**Section A: Research Information**

**Instructions: Please complete and address your completed application to** **Kura\_ISS@kuraoncology.com****. If corresponding with a Kura Medical Science Liaison, please also CC them on the correspondence.**

**Please submit ISS proposals to our partner Kyowa Kirin for those proposed outside of the United States via their website at:** [**https://www.kkna.kyowakirin.com/what-we-do/iis/**](https://www.kkna.kyowakirin.com/what-we-do/iis/)

Disclaimer: Unless you or your institution have an active confidentiality agreement in place with Kura Oncology that covers the content of this ISS application, such content shall not be considered confidential information.

Kura Oncology will consider providing support for studies:

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​1) that will be conducted at one or more institutions with adequate resources to conduct the study in a timely fashion; and

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​2) that will be overseen by an investigator who will be responsible for all Sponsor and Investigator obligations for the initiation, conduct, and completion of the study.

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​It will be the investigator’s responsibility to follow their internal review and approval process as well as all applicable laws, regulations, and guidances that may apply to the study.  Additionally, the investigator will be responsible for managing:

* ​Compliance with all applicable laws and regulations
* ​Adherence to Good Clinical Practice (GCP)
* ​Adverse Event Reporting
* ​All Regulatory Filings (e.g., ClinicalTrial.gov)
* ​Study Drug Management
* ​Detailed Invoice Submissions
* ​Quarterly Updates to Kura Oncology
* ​Data Analysis and Manuscript Development and Submission
* ​Animal Care and Use Committee (ACUC)
* ​Study Close-out​

**Section B: Contact and Funding Information:**

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| **Protocol Title:**  | [Insert the full title as it appears in the proposed protocol.] |
| **Study Drug Requested from Kura Oncology:** | [ ]  ziftomenib ​[ ]  other [please insert] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Principal Investigator Name:** | [Insert name] |
| **Principal Investigator Contact Information:** | [Insert address, phone and fax number, and e-mail address] |
| **Institution Name:** | [Insert Institution where study will be conducted] |
| **Sub-Investigator Name, if applicable:** | [Insert address, phone and fax number, and e-mail address] |
| **Do you plan on using other Institutions or centers to conduct study?** **If yes, please list name(s) and address(es):** | [ ]  YES [ ]  NO[Insert name(s) of other Institution(s) or center(s) and their respective Principal Investigators and Sub-Investigators, if applicable]\*\*Please note that Institution will be responsible for contracting with any sub-sites\*\* |
| **Is Funding from Kura Oncology Requested?** | [ ]  YES [ ]  NO |
| **Requested Budget Total:** | [Insert total budget including overhead costs, please complete **Kura Budget Template Form**]\*\*Please note that the Kura Oncology does NOT fund capital equipment or personnel/salary costs\*\* |
| **Budget breakdown for each year (specify year and budget):** | [Year]: $0.00; [Year]: $0.00; [Year]: $0.00; [Year]: $0.00  |
| **Is this request part of a (please select one)?: ​** | [ ]  ​ [ ]  grant [ ]  [ ]  universal endowment  ​​[ ]  ​ [ ]  charitable endorsement ​[ ]  [ ]  ​ cooperative agreement with the NIH (US)  ​​[ ]  ​ [ ]  cooperative agreement with other national Health Authority  |
| **If yes, please specify:** | **Origin of Support**:   \_\_\_\_\_\_\_\_\_\_\_   **Amount of Support**: $ /year |
| **Has or will another pharmaceutical/biotech company provided/provide support?** | [ ]  YES [ ]  NOIf yes specify: Company Name and/or primary contact information to company representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Other sources of non-Kura study drug:** | [Insert any current or pending sources of study drug supply and other company-sponsored grants.] |
| **Prior Research Involving Study Drug:** | [Identify any pre-clinical or clinical research that you or your institution are performing, or have performed, involving the Study Drug or any other Kura Oncology compounds.] |
| **Intellectual Property Disclosure:** | [List any inventions, planned patent application filings, pending patent applications, or granted patents related to the proposed study or the Study Drug] |
| **Research Team Members/Co-Investigators and all others’ Responsibilities:** | [List members with full contact information] |
| **Insurance:** | [Insert the amount of professional liability, general liability and all other insurance coverage that will be obtained to cover this study.] |
| **Past History and Experience:** | [Insert any previous ISS experience and information regarding debarment, exclusion and/or any prior disciplinary action] |
| **References:** | [Insert references applicable to this proposal – or – provide a separate attachment as a Word document] |
| **IND:** | \*\*Please confirm if you will be submitting for an IND Exemption or Number from the FDA.\*\*[ ]  IND Exemption [ ]  IND Number |

**Section C: Study Description**

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| **Study Background/Rationale/Purpose:** | ​​[Provide a description of the reason(s) why this research should be conducted.  Provide a strong scientific rationale and demonstrate the validity of the research question in this section.  Summarize any prior clinical study experiences or relevant information about the dose and regimen being proposed.  Provide the main literature references that are the basis for the rationale so that the review team can understand the study rationale.  What are the potential benefits and improvements in health to be gained from the study?  What scientific hypothesis is being tested?]​  |
| **Study Design:**  | ​​[Provide a description of the type of study you are conducting including trial design (e.g., open label, placebo controlled, randomized, double-blind, post-marketing surveillance, observational, epidemiological, registry), comparators, and trial stages.  Include a description of the number of visits to be conducted, the visit schedule, and the important data to be collected at each visit.]   |
| **Objectives:** **Study Schema:**  | ​​[Provide a concise statement describing the overall purpose(s) of the study.  Include primary and secondary objectives, if applicable, and definition of the study endpoints and the specific scientific objectives.  What are the primary and secondary endpoints to be measured during the trial to support the objectives (e.g., “survival at 12 months,” “mean change in Total Symptoms Score at 2 weeks compared to baseline”)?]​ **Primary:** [Insert the primary objective(s)]**Secondary:** [Insert the secondary objective(s)][Insert study schema] *A flow chart or figure is preferred.* |
| **Subjects and Centers:** | [Insert a summary of the study population, total number of subjects, subjects per each arm, etc.] |
| **Inclusion Criteria:**  | [Insert all inclusion criteria.] |
| **Exclusion Criteria:** | [Insert all exclusion criteria.] |
| **Other Therapy:**  | [If required, split the therapies into prior and concomitant therapy. Mention any therapy that will be specifically allowed or disallowed by the protocol.] Length of washout period will be [Insert length of washout period]. (Delete this statement if study has no washout period.) |
| **Efficacy Measures:**  | [List all efficacy assessments with a descriptive statement and frequency for each: include clinical, laboratory, radiographic, and subject self-assessment.] (If a Quality of Life, patient-related outcome, or other self-assessment is used, note if translation will be required.) |
| **Safety Measures:** | [List all safety assessments with a descriptive statement and frequency for each: include clinical, laboratory, radiographic, and subject self-assessment.] |
| **Correlative Science:** | [Planned assays and methods, which planned laboratories will be used, planned time points for each assay, and justification for the correlative science.] |
| **Statistical Analysis:** | [Specify power, sample size calculations and rationale, statistical plan, and whether there will be interim analyses.][Insert criteria for evaluability including intent to treat, per protocol, and safety population.] |
| **Data Collection:** | [Describe methods of collecting study data (e.g., Case Report Forms (CRFs), Electronic Data Capture (EDC)).] |
| **Study Drug Regimens:** | [Insert dose, frequency, route of administration, and duration for all investigative or comparative drugs that will be used in the study.] |
| **Study Drug Requested Per Patient:** | [Provide exact amount of drug and/or placebo per patient.]  |

**Section D: Drug Supply**

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| **Are Clinical/Drug Supplies Requested? (**check only 1 box**): [ ]  ‘YES’ [ ]  ‘NO’** [Please note drug product will be shipped brite stock to an identified vendor, and will need to manage inventory control/storage/labeling and distribution and returned drug (if applicable). This includes inventory management for additional subsites] |
| **Total Study Drug amount in units (Include dosage form if known):** |
| **Anticipated supply schedule:** |  |
| **Total Active Drug:** |  |
| **Amount of Pure Substance (if applicable):** |  |
| **Shipping Address:** | Center:Address (City, State):Phone:  |

**Section E: Timelines and Publication/Presentation Plan:**

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| --- | --- |
| **Estimated Length of Enrollment:** | [Insert duration of time in weeks, months or years. First patient in to last patient out.] |
| **Description of Site Enrollment Capabilities:** | [Insert information supporting your/your site’s capabilities for enrolling the patient population included in this study.] |
| **Estimated Study Duration:** | [Insert approximate number of months from fully executed contract to completion of all study-related activities] |
| **Potential written outcomes of this study (check all that apply):** | [ ]  Final Study Report [ ]  Submit for Presentation at scientific conference. [ ]  Submit for Publication [ ]  Submit Abstract/Poster at scientific conference. |
| **Publication Plan (if applicable):** | [Include expected journal name and estimated date of publication submission.] |

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