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): May 29, 2020

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.)**

3033 Science Park Road, Suite 220, San Diego, CA	**92121**
(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 May 29, 2020, Kura Oncology, Inc. (the "Company") issued a press release announcing clinical updates from its Phase 2 clinical trial of tipifarnib in patients with HRAS mutant head and neck squamous cell carcinoma. The Company is presenting these data at the American Society of Clinical Oncology ("ASCO") Virtual Scientific Program being held May 29-31, 2020.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated May 29, 2020
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: May 29, 2020

By: /s/ James Basta

James Basta
Chief Legal Officer

Exhibit 99.1

Kura Oncology Reports Overall Survival Data from Phase 2 Trial of Tipifarnib in HRAS Mutant Head and Neck Squamous Cell Carcinoma

– Median OS of 15.4 months, median PFS of 5.9 months and ORR of 50% observed in recurrent/metastatic HRAS mutant HNSCC –

– Outcomes with approved therapies are poor, with reported median OS of 5-8 months, PFS of 2-3 months and ORR of 13-16% in the second line –

– Compelling single-agent activity also observed in HRAS mutant salivary gland cancer and urothelial carcinoma –

– Data featured in oral presentation at ASCO20 Virtual Scientific Program –

SAN DIEGO, May 29, 2020 – Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer, today announced updated clinical outcome data from its RUN-HN study, a Phase 2 open-label, single-arm trial of tipifarnib in patients with HRAS mutant head and neck squamous cell carcinoma (HNSCC) whose disease had progressed after prior therapy. These data are being presented in an oral session at the American Society of Clinical Oncology (ASCO) Virtual Scientific Program, being held May 29-31, 2020. A copy of the presentation is available on Kura's website at www.kuraoncology.com/pipeline/publications.

At data cutoff, 21 patients with HRAS mutant HNSCC were enrolled[1], of whom 18 were evaluable for efficacy. Nine of the 18 evaluable patients achieved a confirmed partial response (PR), for an objective response rate (ORR) of 50% (95% CI, 26.0 to 74.0), with a median duration of response of 14.7 months. Median progression-free survival (PFS) was 5.9 months (95% CI, 3.5 to 19.2), compared to 2.8 months on the patients' last prior therapy. Median overall survival (OS) was 15.4 months (95% CI, 7.0 to 46.4). Patients had a median of two prior lines of therapy (range 0-6). Robust activity was seen despite resistance to chemotherapy, immunotherapy and/or cetuximab.

ORR for three FDA-approved therapies for treatment of HNSCC in the second line range from 13-16%, with median PFS of 2-3 months and median OS of 5-8 months.

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[1] Patients with HRAS variant allele frequency >35%, or ≥ 20% if serum albumin ≥ 3.5 g/dL, including one patient who was treated off-protocol through an expanded access program

“It’s encouraging to see robust overall survival data for tipifarnib, which demonstrate a potentially meaningful development for HNSCC patients with HRAS mutations in the advanced setting,” said Alan Ho, M.D., Ph.D., of Memorial Sloan Kettering Cancer Center and principal investigator of the study. “These data add to the body of evidence emerging for tipifarnib in second line HNSCC patients, a patient population with very few treatment options and a high unmet need. These results also highlight the importance of tumor genomic profiling to identify patients with HRAS mutations who could potentially be suitable for tipifarnib treatment.”

Patients in the RUN-HN trial received tipifarnib at a starting dose of 600 or 900 mg orally twice daily on days 1-7 and 15-21 of 28-day cycles. Tipifarnib was generally well-tolerated. The most common grade 3 or 4 adverse events (AEs) seen in at least 10% of patients were cytopenias and GI disturbances.

“We believe a median overall survival of 15 months is unprecedented in this patient population and represents a substantial improvement compared to historical benchmarks with current standard of care,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “Taken together, these data support our enhanced focus on patients with HRAS mutant HNSCC, a population in desperate need of effective new treatments, and reinforce our confidence in the ongoing AIM-HN registration-directed trial.”

The AIM-HN registration-directed trial of tipifarnib in patients with recurrent or metastatic HRAS mutant HNSCC is currently recruiting at approximately 90 clinical sites in the U.S., Europe and Asia. Patients interested in participating in this trial may talk to their doctor to have their tumor tested for the HRAS mutation for eligibility to enroll in this trial. Further details regarding the trial are available at clinicaltrials.gov (NCT03719690).

Activity in HRAS Mutant Salivary Gland Cancer and Urothelial Carcinoma

In addition to updated clinical outcome data in patients with HRAS mutant HNSCC, Kura also reported compelling single-agent activity in tumors of the salivary gland and urothelial carcinoma with HRAS mutations.

Seven recurrent/metastatic salivary gland cancer patients were enrolled in the all “other” HRAS mutant squamous cell carcinoma cohort in the Phase 2 tipifarnib trial and six additional patients were treated off-protocol through an expanded access program, of whom a total of 12 were evaluable for efficacy. One patient achieved a confirmed PR and seven achieved disease stabilization. Median PFS was 7.0 months (95% CI, 5.9 to 10.1) and median OS was 18.0 months (95% CI, 9.6 to 22.4). Adverse events observed were consistent with the known safety profile of tipifarnib. Salivary gland cancer is a rare disease for which standard treatments do not exist. Sequencing efforts in salivary gland cancers have identified HRAS mutations in up to 20% of high-grade histologic subtypes[2,3].

[2] Ross JS, et al. Ann Oncol. 2017;28(10):2539-2546
[3] Kato S, et al. Oncotarget. 2015;6(28):25631-25645

In addition, 21 patients with metastatic urothelial carcinoma were treated in an investigator-sponsored trial conducted at the Samsung Medical Center in Seoul, South Korea, including 14 patients with HRAS missense mutations, one patient with an HRAS nonsense mutation and six patients with a polymorphism in the STK11 gene. A confirmed ORR of 24% (95% CI, 6 to 42) was achieved, with all five responses seen in patients with HRAS mutations. Median PFS was 4.7 months (95% CI, 2.5 to 5.6) and median OS was 6.1 months (95% CI, 5.0 to 7.2). The most frequently observed AEs in the study were consistent with the known safety profile of tipifarnib. Approximately 6% of urothelial carcinoma patients are estimated to carry an HRAS mutation[4].

Disclosures

Memorial Sloan Kettering (MSK) has institutional financial interests related to the research in this release in the form of intellectual property rights and associated interests by virtue of licensing agreements between MSK and Kura.

About HNSCC

Head and neck squamous cell carcinoma (HNSCC) accounts for more than 885,000 new cancer cases each year worldwide with many cancers arising due to tobacco and/or alcohol use or human papilloma virus (HPV) infection. Despite advances in immunotherapy, the prognosis for advanced HNSCC patients remains poor with an estimated median overall survival (OS) of 13-15 months in patients when stratified by PD-L1 expression. Although the anti-epidermal growth factor (EGFR) antibody, cetuximab, was approved more than a decade ago, development of biomarker-directed therapies in HNSCC has been stymied by the limited number of druggable targets in the genomic landscape and the challenge of managing drug refractory recurrent/metastatic HNSCC.

About Tipifarnib

Tipifarnib, is a potent, selective and orally bioavailable inhibitor of farnesyl transferase in-licensed from Janssen in December 2014. Previously, tipifarnib was studied in more than 5,000 cancer patients and showed compelling and durable anti-cancer activity in certain patient subsets; however, no molecular mechanism of action had been determined that could explain its clinical activity across a range of solid tumor and hematologic indications. Leveraging advances in next generation sequencing as well as emerging information about cancer genetics and tumor biology, the Company is seeking to identify those patients most likely to benefit from tipifarnib. Tipifarnib has been granted Fast Track designation by the U.S. Food and Drug Administration for the treatment of patients with HRAS mutant HNSCC. Kura has received multiple issued patents for tipifarnib, providing patent exclusivity in the U.S. and foreign countries.

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[4] Der CJ. Are All RAS Proteins Created Equal in Cancer? National Cancer Institute, 2017

About Kura Oncology

Kura Oncology is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. The Company's pipeline consists of two wholly owned small molecule drug candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes by identifying those patients most likely to benefit from treatment. Kura's most advanced drug candidate is tipifarnib, a potent, selective and orally bioavailable farnesyl transferase inhibitor currently in a registration-directed trial in patients with recurrent or metastatic HRAS mutant HNSCC. The Company's pipeline is also highlighted by KO-539, a potent and selective inhibitor of the menin-KMT2A(MLL) protein-protein interaction currently in a Phase 1/2A clinical trial in patients with relapsed/refractory acute myeloid leukemia. For additional information about Kura, please visit the Company's website at www.kuraoncology.com.

Forward-Looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Kura's product candidate tipifarnib. Factors that may cause actual results to differ materially 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 Kura Oncology may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings and applications, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, the risks associated with the COVID-19 global pandemic, 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. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "promise," "potential," "confidence," "expects," "plans," "anticipated," "intends," "continues," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the company faces, please refer to the company's periodic and other filings with the Securities and Exchange Commission, which are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and Kura Oncology assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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