

Open Workshop on Gene Therapy (Draft)

-ICH activities on Gene Therapy Discussion Group (GTDG) and Current Topics on International Gene Therapy Activities-

Sponsored by Human Science Foundation
Auspices of JSGT (need to be approved), NIHS/MHLW, JPMA etc.

Date: June 12th 2009, 10:00-17:00

Place: PACIFICO YOKOHAMA Conference Center 3F 301/302
(1-1-1 Minato Mirai, Nishi-ku, Yokohama, Japan)

Program

- 10:00-10:15 **Opening Remarks**
Prof. Shigetaka Asano (President, JSGT)
- 10:15-11:00 **Overview of GTDG Activities in ICH and
Current Topics on Gene Therapy in EU**
Prof. Dr. Klaus Cichutek (PEI, EMEA)
- 11:00-11:45 **ICH Considerations on General Principles to Address the Risk of
Inadvertent Germline Integration of Gene Therapy Vectors and ?
Current Topics on Gene Therapy in USA**
Dr. Beth Hutchins (PhRMA)
- Lunch
- 13:30-14:00 **Current Topics on Gene Therapy in Japan?**
From JSGT (To be determined)
- 14:00-14:30 **Summary of 3 Topics in Japanese; Oncolytic Viruses,
Germline Integration and Viral/Vector Shedding?**
From MHLW/PMDA (To be determined)
- 14:30-15:00 **Recent activities of Japanese bioventures in the field of gene therapy and ICH
Considerations**
From JPMA (JPMA)
- (Coffee Break)
- 15:15-16:00 **ICH Discussion on Adverse Events on Retroviral Gene Therapy and
Current Topics on Gene Therapy in EFTA**
Dr. Andreas Marti (Swiss Medic, EFTA)
- 16:00-16:45 **ICH Considerations on Viral/Vector Shedding and
Current Topics on Gene Therapy in Canada**
Dr. Anthony Ridgway (Health Canada)
- 16:45-17:00 **Closing Remarks**
Dr. Masahiro Nishijima (President, NIHS To be determined)

(Reception?)

Invited Speakers and Tentative Topics

- Please make suggestions and comments on who does what.

1. Prof. Dr. Klaus Cichutek: Vice President, Paul-Ehrlich-Institute (EMEA), Co-Rapporteur of ICH GTDG,, Chairperson of Gene therapy Expert Working Group in EMEA;

” Overview of GTDG activities in ICH and current topics on gene therapy in EU”?

2. Dr. Beth Hutchins: Director, Bioanalytical & Protein Chemistry Dept., Schering Plough Biopharma (PhRMA) **“ICH considerations on General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors and Current topics on gene therapy in USA”?**

3. Dr. Andreas Marti : Head, Gene Therapy and Preclinical Reviewer, Division of Preclinical Review, Swiss Agency for Therapeutic Products, Swiss Medic (EFTA) **“ICH Discussion about adverse effect of X-SCID and CGD gene therapy and Current topics on Gene Therapy in EFTA**

4. Dr. Anthony Ridgway: Sr. Regulatory Scientist, Office of the Director Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, Biologics and Genetic Therapies, Directorate, Health Canada **“ICH considerations on Viral/vector Shedding and Current topics on Gene Therapy in Canada”**

5. JSGT: “Current Topics on Gene Therapy in Japan” ?

6. Dr. Japanese Regulatory: “ICH considerations on Oncolytic Viruses” ?

Dr Teruyo Arato?; Dr. Teruhide Yamaguchi; Dr. Daisuke Maeda; Eriko Uchida (PMDA, NIHS)

7. JPMA Expert: Summary of 3 topics in Japanese; Oncolytic virus, Germline Integration, Viral/vector shedding?

Dr. Wataru Toriumi: :Dr. Maki Tanaka; Dr.Masafumi Genba

Major Topics

• **ICH considerations on General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors**

• **ICH considerations on Oncolytic Viruses**

• **ICH considerations on Viral/vector Shedding**

• **Current Topics on Gene Therapy in each region**

• **Future activities in ICH**

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