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

|  |  |
| --- | --- |
| SPONSOR INVESTIGATOR | |
| **Name:** |  |
| **Lead Institution:** |  |
| **Address:** |  |
| **Phone:** |  |
| **Fax:** |  |
| **Email:** |  |
| OTHER CONTACTS | |
| **Name:** |  |
| **Phone:** |  |
| **Email:** |  |

|  |  |
| --- | --- |
| 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** | |
| **Synopsis:** |  |
| **Rationale:** |  |
| **Hypothesis:** |  |
| **Objectives:**  Primary |  |
| Secondary |  |
| **Study endpoints:**  Primary |  |
| Secondary |  |
| **Indication:** |  |
| **Study population:** |  |
| **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** |  |
| **Sample Size and justification** |  |
| **Estimated Accrual/Mo:** |  |
| **Estimated Total Study Duration:** |  |
| **Statistical Methods:** |  |
| **Publication Plan:** |  |
| **Do you plan to submit an Investigational New Drug (IND) application or Investigational Device Exemption (IDE)?** | Yes [ *specify* ]  No |
| **Additional Comments: e.g. key challenges and dependencies** |  |

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

**References:**