactions with regulatory bodies, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, and other risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs, as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 filed with the Securities and Exchange Commission ("SEC") on May 10, 2023, as well as discussions of potential risks, uncertainties and other important factors in the Company's other filings and reports with the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Presentation Materials of Kura Oncology, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KURA ONCOLOGY, INC.

Date: June 12, 2023

By: /s/ Teresa Bair
Teresa Bair
Chief Legal Officer

DEVELOPING PRECISION MEDICINES FOR THE TREATMENT OF CANCER

EHA Investor Event – June 12, 2023



Forward-Looking Statements

This presentation contains forward-looking statements. Such statements include, but are not limited to, statements regarding our research, preclinical and clinical development activities, plans and projected timelines for ziftomenib, tipifarnib and KO-2806, plans regarding regulatory filings, our expectations regarding the relative benefits of our product candidates versus competitive therapies, and our expectations regarding the therapeutic and commercial potential of our product candidates. The words "believe," "may," "should," "will," "estimate," "promise," "plan", "continue," "anticipate," "intend," "expect," "potential" and similar expressions (including the negative thereof), are intended to identify forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: our preclinical studies and clinical trials may not be successful; the U.S. Food and Drug Administration (FDA) may not agree with our interpretation of the data from clinical trials of our product candidates; we may decide, or the FDA may require us, to conduct additional clinical trials or to modify our ongoing clinical trials; we may experience delays in the commencement, enrollment, completion or analysis of clinical testing for our product candidates, or significant issues regarding the adequacy of our clinical trial designs or the execution of our clinical trials may arise, which could result in increased costs and delays, or limit our ability to obtain regulatory approval; the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; our product candidates may not receive regulatory approval or be successfully commercialized; unexpected adverse side effects or inadequate therapeutic efficacy of our product candidates could delay or prevent regulatory approval or commercialization; and we may not be able to obtain additional financing. Additional risks and uncertainties may emerge from time to time, and it is not possible for Kura's management to predict all risk factors and uncertainties.

All forward-looking statements contained in this presentation speak only as of the date on which they were made. Other risks and uncertainties affecting us are described more fully in our filings with the Securities and Exchange Commission. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

This presentation also contains statistical and clinical data obtained from and prepared by third parties. The recipient is cautioned not to give undue weight to such disclosures. Neither the Company nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation.

Today's Agenda



Topic	Speaker
Welcome / Opening Remarks	Troy Wilson, Ph.D., J.D., President and Chief Executive Officer
Introduction of KOMET-001 Investigators	Stephen Dale, M.D., Chief Medical Officer
Opportunity in AML / KOMET-001 Trial Design	Ghayas Issa, M.D., MD Anderson Cancer Center
Presentation of KOMET-001 Phase 1b Data	Amir Fathi, M.D., Massachusetts General Hospital
Ziftomenib Clinical Development Path	Mollie Leoni, M.D., Senior Vice President, Clinical Development
Q & A session	All
Closing Remarks	Troy Wilson, Ph.D., J.D., President and Chief Executive Officer



Ziftomenib Represents a Transformational Therapy for AML

- 1 Highly Differentiated** Ziftomenib is uniquely positioned within and outside of menin class with ideal monotherapy properties translating into superior early clinical activity
- 2 Meaningful Durability** Rationale for ziftomenib as a highly durable and well-tolerated maintenance therapy to transform acute leukemias into a chronic disease
- 3 Potential to Sequence Earlier** Clinical evidence building to demonstrate role of ziftomenib sequencing first ahead of IDH1/2i and FLT3i
- 4 Expanding Beyond NPM1 and KMT2A** Demonstrated clinical activity in other AML subtypes beyond *NPM1-m* and *KMT2A-r* to broaden patient potential

KOMET-001 Investigators



Ghayas Issa, M.D.

- Hematology & Oncology, Departments of Leukemia and Genomic Medicine, MD Anderson Cancer Center
- Assistant Professor, Department of Leukemia, The University of Texas MD Anderson Cancer Center



Amir Fathi, M.D.

- Program Director, Center for Leukemia, Massachusetts General Hospital Cancer Center
- Associate Professor of Medicine, Harvard Medical School

***NPM1*-mutant AML is a Large Genetic Subset¹ with a High Unmet Need**



***NPM1*-mutant AML**



~6,000 new cases annually in the U.S.²

5-year Overall Survival ~50%³

Adult patients with *NPM1*-mutant AML and select co-mutations and/or relapsed/refractory disease have a poor prognosis¹

Median overall survival is suboptimal⁴

Second Line – 7.8 mo.

Third Line – 5.3 mo.

Fourth Line – 3.5 mo.

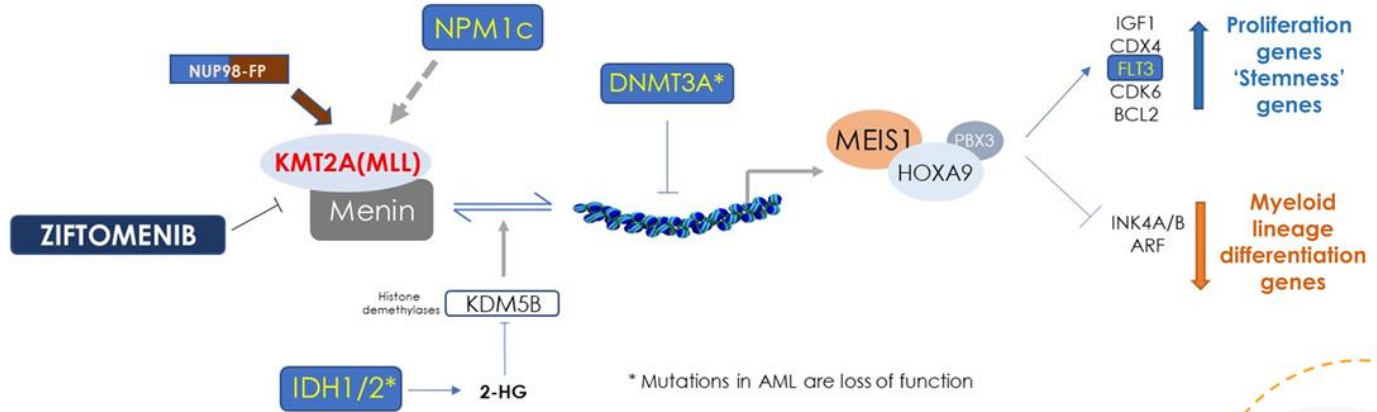
No FDA-approved *NPM1*-m specific targeted therapies exist today in AML

AML, acute myeloid leukemia; *NPM1*-m, nucleophosmin1-mutations; OS, overall survival; R/R, relapsed/refractory.
1. Döhner et al. Blood 2017;129(4):424-47; 2. SEER statistics for AML in the US, accessed April 2020; 3. Angenenndt L, et al. J Clin Oncol 2019;37(29):2632-42; 4. Issa G, et al. Blood Adv 2023;7(6):933-42.



Ziftomenib Targets the Menin-KMT2A Pathway, a Foundational Target in AML

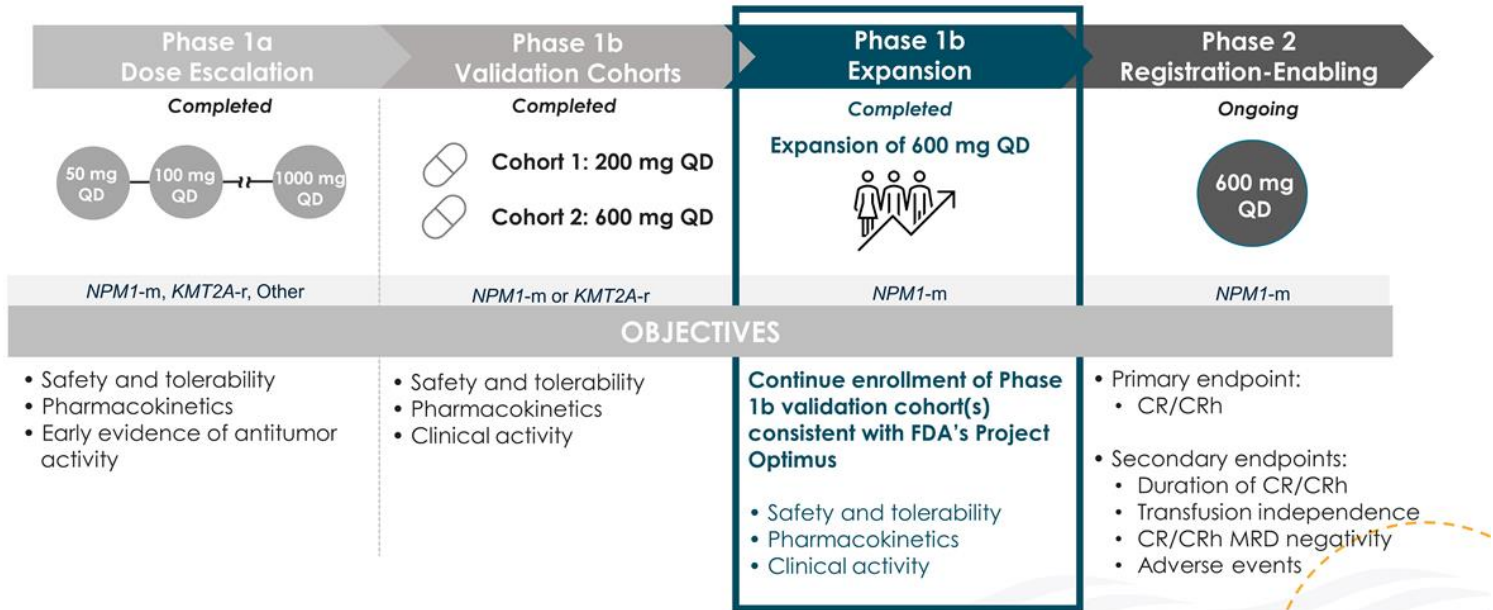
- *NPM1*-m and *KMT2A*-r drive overexpression of *HOXA9/MEIS1* genes, critical for transformation to AML
- *KMT2A*(*MLL*) sits upstream from major AML targets (*i.e.*, *FLT3*, *IDH1/2*, *DNMT3A*)
- *KMT2A*(*MLL*)-dependent genes contribute to therapeutic resistance and relapse to current therapies
- Menin inhibition downregulates *HOXA9/MEIS1*, leading to differentiation of leukemic blasts



1. Lu et al. *Cancer Cell* 2016;30(1):92-107; 2. Ferreira et al. *Oncogene* 2016;35(23):3079-82; 3. Jeong et al. *Nat. Genet* 2014;46(1):17-23; 4. Wang et al. *Blood* 2005;106(1):254-64; 5. Chowdhury et al. *EMBO Rep* 2011;12(5):463-9; 6. Schmidt et al. *Leukemia* 2019;33(7):1608-19; 7. Xu et al. *Cancer Cell* 2016;30(6):863-78; 8. Collins & Hess. *Curr Opin Hematol* 2016;23(4):354-61; 9. Brunetti et al. *Cancer Cell* 2018; 34(3):499-512.



KOMET-001 Phase 1/2 Study of Ziftomenib in Relapsed/Refractory AML



CR, complete remission; CRh, complete remission with partial hematological recovery; FDA, United States Food and Drug Administration; MRD, measurable residual disease; R/R, relapsed/refractory; RP2D, recommended phase 2 dose.

Ziftomenib Demonstrates Encouraging Safety Profile in NPM1-mutant Patients Treated at 600 mg Dose



≥ 20% Treatment-Emergent Adverse Events, n (%)	NPM1-m, n = 20	≥ 20% Treatment-Related Adverse Events, n (%)	NPM1-m, n = 20
Patients with TEAEs (All Grades)	19 (95)	Patients with TRAEs (All Grades)	12 (60)
Diarrhea	9 (45)	Nausea	4 (20)
Hypokalemia	8 (40)	Differentiation Syndrome	4 (20)
Nausea	6 (30)	Patients with TRAEs (≥Grade 3)	6 (30)
Anemia	6 (30)	N/A	
Back pain	6 (30)	<ul style="list-style-type: none"> • No reports of drug-induced QTc prolongation • 1 report of grade 3 differentiation syndrome <ul style="list-style-type: none"> • Manageable with mitigation strategy • Other reports of DS Grade ≤ 2 	
Epistaxis	5 (25)		
Patients with TEAEs (≥Grade 3)	17 (85)		
Anemia	5 (25)		
Thrombocytopenia	4 (20)		



Ziftomenib Demonstrates Encouraging Clinical Activity

Best Overall Response, Ph.1b, n (%)	600 mg, n = 20	
Complete remission rate (CR)	7 (35)	33% CR co-FLT3m (N=6) 50% CR co-IDHm (N=8)
CRc rate (CR+CRh+CRi)	8 (40)	
Overall response rate (CR+CRh+CRi+MLFS)	9 (45)	
CR	7 (35)	
CRh	0	
CRi	1 (5)	
MLFS	1 (5)	

- Co-mutations in FLT3 and IDH1/2 did not affect chances of response to single agent ziftomenib
- 1 patient achieved CRi, proceeded to HSCT, and achieved and remains in CR
- Median time to first response: 51 days

CR Rates vs. SOC in Heavily Pretreated Patients

	MUTATION	CR %	mDOR	MEDIAN PRIORS
Ziftomenib 600mg QD	NPM1m	35%	8.2 mo*	3
	FLT3m	33%	-	
	IDH 1/2	57%	-	
Gilteritinib	FLT3m	14.2%	14.8 mo	1
Enasidenib	IDH2	19%	8.2 mo	2
Ivosidenib	IDH1	25%	10.1 mo	2

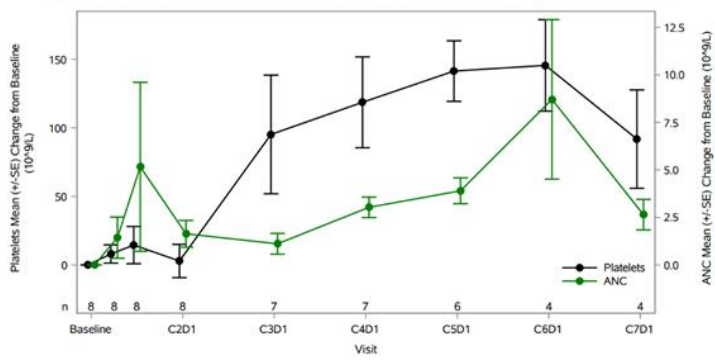
*Median DoR for CRc without censoring at HSCT
Source: USPI's

Fathi et al, EHA 2023 #LB2713 (preliminary data as of April 12, 2023)
HSCT, hematopoietic stem cell transplantation; MLFS, morphological leukemia-free state

Ziftomenib Drives Durable CRs with Maintained Count Recovery as a Monotherapy in Late-Line *NPM1*-mutant AML Patients



***NPM1*-m CRc Responders**
Mean Change in Platelets and ANC up to C7D1



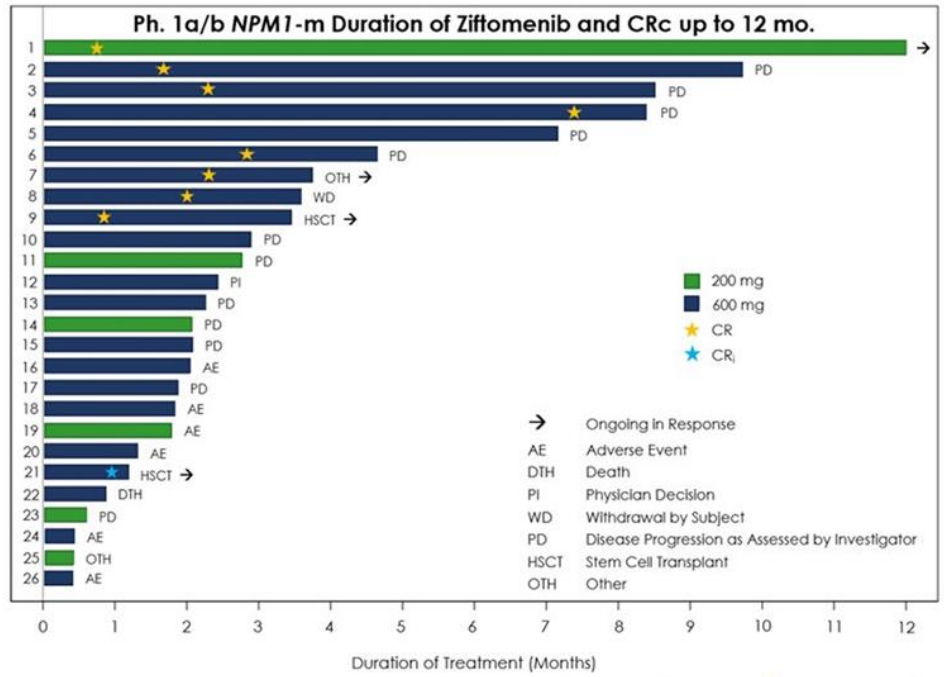
- Maintained count recovery after durable CRs suggests no drug-induced myelosuppression
- Excellent safety profile and no predicted adverse drug-drug interactions support potential for combinations



Ziftomenib Monotherapy Drives Durable Responses

- Median DoR **8.2 months** (95% CI: 1.0 to Not Evaluable) with a median follow up time of 8.8 months

- Patient 1 on ziftomenib in CR (MRD-) through Cycle 36
- Patients 9 and 21 proceeded to HSCT
- Patient 9 remains on ziftomenib for post-HSCT maintenance
- Patient 21 achieved CRi, proceeded to HSCT, and achieved and remains in CR



Fathi et al. EHA 2023 #LB2713 (preliminary data as of April 12, 2023)



Durable CR for 36 cycles on ziftomenib in 8th line including 2 HSCTs

**44 yo female with NPM1-m, DNMT3A and IKZF1 AML
7 Prior Tx**

Baseline bone marrow blasts: 14%

ziftomenib at 200 mg

Response

- CRmrd- after Cycle 1
- CRmrd- through Cycle 36

Enthusiasm among investigators and patients to utilize ziftomenib earlier and initiate maintenance

**22 yo male with NPM1-m AML
1 Prior Tx (refractory to 7+3)**

Baseline bone marrow blasts: 90%

ziftomenib at 600 mg

Response

- CRmrd- after Cycle 1
- HSCT
- CRmrd- maintained on Cycle 2 post-HSCT



Ongoing Central MRD Analysis, by NGS*

Subject: Prior Tx with midostaurin	NPM1	FLT3-TKD	IDH1
	Variant Allele Frequency (%)		
C1 D28	33	33	35
C5 D28	Not detected	Not detected	Not detected

Ziftomenib drives CR and brings co-mutations down to near undetectable levels **following failure with midostaurin and sequenced ahead of IDH1 inhibitor**

Subject: Prior Tx with midostaurin and gilteritinib	NPM1	FLT3-ITD	IDH2
	Variant Allele Frequency (%)		
C1 D28	47	91	46
C4 D28	0.37	0.87	0.41

Ziftomenib drives CR and low levels of co-mutations **following failure with midostaurin and gilteritinib and sequenced ahead of IDH2 inhibitor**

* Mutations detected in MyMRD NGS (Invivoscribe, San Diego, CA)

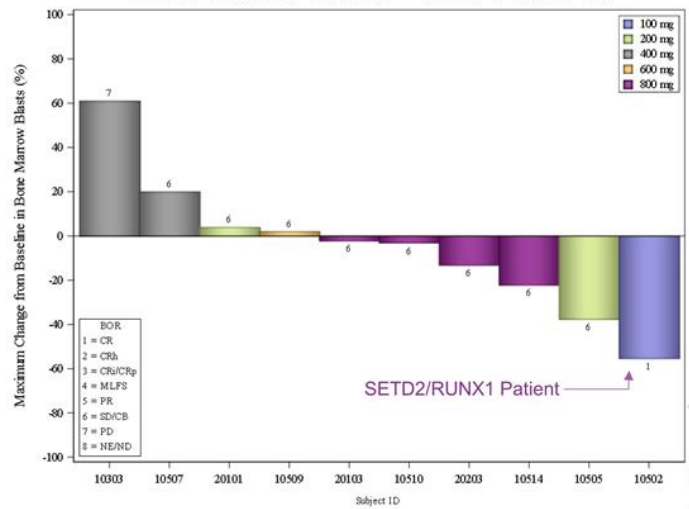
Targeting the Menin-KMT2A Pathway has Potential to Benefit a Broader Subset of AML Patients



Ziftomenib has Demonstrated Evidence of Activity in Non-NPM1-m/KMT2A-r Patients

- *SETD2/RUNX1* patient achieved a CR at 100mg dose in Phase 1a
- Notable evidence of blast reduction in range of off-target patients
- KOMET-001 study will continue to evaluate additional AML populations
- Potential to be incorporated into KOMET-007/008 combination studies

Off-Target Mutations: Best Change from Baseline in Bone Marrow Blasts – mITT Phase 1a

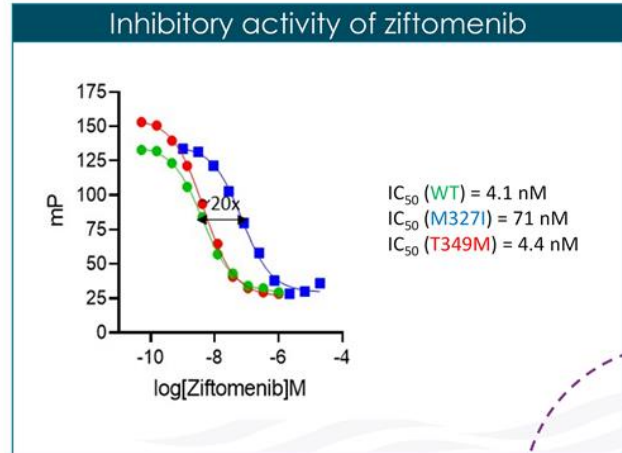
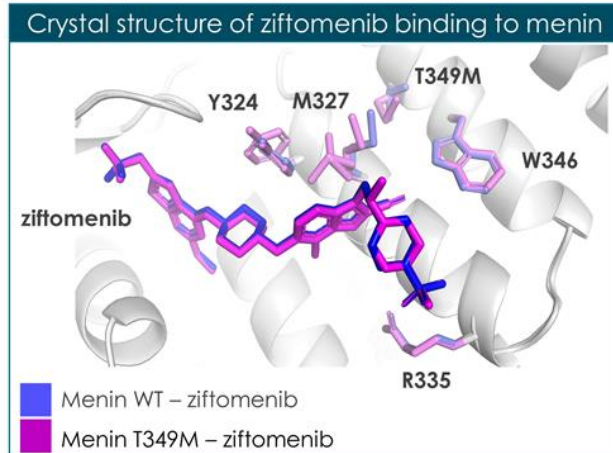


Graphic excludes subjects where post-baseline BM samples not collected



Ziftomenib Active Against Known Menin Gatekeeper Mutations

- No major conformational changes observed in Menin^{T349M} vs. wild-type (WT) protein
- M327 and Y324 side chains adopt new conformations in Menin^{T349M} but do not affect ziftomenib binding
- Binding affinity of ziftomenib is reduced for Menin^{M327I} but unaffected for Menin^{T349M}
 - Per Armstrong lab¹, ziftomenib also retains activity against Menin^{G331R}
- Ziftomenib retains activity against 2 of 3 known *MEN1* mutant loci



¹Perner et al. Abstract #3457 presented at AACR April 14-19, 2023, Orlando, FL.

Ziftomenib Appears Less Susceptible to Observed Mutations Associated With Resistance to Menin Inhibition



- Following reports of *MEN1* resistance mutations with another menin inhibitor¹, an analysis of KOMET-001 identified 1 of 29 subjects (3.4%) with the resistance mutation (*MEN1*-M327I) acquired while on ziftomenib²



- MEN1* mutant RNA was not detected in 13 of 13 other subjects who received ≥ 2 cycles of ziftomenib and had best response of SD or PD, suggesting that progression or lack of response in these subjects is not due to *MEN1* mutations
- Ziftomenib's ability to target *MEN1* harboring G331R or T349M mutations may explain the low frequency of *MEN1* resistance mutations detected in KOMET-001 subjects
- Further analysis underway to continue to characterize mechanisms of menin resistance

¹ Perner et al, Nature 2023; 615(7954):913-19.

² *MEN1* mutant transcripts detected from serial analysis of bone marrow aspirate (BMA) of patients treated with at least 1 cycle of ziftomenib using RNA NGS



Summary: KOMET-001 Phase 1 Clinical Trial of Ziftomenib

- Ziftomenib demonstrates significant clinical activity with 45% ORR (35% CR rate) and non-myelosuppressive with maintained count recovery in heavily pretreated R/R *NPM1-m* AML
- Durable remissions with MRD clearance of foundational *NPM1-m* and other key co-mutations, including *FLT3* and *IDH1/2* co-mutations, observed with ziftomenib monotherapy
- Resistance mutations have developed infrequently and ziftomenib retains activity against common menin gatekeeper mutations
- Ziftomenib is well tolerated, with no drug induced QTc and manageable DS; the lack of predicted adverse drug-drug interactions is supportive of combination approaches



Ziftomenib Clinical Development Path

DEVELOPMENT APPROACH	STUDY STARTUP	PHASE 1	REGISTRATION DIRECTED	TRIAL
MONOTHERAPY (Relapsed/refractory)	NPM1-mutant acute myeloid leukemia (AML) Non-NPM1-m/KMT2A-r AML KMT2A-rearranged ALL			komet-001 ACUTE LEUKEMIAS KURA KO-MEN-001
COMBINATIONS WITH VENETOCLAX + AZACITIDINE, CYTARABINE + DAUNORUBICIN (7+3) (Relapsed/refractory, frontline)	NPM1-mutant AML KMT2A-rearranged AML			komet-007 ACUTE LEUKEMIAS KURA KO-MEN-007
COMBINATIONS WITH GILTERITINIB, FLAG-IDA, LDAC (Relapsed/refractory)	NPM1-mutant AML KMT2A-rearranged AML			komet-008 ACUTE LEUKEMIAS KURA KO-MEN-008
POST-TRANSPLANT MAINTENANCE	NPM1-mutant AML KMT2A-rearranged AML			Company-sponsored study
COMBINATION WITH FLA	Pediatric AML & ALL			Investigator-sponsored studies
COMBINATION WITH BV-DAM	Pediatric ALL			



Ziftomenib Represents a Transformational Therapy for AML

- Targets foundational mutations at the core of up to 50% of AML cases
- Has demonstrated durable CRs and maintained count recovery as a monotherapy in late-line AML patients
- Favorable tolerability and once-daily oral dosing, ideal for chronic therapy
- Strong mechanistic synergy with current standards of care
- Optimal pharmaceutical properties for combinations
- **We believe ziftomenib has ideal properties to become a backbone of therapy across the continuum of care for AML patients**
- **Pursuing a broad-based ziftomenib development program coupled with potential to convert 50% of AML from an acute to chronic condition**

Q & A

DEVELOPING PRECISION MEDICINES FOR THE TREATMENT OF CANCER

EHA Investor Event – June 12, 2023