



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 February 2010
EMA/CAT/80413/2010

Draft agenda – Workshop on stem-cell based therapies

10 May 2010 | 9:30 – 17:30

Meeting Room 2A | European Medicines Agency | London, UK

Co-Chairperson: Dr C. Schneider (CAT Chair, CHMP) / Dr P.Salmikangas (CPWP Chair, CAT Vice chair)

Time	Topic	Speaker
9:30	Opening words	Mr Thomas Lönngren, Executive Director EMA
9:40	Welcome	Dr Christian Schneider
9:45	EU support to stem cell research	Dr Charles Kessler, EC DG Research
	<i>Keynote Lectures:</i>	
9:55	Human embryonic stem cells: Consideration for therapeutic development	Dr Jane S. Lebkowski, Geron Corporation
10:15	Induced pluripotent stem cells	Prof Marc Peschanski I-stem, Evry, France
10:35	Mesenchymal stem cells: Science and therapeutic applications	Dr Dirk Buscher Grifols
10:55	<i>Coffee Break</i>	
11:10	Haematopoietic stem cells	Dr Neil Rodrigues, NIH Center of Biomedical Research Excellence in Tissue Repair and Stem Cells, Providence, RI, USA
11:30	Neural stem cells	Prof Gianvito Martino, Division of Neuroscience San Raffaele Hospital, Milan, Italy



Time	Topic	Speaker
11:50	Regulatory Note Stem cell-based medicinal products as ATMPs in the EU Introduction of EMA reflection paper	Dr Paula Salmikangas Dr Tiina Palomäki (CPWP member, Rapporteur)
12:10	Regulatory Note Overview of Regulation of Stem Cell-based products by the USA FDA	Dr Kimberly Benton Division of Cellular and Gene Therapies, Office for Cellular, Tissue and Gene Therapy, CBER, FDA

Lunch Break at EMA Restaurant 12:30 – 13:30

Time	Topic	Speaker
13:30	Panel Discussions	Dr C Schneider / Dr P Salmikangas
13:35	Topic 1. Quality criteria and starting material	Chair: Dr M. Menezes-Ferreira (CAT, CPWP, BWP) Prof Jean-Hugues Trouvin (BWP Chair, CAT) Dr Lyn Healy (UK stem cell bank, NIBSC) Dr María Pascual (Cellerix) Dr Paula Salmikangas (CPWP, CAT) Dr Stephen Minger (Cell Technologies, GE Healthcare)
14:30	Topic 2. Animal Models	Chair: Dr Carla Herberts (CPWP) Dr Hans Ovelgönne (CAT, SAWP) Prof Beatriz Silva Lima (CAT, CHMP, SWP) Prof Balázs Sarkadi (CAT) Dr Tiina Palomäki (CPWP) Prof Jürgen Hescheler (Universität Köln, DE)
15:00	Topic 3. Biodistribution and Niche	Chair: Prof Asterios Tsiftoglou (CAT, CPWP) Dr Egbert Flory (CAT, CPWP) Prof Kathryn Wood (University of Oxford, UK) Dr Denis Corbeil (Technische Universität Dresden, DE) Dr Roland Fleck (NIBSC)
15:30	<i>Coffee Break</i>	
15:45	Topic 4. Tumorigenicity	Chair: Dr Egbert Flory (CAT, CPWP) Prof Toivo Maimets (CAT) Dr Jane S. Lebkowski (Geron Corporation) Dr Sophie Lucas (CAT, CPWP) Dr Heidrun Holland (Universität Leipzig, DE) Dr Arnaud Foussat (TxCell)
16:15	Topic 5. Clinical aspects	Chair: Prof Giovanni Migliaccio (CAT, CPWP) Prof Andreas Zeiher (J.W. Goethe University Frankfurt, DE) Prof Paolo De Coppi (UCL, London, UK) Dr Gopalan Narayanan, (CAT, GTWP) Dr Romaldas Mačiulaitis, (CAT, CHMP, CPWP, PDCO) Ms Elona Baum (CIRM)
17:15	Closing remarks	Chairs