

## AGENDA

### WHO Independent Evaluation of the Safety and Efficacy of HIV-1 Immunogen (REMUNE®) January 12-14, 2004

Venue: Thai FDA Meeting Room, 1<sup>st</sup> Floor FDA, MOPH, Nonthaburi, Thailand

#### January 12, 2004 (Monday)

##### *Open Session:*

- 09.00-09.15 : - Introduction to the Purpose of the Meeting and Opening Remarks made by Prof. Dr. Pakdi Pothisiri, Deputy Permanent Secretary, MOPH, Thailand and Dr Bjorn Melgaard, WHO, Thailand  
- Self-introduction by the Participants and the Observers of the Meeting present in the meeting room as requested by Dr. Visanu Thamlikitkul
- 09.15-09.30 : Keynote Address on REMUNE® Clinical Trials in Thailand based on Ethical and Scientific Standard and Validity of Scientific Data by Prof. E. Dr. Natth Bhamarapravati
- 09.30-10.15 : Overview - REMUNE® Studies in Thailand by Dr. Vina Churdboonchart, Project Principal Investigator, Mahidol University

##### *Trial Conduct Issues:*

- 10.15-11.00 : Clinical Practice and Outcome from the Thai Clinical Site Investigators  
Panelists: Dr. Boonsri Israngkura-Na-Ayudhtaya  
Dr. Verapol Chandeying  
Dr. Sang-a-roon Kulpradist  
Dr. Wisut Sukeepaisarncharoen  
Dr. Buranaj Smutharaks (Moderator)
- 11.00-11.30 : Validity of Laboratory Results  
Panelists: Dr. Wasun Chantratita  
Dr. Worachart Sirawaraporn (Moderator)
- 11.30-12.00 : Open Forum on Trial Conduct Issues

12:00-13.00 : **Lunch**

##### *Safety & Efficacy Issues:*

- 13.00-13.45 : REMUNE® Safety and Efficacy by Dr. Ronald Moss
- 13.45-14.45 : Statistical Analysis to evaluate surrogate marker, CD4<sup>+</sup> cells, for Clinical Efficacy by Asst. Prof. Chaweewon Boonshuyar and Asso. Prof. Dr. Wisut Sukeepaisarnchareon
- 14.45-15.00 : Independent Expert Opinion on Biostatistical Analysis by Dr. John Henstridge, Adjunct Professor of the University of Western Australia

##### *Summary & Open Discussion:*

- 15.00-15.15 : Summary by Dr Vina Churdboonchart
- 15.15- 17.00: - Open Forum on Safety and Efficacy Issues  
- Query Session and the Handover of the set of questions prepared by the WHO Experts to the Thai Investigators
- 17.00-17.15: Closing Remarks

## **January 13, 2004 (Tuesday)**

### ***Site Visit Session:***

- 09.00 - 10.00 :- Short Meeting at the Faculty of Science, Rm. Pr118 by the WHO five Experts accompanied by FDA officials: Khun Tasanee Lorchaivej and Khun Prapassorn Savaitnisagon.
- Handover of the Thai Investigators' Reply to the set of questions prepared by the WHO Experts
  - Handover of the following documents to the WHO Experts by the Thai Investigators:
    - (1) Approved Original Protocol for P2101B dated May 8, 1997
    - (2) Final Statistical Analysis Plan dated July 21, 1999 by Protocol Statisticians, Drs. Lagakos and Kim
    - (3) Statistical Analysis Report by Dr. Lagakos, et al.
- 10.00 – 10.45 : Site Visit at the Virology and Molecular Laboratory, Ramathibodi Hospital, Bangkok where the viral load and genotypic-testing analysis are being done.
- Hosted by Dr. Wasun Chantratita and Staff
- 10.45 – 11.15 : Site Visit at the BioScience Unit (BSU) Laboratory of the Ministry of Science and Technology, Bangkok where the CD4 and CD8 cells analysis are being done.
- Hosted by Prof. Dr. Worachart Sirawaraporn and Staff
- 11.15 – 12.30 : Clinical Study Site (Cohort #2) Visit at the Pramongkutkiao College of Medicine, Pramongkutkiao Hospital.
- Hosted by Major Gen. Dr. Boonsri Israngkura-Na-Ayudhtaya and Staff
- 12.30 – 14.00 : Visit at the Data Center at the REMUNE<sup>®</sup> Trial Center, Pr107, Dept. of Pathobiology, Faculty of Science, Mahidol University to audit randomly the data documentation, and calculation.
- Hosted by Dr. Vina Churdboonchart and Staff

### ***Closed Session:***

14.00 - 17.00: Independent meeting among WHO Experts

## **January 14, 2004 (Wednesday)**

### ***Closed Session:***

- 09.00 - 12.00: Independent meeting among WHO Experts & Preparation of written document on WHO Experts' opinion on safety and efficacy of REMUNE<sup>®</sup>
- 12.00 – 13.00: Lunch

### ***Open Session:***

- 13.45 – 15.00: Presentation of WHO Experts' observations and recommendations
- 15.00 – 15.30: Discussion on WHO Experts' Recommendations and Review on pre-specified purpose of the meeting requested by the Thai FDA to the WHO
- 15.30 - 16.00 Closing remarks by WHO Representative of Thailand, Dr. Bjorn Melgaard and the Thai FDA Secretary General, Dr. Supachai Kunaratanapruk

- Notes:**
1. WHO Expert Committee's official report will be submitted to the Thai FDA within 7 days from January 14, 2004.
  2. The Thai Investigators will provide the minute-meeting, video tapes, and investigators' opinion on this workshop and REMUNE to the Thai FDA and to all institutes involved.