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| **HOOSIER CANCER RESEARCH NETWORK LETTER OF INTENT** |
| Study Title |  |
| **Study Phase** |  |
| **LOI submission Date** |  |

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| SPONSOR INVESTIGATOR |
| **Name** |  |
| **Lead Institution** |  |
| **Address** |  |
| **Phone** |  |
| **Fax** |  |
| **Email** |  |
|  COLLABORATING INVESTIGATOR |
|  **Name** |  |
|  **Phone** |  |
|  **Email** |  |

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| STUDY DRUG (S) AND FUNDING SOURCE |
| **Name of Study Drug(s)** |  |
| **Study Drug Supplier** |  |
| **Placebo?** | [ ]  Yes [ ]  No |
| **Name of Commercial Drug(s)** |  |
| **Trial Funding Source(s)** |  |
| **MSL contact** |  |

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| **STUDY DESIGN INFORMATION** |
| **Background and Rationale** |  |
| **Hypothesis** |  |
| **Objectives**Primary |  |
| Secondary |  |
| **Endpoints**Primary |  |
| Secondary |  |
| **Indication** |  |
| **Study population** |  |
| **Diversity and Inclusion***How will your proposal support diversity in enrollment access and inclusion of people of varying age, race, ethnicity, and gender?* |  |
| **Key inclusion/exclusion criteria** |  |
| **Treatment Plan***State the dose, method of administration, and schedule of each drug, and, if phase 1, provide the dose escalation scheme, and definitions of DLTs.* |  |
| **Study Assessments** *Specify all non-routine care assessments and their specific time points using objective practice guidelines (e.g., NCCN).* |  |
| **Follow-up durations** |  |
| **Estimated Accrual (per month)** |  |
| **Estimated Total Study Duration** |  |
| **Statistical Methods***Include sample size justification and stopping rules.* | Sample size justification:Stopping rules: |
| **Publication Plan***List specific journals, scientific meetings, and target dates for publication and presentation.* |  |
| **Does this proposal involve an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application?** *(Please choose one)* | [ ]  IND[ ]  IDE[ ]  N/A |
| **Additional Comments (e.g., rare population, significant challenges, contingencies)** |  |

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| CORRELATIVE STUDIES (PHARMCOKINETICS / PHARMACOGENOMICS) |
| **Describe proposed correlative studies. Please specify which sample collections are optional vs. mandatory for study participation.** |  |
| **Funding source for correlative studies** |  |

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| REFERENCES |
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