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): December 8, 2019

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))

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

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 December 8, 2019, Kura Oncology, Inc. (the "Company") issued a press release announcing clinical and regulatory updates from its Phase 2 clinical trial of tipifarnib in patients with angioimmunoblastic T-cell lymphoma relapsed (AITL) or refractory peripheral T-cell lymphoma (PTCL). The Company presented these data at the American Society of Hematology (ASH) Annual Meeting held December 7-10, 2019 in Orlando, Florida.

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 December 8, 2019

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: December 9, 2019

By: /s/ James Basta

James Basta
Chief Legal Officer

Exhibit 99.1

Kura Oncology Reports Clinical and Regulatory Updates for Tipifarnib in Angioimmunoblastic T-Cell Lymphoma

– Tipifarnib demonstrates robust and durable activity as a monotherapy in advanced AITL, an aggressive form of T-cell lymphoma –

– Enhanced activity (40% CR rate, 70% ORR) observed in AITL patients with KIR mutations, a CXCL pathway-associated biomarker –

– Company to conduct a single-arm, Phase 2 registration-directed trial of tipifarnib in AITL following positive feedback from FDA –

– Trial could support an NDA seeking accelerated approval for tipifarnib monotherapy in AITL and/or AITL with KIR mutations –

ORLANDO and SAN DIEGO, Dec. 8, 2019 – Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for the treatment of cancer, today announced clinical and regulatory updates for its lead drug candidate, tipifarnib, in angioimmunoblastic T-cell lymphoma (AITL), including data from the Company's ongoing Phase 2 clinical trial of tipifarnib in relapsed or refractory peripheral T-cell lymphoma (PTCL). The updated interim data are being presented during an oral session today at the American Society of Hematology (ASH) Annual meeting in Orlando. A copy of the presentation is available on the Company's website at www.kuraoncology.com.

"Tipifarnib continues to demonstrate clinically meaningful activity in advanced PTCL, including patients with AITL for whom there are few treatment options," said Thomas Witzig, M.D., a Hematologist at Mayo Clinic and a principal investigator in the trial. "The high level of clinical activity of tipifarnib, including complete responses, in third- and fourth-line patients, coupled with the fact that tipifarnib is an oral medication means it could be another treatment option for a patient population with high unmet need."

In June 2019, Kura reported that the primary efficacy endpoint was achieved in each of the expansion cohorts in its Phase 2 trial of tipifarnib in relapsed or refractory PTCL: 1) patients with AITL, an aggressive form of T-cell lymphoma often characterized by high levels of CXCL12 expression, and 2) patients with PTCL who lack a single nucleotide variation in the 3'-untranslated region of the CXCL12 gene. Given the high level of activity observed among AITL patients, Kura continued to enroll patients to acquire more experience regarding safety and tolerability in this population. Based upon the

2016 revision of the World Health Organization classification of lymphoid neoplasms[1], AITL and AITL-like histologies represent approximately one-third of all PTCL cases.

As of the November 11, 2019 data cutoff date, a total of 26 patients with relapsed or refractory AITL were enrolled in all stages of the trial. Among the 20 patients evaluable for efficacy, five achieved a complete response (CR) and five achieved a partial response (PR), for an objective response rate (ORR) of 50% on an evaluable basis and 38% on an intent-to-treat basis. In addition, three patients experienced disease stabilization. Patients had a median of three prior regimens (range 1-7).

Next-generation sequencing of 19 available patient biopsies showed that 10 (53%) carried C336R/Q386E variants in the killer-cell immunoglobulin-like receptor (KIR) 3DL2, an immune checkpoint receptor. Four of the 10 patients with KIR3DL2 variants achieved a CR and three achieved a PR, for a CR rate of 40% and an ORR of 70%. This compares to a CR rate of 11% and an ORR of 22% among the nine AITL patients with KIR3DL2 wild type.

Tipifarnib was generally well-tolerated in this Phase 2 trial, with adverse events consistent with its known safety profile. The most frequently observed treatment-related adverse events (grade ≥ 3) were hematology-related, including thrombocytopenia, neutropenia, leukopenia, anemia, febrile neutropenia and lymphopenia.

“We are encouraged by our growing body of data for tipifarnib in AITL” said Antonio Gualberto, M.D., Ph.D., Head of Development and Chief Medical Officer of Kura Oncology. “We believe these data support our efforts to expand the development of tipifarnib beyond our initial focus in HRAS mutant solid tumors and could enable registrational strategies in multiple CXCL12-dependent hematologic and solid tumor indications.”

Regulatory Update

Following FDA feedback from an end-of-Phase 2 (EOP2) meeting, Kura plans to initiate a Phase 2 registration-directed trial of tipifarnib in patients with relapsed or refractory AITL and related lymphomas in 2020. The multi-center, single-arm trial will target enrollment of 128 patients with AITL and AITL-like histologies who are relapsed or refractory to at least one prior systemic cytotoxic therapy.

The trial has two independent primary objectives: 1) Efficacy in terms of ORR in all patients enrolled and 2) Efficacy in terms of ORR in patients who carry KIR3DL2 variants. Patients will be enrolled on the basis of a pathological diagnosis of AITL and AITL-like histologies, and KIR3DL2 mutational status will be determined retrospectively. Each of the two primary objectives has a null hypothesis of 9%, and each one can be met independently. FDA EOP2 meeting minutes indicate that the trial, as designed, may be adequate to support an NDA seeking accelerated approval of tipifarnib in AITL and AITL-like histologies, and/or AITL and AITL-like histologies with KIR3DL2 mutations.

[1] Blood (2016) 127 (20): 2375-2390

“We are grateful for the regulatory feedback from the FDA on our single-arm trial design, providing an opportunity for a potential path for accelerated approval for tipifarnib in AITL and AITL-like histologies, an indication of significant unmet need and one for which they are no FDA approved therapies,” said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. “Consistent with our development strategy in HRAS mutant solid tumors, we have chosen to focus initially on AITL and AITL-like histologies, an indication that can be pursued with small, single-arm, registration-directed study. Once we establish a foothold there, we expect to see a clear path to expand the potential commercial opportunity by moving both to earlier lines of therapy and expanding to additional CXCL12-driven hematologic malignancies and solid tumor indications.”

About Angioimmunoblastic T-Cell Lymphoma

Angioimmunoblastic T-cell lymphoma (AITL) is an aggressive form of T-cell lymphoma frequently characterized by high levels of CXCL12 expression. Significant advances in the genetic landscape of T-cell and NK-cell neoplasms as the result of genomic studies, as well as the introduction of more powerful diagnostic technologies have led to revisions in the classification and introduction of new entities. Many of the same genetic changes observed in AITL are also observed in cases of peripheral T-cell lymphoma, not otherwise specified (PTCL-NOS) that manifest a T follicular helper (TFH) phenotype. This common genotype/phenotype has led to follicular T-cell lymphoma (FTCL) and AITL being unified under a common heading. Cases of nodal PTCL with TFH phenotype are now included in the same grouping as well. As a result, patients with the PTCL-NOS phenotype are increasingly being characterized as having AITL and/or AITL-like histologies.

About Tipifarnib

Kura Oncology’s lead drug candidate, 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, Kura is seeking to identify those patients most likely to benefit from tipifarnib. Kura initiated its first Phase 2 registration-directed trial of tipifarnib in patients with recurrent or metastatic HRAS mutant head and neck squamous cell carcinoma (HNSCC) in November 2018. Later that month, the U.S. Patent and Trademark Office issued a new patent for tipifarnib as a method of treating patients with AITL, providing exclusivity in the United States to 2037.

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 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 lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, for which the Company is conducting a registration-directed trial in recurrent or metastatic patients with HRAS mutant head and neck squamous cell carcinomas. In addition, tipifarnib is being evaluated in multiple other Phase 2 clinical trials in solid tumor and hematologic indications. Kura's pipeline also includes KO-947, an ERK inhibitor, and KO-539, a menin-MLL inhibitor, both of which are currently in Phase 1 dose-escalation trials. 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, Kura Oncology's potential for growth. 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, 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," "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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