**FINAL REPORT**

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| **SECTION 1** (*To be filled up by PI*) |

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| **MCU-FDTMF PROTOCOL CODE** |  | **Submission Date** |  |
| **Sponsor Protocol Number** |  | **Approval Date**  |  |

|  |  |
| --- | --- |
| **Protocol Title** |  |

|  |  |  |
| --- | --- | --- |
| **NAME** | **Email** | **Mobile / Phone / Fax Number** |
| **Principal Investigator(s)** |  |  |  |
| **Sponsor** |  |  |  |

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| **Note: Use extra blank paper, if more space is required** |
| **Study Site** |  | **Study Arms** |  |

|  |  |  |
| --- | --- | --- |
| **Number of study participants at the start of the study** | **Number of participants at the end of the study** | **Number of participants who received the test articles** |
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| 1. Summary of amendments to the original protocol (include dates of approval)
 |  |
| 1. Summary of SAE reported
 |  |
| 1. Summary of SUSARs reported
 |  |
| 1. Summary of participants’ complaints, if applicable
 |  |
| 1. Summary of benefits documented
 |  |
| 1. Summary of indemnification, if applicable
 |  |
| 1. If terminated early, state the reason
 |  |
| 1. Progress report with corresponding MCU-FDTMF IRB actions
 |  |
| 1. Summary of study materials used
 |  |
| 1. Treatment or interventions
 |  |
| 1. Study dose(s)
 |  |
| 1. Duration of the study
 |  |
| 1. Summary of Recruitment
 |  |
|  |  |  | Accrual ceiling set by MCU-FDTMF IRB |
|  |
|  |  |  | Total number of participants accrued since protocol began |
|  |
|  |  |  | No. of participants who are lost to follow-up |
|  |
|  |  |  | No. of participants withdrawn from the study |
|  |
|  |  |  | No. of participants who experienced SAEs / SUSARs |
|  |
|  |  |  | No. of participants who completed the study |
|  |
| 1. List of informed consent form used (version/date) and attached most recent version
 |  |
| 1. Study objectives
 |  |
| 1. Summary of results
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| **Principal Investigator’s Signature** |  | **Date** |  |

**SECTION 2** *(To be filled up by the MCU-FDTMF IRB)*

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| **Comments / Conclusions** |  |
| **Recommendations**  |  |  |  |  |
|  |  |  | Approve  |
|  |  |  |  |
|  |  |  | Request Additional Information, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |
|  |  |  | Further action required, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| **Primary Reviewer/s** | **Signature** | **Date** |
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| **MCU-FDTMF IRB Decision** |  |

|  |  |  |
| --- | --- | --- |
| **MCU-FDTMF IRB Chair** | **Signature** | **Date** |
|  |  |  |