AGENDA

WHO Independent Evaluation of the Safety and Efficacy of 
HIV-1 Immunogen (REMUNE®) 
January 12-14, 2004 
Venue: Thai FDA Meeting Room, 1st 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 Sukeeapaisarncharoen
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+ cells, for Clinical Efficacy by Asst. Prof. Chaweewon Boonshuyar and Asso. Prof. Dr. Wisut Sukeeapaisarncharoen
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 Pramongkutklao College of Medicine, Pramongkutklao Hospital.
- Hosted by Major Gen. Dr. Boonsri Israngkura-Na-Ayudhtaya and Staff
12.30 – 14.00: Visit at the Data Center at the REMUNE® 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®
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 Kunaratapanpruk
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.