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): April 18, 2023

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

Delaware	001-37620	61-1547851
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12730 High Bluff Drive, Suite 400, San Diego, CA	92130
(Address of Principal Executive Offices)	(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 April 18, 2023, an abstract providing data as of a January 31, 2023 data cutoff from Kura Oncology, Inc.'s Phase 1/2 clinical trial of ziftomenib in relapsed or refractory acute myeloid leukemia, or KOMET-001, was published on the European Hematology Association's ("EHA") website. A copy of the EHA abstract is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	EHA Abstract
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: April 19, 2023

By: /s/ Teresa Bair

Teresa Bair
Chief Legal Officer

Background:

The menin and histone-lysine-*N*-methyltransferase 2A (*KMT2A*) protein complex is an essential epigenetic regulator of genes critical for maintenance of multiple genetic subtypes of leukemia. This complex is implicated in NPM1 mutant acute myeloid leukemia (AML) (*NPM*1m, 25-30% of AML) as well as AML with *KMT2A* gene rearrangements (*KMT2A*r; 5-10% of AMLs). The presence of co-mutations in genes such as *IDH1/2* and *FLT3* portend a poor prognosis, particularly in the relapsed/refractory (R/R) setting. There is high unmet need for the development of agents able to address these patient populations.

Aims:

The purpose of the Phase (Ph) 1 portion of KOMET-001 (NCT04067336) is to establish the safety, tolerability, and recommended phase 2 dose (RP2D) for ziftomenib monotherapy in *NPM1*-m and *KMT2A*-r R/R AML.

Methods:

KOMET-001 is a global, open-label Ph 1/2 study of ziftomenib in adult patients (pts) with R/R AML. The dose escalation and randomized, multi-dose expansion in pts with *KMT2A*r or *NPM1*m R/R AML is fully enrolled. The single-arm Ph2 registration-enabling portion evaluating the ziftomenib monotherapy RP2D in pts with R/R *NPM1*m AML is currently enrolling. Ziftomenib is dosed orally, once daily, in 28-day cycles until relapse, progression, or unacceptable toxicity.

Results:

This report provides updates on the Ph 1 *NPM1*m pts dosed at the 600mg RP2D (n=20) and on duration of remission (DoR) for a 200mg pt as of 31JAN2023. The median age for pts treated at RP2D was 70.5 years (22 to 86y). FLT3 and IDH1/2 mutations were common (35% FLT3, 30% IDH1/2, and 20% both co-mutations). Median number of prior therapies was 2.5 (r: 1 to 8), including 15% with ≥1 prior stem cell transplant (SCT) and 60% with prior venetoclax.

The cumulative safety profile for the ziftomenib RP2D is consistent with prior reports. Most (85%) had at least one ≥Gr 3 treatment-emergent adverse event (TEAE), with 30% of TEAEs considered potentially treatment-related. The most frequent (>10%) TEAEs ≥ Gr 3 were anemia (25%), pneumonia (20%), thrombocytopenia, neutropenia and hyperglycemia (15% each). Any grade differentiation syndrome (DS) was reported in 20%; 5% (n=1) as Gr 3.

As of 31JAN2023, the complete remission (CR) rate for *NPM1*m pts treated with 600mg was 30%, composite CR rate (CRc) was 35%, and ORR rate was 40% (see Table 1). The median DoR for pts achieving CRc, which continues to mature, was 8.2 months (m) per Kaplan-Meier estimate (95% CI: 1.5 to NE). One CR was noted at the 200mg dose with an ongoing DoR of 32 cycles. Median time to

CR was 70 days (r: 26 to 89). Two pts (1 CR and 1 CR with incomplete hematologic recovery [CRi]) proceeded to SCT and both remain in remission as of the cutoff. Median overall survival for *NPM1*m pts treated with 600mg was 5.1m (95% CI: 2.1 to NE), with a median duration of follow-up of 8.0m. At the cutoff, 57.1% of pts achieving CRc at RP2D remain on treatment or in post-SCT follow-up; those on treatment continue to show evidence of evolving responses.

Summary/Conclusion:

Ziftomenib continues to demonstrate significant clinical activity in heavily pretreated and co-mutated R/R *NPM1*m AML pts. The safety profile remains consistent and the on-target effect of DS continues to be manageable. Data suggest durable remissions as the DoR continues to mature with 5 of 8 pts with CRc ongoing at the cutoff. A single-arm registration-directed Ph 2 study is currently accruing to further evaluate ziftomenib monotherapy in R/R *NPM1*m AML.

Table 1. Response Rates for *NPM1*-m Patients treated at the Ziftomenib RP2D

CR Rate	
n (%)	6 (30)
95% (CI)	(12, 54)
CR/CRH Rate	
n (%)	6 (30)
95% (CI)	(12, 54)
CRc Rate (CR+CRh+CRi)	
n (%)	7 (35)
95% (CI)	(15, 59)
MRD Negativity Rate[1]	
n (%)	3 (43)
95% (CI)	(10, 82)
ORR Rate (CR+CRh+CRI+MLFS)	
n (%)	8 (40)
95% (CI)	(19, 64)

[1] Five of 7 patients achieving CRc were evaluated for MRD. Of those evaluated, 60% were MRD negative.