MINISTRY OF HEALTH
INSTIUTIONAL REVIEW BOARD IN BIOMEDICAL RESEARCH

No.: 40/CN-HĐĐĐ

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, 24th MAY, 2018

CERTIFICATE
Approval on protocol for clinical trials

Based on Decision no. 1122/QĐ-BYT dated 02 February 2018 of the Minister, Ministry of Health on the establishment of the National Institutional Review Board in biomedical research, term 2018-2023;

Based on Decision no. 1155/QĐ-BYT dated 02 February 2018 of the Minister, Ministry of Health on the issuance of the regulations on the organization and operation of the National Institutional Review Board in biomedical research, term 2018-2023;

Based on the summary of proceedings no. 12/TH-HĐĐĐ dated 23 May 2018 of the National Institutional Review Board in biomedical research.

Reviewing the documents attached with official letter no. 175/YHDP-DA dated 10 May 2018 of the Military Institute of Preventive Medicine on the ethical evaluation in the research.

The National Institutional Review Board in biomedical research approved:

A. Scientific and ethic aspects for the study:

1. Project number: VNPA-1.0
2. Project title: An open label study to assess the efficacy, safety and tolerability of pyronaridine-artesunate in the treatment of malaria infection caused by single or mixed species of *Plasmodium falciparum, P. vivax,* or *P. malariae* in Vietnam.
3. Principal investigator: Nguyen Ngoc San (MD, PhD)
4. Testing organization: Military Institute of Preventive Medicine
5. Sponsor: Vysnova Partner Inc. (USA)
6. Study location: Dak D'rong commune, Cu Rut District and Thuan An commune, Dak Mil District, Dak Nong Province
7. Participants: Patients with acute uncomplicated mono-infections of *P. falciparum, P. vivax* and *P. malariae* malaria or mixed infections of the *Plasmodium* species.
8. Anticipated number of participants: 120 patients (55 patients each for both the *P. falciparum* and *P. vivax* mono-infection arms. With the additional inclusions of 10 patients with *P. malariae* and/or mixed *Plasmodium* species)
9. Execution time: from May 2018 to May 2021.
10. Level to risk to the human subjects of the study: greater than minimum risk

B. The following documents are approved to be used in the study:

No.	Documents	Version	Date
1	Protocol	2.0	9 December 2017
2	Case Screening Form	2.0	9 December 2017
3	Case Report Forms	2.0	9 December 2017
4	Adult information and consent form (≥18 years)	2.0	9 December 2017

5	Parent/guardian permission from for children to be in the study	2.0	9 December 2017
6	Statement of assent for children (age 10 to 17 years)	2.0	9 December 2017
7	Statement of Consent for a Pregnancy Test for Adults (Age ≥18 years)	2.0	9 December 2017

Date of approval: 24 May 2018

Responsibilities of the principal investigator:

- Strictly follow the approved protocol, standard operating procedures, GCP principles, current legal regulations on ethics in research.
- Report the final findings of the study to the National Institutional Review Board in biomedical research (IRB) after the completing the study.
- Report any serious adverse event (SAE) relating to the study in accordance with recent instructions and regulations.
- Report and get approval from the IRB on any changes, errors or amendments to the approved protocol, consent forms and documents providing to the study participants before using them for the study, except a very clear and necessary change to eliminate immediate risks for the participants.
- Report the National Institutional Review Board in biomedical research (IRB) on the research progress at least once per year or as per request of the IRB.
- Report on the research termination; research closure before anticipated completing date, reasons of the early closure.
- Prepare for the possibility of visiting the research sites by the National Institutional Review Board.

Recipients:
- Principal investigator;
- Testing organization;
- Sponsor;
- K2DT (for report);
- File: VT, TNLS.

CHAIRMAN

(Signed and sealed)

Truong Viet Dung