ETHICS COMMITTEE

Date: 25th July 2009

Dr. J.D. Lakhani
Prof. & H.O.D
Medicine Dept.
SBKS MI&RC
Piparia, Waghadia
Vadodara: 391760

Dear Dr. J.D. Lakhani,

The Sumandeep Vidyapeeth University Institute Ethics Committee, Baroda reviewed and discussed your application to conduct the trial entitled “Protocol: ipca/ALFD/PIII-07: Comparative evaluation of efficacy and safety of artesunate-lumefantrine fixed dose combination Vs artemether-lumefantrine fixed dose combination in the treatment of uncomplicated plasmodium falciparum malaria” on date 25/6/09. Ref. No. ipca/01/2009

The following documents were reviewed:

1. Trial Protocol, dated 05/05/2009 version no.01
2. Patient information Sheet and Informed consent form in English, Hindi and Gujarati
3. Investigator Brochure, dated 05/05/2009 version 01
4. Principal investigator’s current CV
5. Insurance Policy
6. Investigator’s agreement with the Sponsor
7. Investigator’s undertaking

The following members of the SVU Ethics committee were present at the meeting held on 13th July 2009 at 11.00 am, at the Conference Hall, Administrative Block, Sumandeep Vidyapeeth University.

1. Dr. Sandeep H Shah, Member-Secretary, Associate Professor, Dept. of Psychiatry.

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2. Dr. G.V. Shah, Dean, SBKS MIRC.
3. Dr. J. D. Lakhani, Prof. and Head, Dept. Of Medicine.
4. Dr. Rajul Desai, Prof. and Head, Dept of Pathology.
5. Dr. V. H. Yajnik, Professor, Dept of Medicine.
6. Dr. Sagun Desai, Professor of Pharmacology.
7. Mrs. Dipti Joshi, Social Worker.
8. Mr. Sanjay Joshi, Legal Expert.
9. Mr. Rakesh Patel, Member, Lay person.
10. Dr. Prasad Muley (Asst.Prof.dept.of pediatrics SBKS MI&RC, Dhiraj General Hospital.)
11. Dr. Niraj Pandit (Asst.Prof.Dept.of. of PSM, SBKS MI&RC, Dhiraj General Hospital.)

We approve the trial to be conducted in its presented form.

The SVU Independent Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

We have noted that neither you nor any of your proposed study team members for the Referenced study participated in the meeting during the decision-making/voting procedures of the Ethics Committee.

I hereby certify that this committee is organized and operates according to ICH GCP Guidelines and at the time of the voting the required quorum was present.

Yours sincerely,

Mr. Mustakim Mansuri
The Chairman
SVU Ethics Committee.

Date: 25/3/09

ETHICS COMMITTEE
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Dist. Vadodara - 391760.