Annex 2

ICH Press Release

Brussels May 2005

Communication Paper

Gene Therapy Discussion Group Meeting
Brussels, 9-10 May 2005

1. Status Report:

The scope of the meeting included an update on new gene therapy developments in the regions and an exchange of information on the main topics agreed upon during the 2004 meeting of the ICH GT discussion group (GTDG). The group also discussed organizational matters relevant to future activities in 2005 and 2006. Representatives from the three ICH regions (including experts from regulatory authorities and industry), Health Canada, EFTA and WHO participated.

1. UPDATE FROM REGIONS

SCID gene therapy

Updates on the activities ongoing in the regions following the report of a third case of T-cell lymphoproliferation in the French SCID-XI clinical trial were provided. Advisory scientific committees were called upon in the Regions and appropriate regulatory actions were put in place. Regions who have SCID-related trials on-going are assessing risks and benefits on trial-by-trial basis. Despite the leukemias seen in one of several SCID trials, clinical benefits have been observed. Encouraging preliminary results are being generated in a clinical trial in Chronic Granulomatous Disease (CGD) as well.

The regions continued to discuss the risk of oncogenesis due to retroviral insertion. There is insufficient information to draw any definitive conclusions at this time. The group discussed the value of creating research programs to assess the functionality and impact of vector design on the risk of insertional oncogenesis.

New tools for information exchange

The EU representatives indicated that the European Commission and the EMEA have recently opened dedicated webpages on advanced therapies and emerging technologies, including cell, tissue and gene therapy. The Japanese

representatives indicated that there is now a MHLW/NIHS web page in English which reviews oncolytic viruses and gene therapy in Japan. The GTDG agreed to exchange within the group the addresses of the web pages. These web pages are intended to facilitate the exchange of information on these specific areas.

2. ICH CONSIDERATIONS FOR THE MINIMIZATION OF THE RISK OF GERMLINE TRANSMISSION

There was agreement within the GTDG that this topic is now appropriate for development of ICH Considerations. The group agreed to draft a proposal containing principles agreeable to the regions. A workshop on this topic is planned for 2006. Based on ensuing feedback and the experience acquired in the regions on this topic, the ICH Considerations would be finalized. The ICH Considerations would represent the first step toward harmonization in this area.

3. ICH GENE THERAPY WORKSHOP NOVEMBER 2005

The SC previously agreed that an ICH GTDG public workshop on oncolytic viruses could be undertaken under the ICH umbrella in November 2005 in the U.S. The objectives of the workshop will be to identify and discuss issues relevant to clinical development of oncolytic viruses including safety. Viruses to be covered include: adenovirus, herpes simplex virus, reovirus, Newcastle disease virus, measles virus, and Sendai virus. The GTDG plans to write a summary of the workshop for presentation to the SC.

4. OTHER FUTURE ACTIVITIES

The group re-affirmed the usefulness of the exchange of information taking place at the GTDG meetings. In addition the group agreed that there are two main lines of outcomes possible following discussions:

- ICH Considerations could be written for topics for which the science is still rapidly evolving.
- ICH Guidelines could be prepared for topics where sufficient experience has been accrued in the Regions.

The next formal meeting of the GTDG will take place in parallel with the ICH SC EWG meeting in November 2005.