# REPORT DATE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study IRB Number:**

**Study Title:**

Principal Investigator:

Name of Person Submitting Form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone Number and Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Review Frequency (circle one): Annual Semi-annual Quarterly Interim Other \_\_\_\_\_

Data reported as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date)

1. Are there study stopping rules for toxicity in this study? YES NO

2. Are there study stopping rules for response in this study? YES NO

3. If yes to question 1 or 2, include stopping rule chart and describe any toxicities and their relationship to established stopping rules. Attach minutes from team meetings in which toxicities and stopping rules were discussed.

4. Are there subject stopping rules in this study? YES NO

5. If yes to question 4, please describe subject stopping rules.

6. Summarize all grade 3 or greater adverse events (if any) to date using protocol defined criteria.

7. Describe any significant safety issues, developments, unexpected toxicities, or concerns that have arisen since the time of last review.

8. Describe any significant changes to the protocol since the time of last review. Attach an up to date copy of the IRB application and safety monitoring plan for this protocol.

SECTION I: Enrollment Data: Indicate subject data by study arm if DSMB review is unblinded

1. Please describe the anticipated enrollment timeline and enrollment goals for this study

2. Please describe current enrollment situation and if enrollment goals are being met. If accrual or retention rates are insufficient to meet enrollment goals, what actions are in place to increase those rates?

**Table 1a: Recruitment / Enrollment Summary**

|  |  |
| --- | --- |
|  | Study Numbers |
| Total enrollment # approved by IRB |  |
| Total # screened in the study to date |  |
| Total # enrolled in the study to date |  |
| Total # enrolled in past year |  |
| Projected # to be enrolled in coming year |  |
| Anticipated start date for enrollment |  |
| Anticipated stop date for enrollment |  |

**Table 1b: Subject Disposition**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)N = # | Placebo (Arm B)N = # | TotalN = # |
| **Subject Disposition (all subjects)** |  |  |  |
| Screened (consented) |  |  | #  |
| Randomized | # | # | # |
| Currently in trial | # (%) | # (%) | # (%) |
| Completed trial | # (%) | # (%) | # (%) |
| Discontinued trial | # (%) | # (%) | # (%) |
|  |  |  |  |

Future reports should include separate displays both over all patients and since last report

Table 1c: Reasons for Discontinuations for any subject discontinued from study

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)N = # | Placebo (Arm B)N = # | TotalN = # |
| **Primary Reason for** **Discontinuation – All Subjects** |  |  |  |
| Adverse event(s) | # (%) | # (%) | # (%) |
| Subject lost to follow-up | # (%) | # (%) | # (%) |
| Subject non-compliance | # (%) | # (%) | # (%) |
| Serious adverse event(s) | # (%) | # (%) | # (%) |
| Death | # (%) | # (%) | # (%) |
| Other reason | # (%) | # (%) | # (%) |
|  |  |  |  |

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Table 1d: Primary Reason for Discontinuations, by Subject

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject Number | Study Arm or Treatment | RandomizationDate | DiscontinuationDate | Last Completed Visit | Primary Reason for Discontinuation | Comments |
| *#005* | *Active Drug* | *2-1-2010* | *3-5-2010* | *3-5-2010* | *Non-compliance* | *Stopped drug X 2 wks*  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
|  |  |  |  |  |  |  |

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SECTION II: Subject Specific Data. Indicate subject data by study arm if DSMB review is unblinded

Table 2a: Serious Adverse Events, by arm and relationship to treatment/study drug

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Subject Number | Study Arm or Treatment | Date of SAE | \*Relationship to Treatment/ Study Drug | Study Discontinuation Y or N | Description of Event  |
| *006* | *Active* | *4-5-2010* | *Possibly* | *Yes* | *Anaphylactic reaction within ½ hr drug admin.* |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
| ID # | A or B |  |  |  |  |
|  |  |  |  |  |  |

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***\* Relationship:*** *Definitely Related, Probably Related, Possibly Related, Not Related, Unknown*

Table 2b: Adverse Events, by Severity, Relationship to Study Drug, and Discontinuation

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)N = # | Placebo (Arm B)N = # | TotalN = # |
| **Number of Adverse Events, by Severity** |  |  |  |
| All severities | #  | #  | #  |
| Mild | # (%) | # (%) | # (%) |
| Moderate | # (%) | # (%) | # (%) |
| Severe | # (%) | # (%) | # (%) |
| Life threatening | # (%) | # (%) | # (%) |
| **Number of Subjects with at least****One Adverse Event, by Severity** |  |  |  |
| All severities | # (%) | # (%) | # (%) |
| Mild | # (%) | # (%) | # (%) |
| Moderate | # (%) | # (%) | # (%) |
| Severe | # (%) | # (%) | # (%) |
| Life threatening | # (%) | # (%) | # (%) |
| **Number of Adverse Events, by****Relationship to Study Drug/Tx** |  |  |  |
| Not Related | # (%) | # (%) | # (%) |
| Probably Related | # (%) | # (%) | # (%) |
| Definitely Related | # (%) | # (%) | # (%) |
| Unknown | # (%) | # (%) | # (%) |
| **Number of Adverse Events Leading****To Study Discontinuation** |  |  |  |
| All severities | # (%) | # (%) | # (%) |
| Mild | # (%) | # (%) | # (%) |
| Moderate | # (%) | # (%) | # (%) |
| Severe | # (%) | # (%) | # (%) |
| Life threatening | # (%) | # (%) | # (%) |
|  |  |  |  |

Table 2c: Adverse Events Leading to Study Discontinuation

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject Number | Study Arm or Treatment | Study Visit or Date | \*\*Severity | \*Relationship to Treatment/ Study Drug | Category (AE Term) | Description of Event  |
| *#009* | *Placebo (Arm B)* | *4-15-2010* | *Moderate* | *Unknown* | *GI Symptoms* | *Stomach upset after starting drug* |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
|  |  |  |  |  |  |  |

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***\* Relationship:*** *Definitely Related, Probably Related, Possibly Related, Not Related, Unknown*

***\*\* Severity:*** *Mild, Moderate, Severe or Grades 1 – 5*

Table 2d: Adverse Events, by Category and Severity

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)N = # | Placebo (Arm B)N = # | TotalN = # |
| **Number of Adverse Events by Category,** **Moderate Severity or Higher** |  |  |  |
| *Shortness of breath* | *3 (17 %)* | *3 (19%)* | *6 (18 %)* |
| *Hypertension* | # (%) | # (%) | # (%) |
| *GI Symptoms* | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
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|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  |  |  |  |

Table 2d: Adverse Events, by Category and Severity

|  |  |  |  |
| --- | --- | --- | --- |
|  | Active (Arm A)N = # | Placebo (Arm B)N = # | TotalN = # |
| **Number of Adverse Events by Category,****All Severities** |  |  |  |
| *Shortness of breath* | *3 (17 %)* | *3 (19%)* | *6 (18 %)* |
| *Hypertension* | # (%) | # (%) | # (%) |
| *GI Symptoms* | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
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|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  | # (%) | # (%) | # (%) |
|  |  |  |  |

Table 3: All Randomized Patients

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject Number | Study Arm or Treatment | Tx Start Date | Tx End Date | Most Recent Study Visit | Grade 2 -4 or Serious Adverse Events | Study Status |
| *001* | *Placebo* | *4-5-2010* | *8-5-2010* | *Month 4* | *None* | *Completed* |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
| ID # | A or B |  |  |  |  |  |
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