Amendment N°: **3**

Protocol N°: **ST3073-ST3074 DM040010**

Title:

A Phase III, randomized, non-inferiority trial, to assess the efficacy and safety of Dihydroartemisinin+Piperaquine (DHA+PPQ, Artekin) in comparison with Artesunate+Mefloquine (AS+MQ) in patients affected by acute, uncomplicated *Plasmodium falciparum* malaria.

- MULTICENTRE STUDY IN ASIA-

Final protocol dated : **10 January, 2005**

Revised protocol incorporating Amendment N° 1, 2& 3 dated: **24 November 205**

Amendment N° 3A (SMRU sites only)dated: **6 January 2006**

PURPOSE:

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This amendment has been formulated in response to specific recommendations from the Thai MoPH.

MODIFICATION:
Page 5: Synopsis Diagnosis and Main Inclusion Criteria
Reason for modification: To amend the age range to reflect that only adults will be recruited

Therefore:

Males and Females aged between 3 months and 65 years inclusive, body weight at least 5 Kg, microscopically confirmed, monoinfection of *Plasmodium falciparum* or mixed infection, history of fever or presence of fever (temperature at ≥ 37.5 °C), written informed consent

is modified as follows :

Males and Females ≥18 years with microscopically confirmed, monoinfection of *Plasmodium falciparum* or mixed infection, history of fever or presence of fever (temperature at ≥ 37.5°C), written informed consent

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MODIFICATION:
Page 22: Section 3. Selection of the Patients
Inclusion Criteria Number 1
Reason for modification: To amend the age range to reflect that only adults will be recruited.

Therefore:

Males and Females aged between 3 months and 65 years inclusive.

is modified as follows :

Males and Females aged ≥ 18 years

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