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| GENERAL PROTOCOL INFORMATION | | |
| Report Date: | Protocol No. | IRB No. |
| **Protocol Title:** | | **Phase:**  **Risk/Complexity:** |
| **Principal Investigator:** | | **Original IRB Approval Date:** |
| Report Frequency *(select initial if first review):* Initial Annual Semi-Annual Quarterly Other | | |

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| 1. ENROLLMENT STATUS | |
| * 1. Please indicate where each patient is in this trial by filling out the table below *(please add notes when necessary for clarification)*:  |  |  |  |  | | --- | --- | --- | --- | | Target Accrual: | | | | | Last Review: |  |  |  | | Totals Since Study Opened | | | | | \*\*TOTAL ACCRUAL | |  | | | Total consented | |  | | | Total consent not treat | |  | | | Total eligible to go on treatment/study | |  | | | Total screen fail or ineligible (pt unable to be put on study after consent) | |  | | | \*\*CURRENT: Total on treatment/study | |  | | | \*\*CURRENT: Total on follow-up | |  | | | Total completed active treatment/study procedures – now on follow-up (if study has specified number of tx/procedures) | |  | | | Total discontinued early – now on follow-up (ex. PD, Death, Toxicity) | |  | | | \*\*OFF STUDY: total PD, death, toxicity – unable to complete study or follow-up | |  | | | \*\*OFF STUDY: total completed all tx/ procedures and all follow-up | |  | | | \*\* Highlighted columns should add up to TOTAL ACCRUAL | |  |  | | New/Changes in pt status/movement (on/off) since last DSMC review/report | | | | | New consents | |  | | | New consent not treat | |  | | | New or determined eligible since last report | |  | | | New screen fail/ineligible since last report | |  | | | New on treatment/study procedures | |  | | | New placed on follow-up | |  | | | New discontinued | |  | | | New off study | |  | |  1. If more than 2 new patients have been consented not treated SINCE LAST REPORT, provide explanation for each: 2. Patients that did not complete treatment SINCE LAST REPORT, list treatment non-completion reason for each: | |
| 1. STOPPING RULES | |
| * 1. Are there stopping rules for toxicity in this study? Y N N/A   If YES – attach/submit copy of stopping rules for toxicity with report | |
| * 1. Are there stopping rules for response in this study? Y N N/A   If YES – attach/submit copy of stopping rules for response with report | |
| * 1. If YES to question 1 or 2 please include:      1. Meeting minutes discussing number of toxicities in relation to stopping rules   Meeting minutes attached?: Y (Please highlight related information) | |
| 1. TOXICITIES: AEs, ≥ GR 3 AEs, SAEs and PRI | |
| * 1. Report of all AEs, SAEs, PRIs since study inception:      1. CTO-studies: OnCore generated AE reports and copies of SAE/PRI reports.      2. Non-CTO studies: AE list/report, and copies of SAE/PRI reports. All AE/SAE/PRI events MUST include date of event, grade/s, and attribution.   Attachment: Y None to report N/A  Please check box below if any of the following are included in the attached reports:  SAE  DLT  Hospitalization     * 1. Please attach report of all GR 3 or greater AEs to-date:      1. CPO-studies: OnCore generated AE reports.      2. Non-CPO studies: List/report of AEs   Attachment: Y None to report N/A  Please check box below if any of the following are included in the attached reports:  SAE  DLT  Hospitalization   * 1. Please attach all SAEs since last DSMC report (or study start if first review).      1. Please attach FULL SAE/MedWatch report (including attribution):   Attachment: Y None to report  *If N/A to any of the above items, please provide explanation here*: | |
| REVIEWER COMMENTS: | |
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| 1. DEVIATIONS/VIOLATIONS, UNANTICIPATED PROBLEMS (UPs) | |
| * 1. Attach UPs that required immediate reporting since last review (or study start if first review).      1. Please attach full UP report submitted to the IRB:   Attachment: Y None to report N/A If yes, is IRB Report attached?   * 1. Attach ALL deviations/violations since last review (or study start if first review).   Attachment: Y None to report N/A (Please provide report in chronological order by “Report Date”)  Are there new deviations to report since last review?  *If N/A to any of the above items, please provide explanation here*: | |
| REVIEWER COMMENTS: | |
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| 1. HIGH RISK PH I OR PH I/II TRIALS ONLY | |
| * 1. Phase I or I/II with dose escalation: What dose finding design is used in the trial? Indicate adherence to dose escalation scheme in table below. If using 3+3 design, please show data by cohorts of three rather than cumulative: N/A  |  |  |  |  |  | | --- | --- | --- | --- | --- | | Dose Level(s)  (List below – please specify dosing at each level) | # of Pts in Dose Level | | # of DLT in Any Pta | | | Pts since  study start | Since Last DSMC Report | Since study start | Since Last DSMC Report | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | Totals (Should equal sum of prior rows) |  |  |  |  |  1. For any patient that had a Dose Limiting Toxicity (DLT), please list each by type and cohort: | |
| * 1. Phase I/II Only:      1. Describe transition to Phase II: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      2. Attach preliminary report of response and other endpoints listed in primary and secondary objectives   Attachment: Y None N/A | |
| 1. ELIGIBILITY/TREATMENT EXCEPTION(S) | |
| * 1. List eligibility or tx exceptions since last review (or study start if first review):   Y None N/A | |
| 1. MONITOR/AUDIT REPORT(S) | |
| * 1. If study monitored and/or audited during review period – attach signed copy of report   Attachment: Y None during review period N/A  Provide check all that apply:  CAPA (Describe Finding):  Action Items  Regulatory  Patient Data  Pharmacy  Eligibility and/or Consent  Other  Explain: | |
| REVIEWER COMMENTS: | |
|  | |
| 1. LITERATURE: Developments that may affect safety or ethics of study | |
| * 1. Attach copy of significant literature:   Attachment: Y None during review period N/A | |
| 1. TEAM MEETING MINUTES | |
| * 1. Attach copies of team meeting minutes since last review *Please highlight study specific discussion within team minutes:*   Attachment: Y None N/A | |
| 1. INTERIM ANALYSES | |
| * 1. Attach results of interim analyses (if applicable):   Attachment: Y None N/A | |
| 1. PROTOCOL | |
| * 1. Attach most recent approved version of protocol - No change   New Amendment Updates or changes include: Scientific  Editorial  Eligibility | |
| REVIEWER COMMENTS: | |
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| STUDY TEAM SUMMARY (Please add any pertinent information not otherwise included) |
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| CONTACT INFORMATION |
| Name of person submitting form:  Email:  Phone number: |

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| **REVIEWER COMMENTS & RECOMMENDATION:** |
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