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|---|---|---|
| | **FINAL CLINICAL TRIAL REPORT** | MCA-F-501/10 |

**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220)4380632, www.mca.gm

| **SECTION A ADMINISTRATIVE INFORMATION** | | | | | |
|---|---|---|---|---|---|
| **Title of Clinical Trial:** | | | | | |
| **Sponsor:** (*Please insert name and address),* | | | | | |
| **Principal Investigator:** (*Please insert name, address, email, phone*) | | | | | |
| **Protocol Number** | | **MCA CT Number** | | | |
| **PACTR Number** | | **Other** | | | |
| **Date of Start of the Trial:** | | | | | |
| **Date of End of the Trial:** | | | | | |
| **Date of interim data analysis, if any:** | | | | | |
| **Date of final data analysis:** | | | | | |
| **Was it an early termination** | | | Yes | | No |
| **Date of this report:** | | | | | |

| **SECTION B General Information about the Clinical Trial** |
|---|
| **Main objectives of the trial:** |
| **Trial design:** |

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| **Scientific background and explanation of rationale:** |
| **Measures of protection of subjects taken:** |
| **Background therapy:** |
| **Statistical methods used:** |

| **SECTION C POPULATION OF SUBJECTS IN THE GAMBIA** | |
|---|---|
| **Inclusion criteria** | |
| **Exclusion criteria** | |
| **Number of subjects screened** | |
| **Number of subjects recruited** | |
| **Number of subjects included in the clinical trial** | |
| **Number of subjects withdrawn** | |

| **SECTION D INVESTIGATIONAL PRODUCTS** |
|---|
| **Description of investigational products used:** |
| **Randomisation details:** |
| **Blinding details** (if applicable)**:** |

| **Accountability (**repeat information for each product**):** | |
|---|---|
| **Total quantity imported**<br>**Total quantity purchased locally**<br>**Total quantity used in the trial**<br>**Total quantity wasted (spilled/lost)**<br>**Total quantity onsite (if applicable)**<br>**Total quantity returned to sponsor**<br>**Total quantity disposed** | |

| **SECTION E BASELINE CHARACTERISTICS** | |
|---|---|
| **Age and age group breakdown** | |
| **Gender and gender breakdown** | |
| **Study Specific Characteristic**<br>(if applicable) | |

| **SECTION F END POINTS** |
|---|
| **End point definitions*:** |
| **End Point #1 Statistical Analyses:** |
| **End Point #2 Statistical Analyses:** |

*Information shall be provided for as many end points as defined in the protocol

| **SECTION G ADVERSE EVENTS** |
|---|
| **Description of overall adverse event experience:** |
| **Summary and narratives of serious adverse events, indicating those suspected to be related to the IP** (attach tables) |
| **Summary of non-serious adverse events** (attach tables) |

| SECTION H ADDITIONAL INFORMATION | |
|---|---|
| **Substantial Modifications:** | |
| **Interruptions and re-starts** | |
| **Limitations:** | |
| **Sources of potential bias and imprecisions:** | |
| ***For clinical trials replicating studies on already authorised investigational products and used in accordance with the terms of the marketing authorisation*** | |
| **Indicate identified concerns to relevant aspects of the efficacy of the IP** | |

| SECTION I OVERALL RESULTS OF THE CLINICAL TRIAL |
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***List the documents attached to this report***

I, the undersigned certify that this clinical trial was conducted in compliance with ICH E6-GCP Guideline including the archiving of essential documents, and any applicable regulatory requirements, and that the information submitted in this report is accurate.

Signature of Principal Investigator in The Gambia:

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Signature Date