Report on kick-off meeting on June 04, 2012, in preparation of REMEDIC conference on regulations, rules and standards in regenerative medicine in May 2013

Summary

One of the most important scientific activities of the RNP REMEDIC in 2012 – 2013 will be a big final conference on regulations, rules and standards in regenerative medicine in May 2013. National regulatory hurdles are still a major problem in marketing advanced therapies in Europe. The aim of this conference is to bring together European regulators, e.g. EMA, national regulators, academia, company representatives, representatives of tissue banks, but also young scientists in order to advance the field of regenerative medicine and provide an incentive to tackle regulatory problems in Europe. A large part of the budget for 2012/2013 (70 000€) is dedicated to this activity. The aim of the 4-hour kick-off meeting in Frankfurt was to discuss the format, ideas, structure, topics, date and venue of the conference to take place in May 2013. Participants were representatives of the REMEDIC Steering board, of CAT, of the Alliance for Advanced Therapies, and of the ESF. Overall, the kick-off meeting was very successful, because a European conference on regulations, rules and standards in regenerative medicine in 2013 was considered very timely by all participants, and the participants were able to successfully define a general outline of the planned 2013 conference.

Description of the scientific content and discussion of the event

All individuals invited to this kick-off meeting attended the 4-hour meeting on June 04 from 11:00 – 15:20 at the Frankfurt Airport Centre: Reinhold G. Erben, Enrique Gómez-Barrena, Frank Luyten, Gustav Steinhoff, and Eva Syková from the **REMEDIC Steering Committee**, Martina Schüssler-Lenz from the **Committee for Advanced Therapies (CAT)**, Alexander Vos from the **Alliance for Advanced Therapies (AAT),** Kirsten Steinhausen from the **ESF,** and Gudrun Tiedemann as **invited guest.**

It was generally felt that the planned 2013 conference on regulatory issues is very timely, and would fill an important gap in Europe.

1) During the lively discussion, the following **important needs** were identified which should be addressed in the planned meeting:

- More interaction between disciplines
- Reimbursement & treatment algorithms & European (?) registry (Focus on centres of excellence?)
- Development of non-clinical efficacy and safety models
- Improved safety models, especially for tumorigenesis (long-term safety)
- Increase treatment success by removing boundaries between academia and industry
- Models for regulation of IPR issues between academia and industry
- Manufacturing challenges
- Roadmap for ATMPs
- More focus on personalized medicine
- Quality assurance in multi-centre settings
- Better educational models

- European post-marketing registry
- Better strategies to deal with ethical issues

2) Another important aim was to discuss the **format, structure, participants, and topics of the May 2013 conference.** The participants agreed on the following outline of this conference:

Tentative title "European Interdisciplinary Summit on Cell-Based ATMPs", approximately 200 participants, 2-day or 2.5-day meeting, no parallel sessions, case product development presentations; regulators, academia, industry should be present in each session.

Participants: EMA/CAT (Christian Schneider, chair of CAT, should give his input about EMA participants), AAT, legal people, notified bodies, academia

Tentative sessions:
Ethics and Economy (Chairs Dirix? Oliver Bruestle?)
Treatment Algorithms and Reimbursement (Chairs Frank Luyten, Eduardo Bravo)
Manufacturing challenges (in FP7 projects and in companies) (Chairs Alexander Vos, Gudrun Tiedemann)
Non-clinical models (Chairs Reinhold Erben, Gerjo van Osch)
Safety models/Tumorigenesis (long-term safety) (Chairs EMA, Company representative)
Interdisciplinarity and Education (Chairs Ana Pego, Eva Syková)
Clinical studies/Quality assurance (Chairs Gustav Steinhoff, Enrique Gomez-Barrena); regulator's role: Martina Schüssler-Lenz
Roadmap 2020 for ATMPs (EMA, EC, EMRC, Industry, Academia = larger panel)

Date and venue of the May 2013 conference: May 02 – 04, 2012, in Vienna

3) Another item on the agenda was to discuss a possible initiative to establish a **European Graduate School of Regenerative Medicine**. It was generally felt that such an initiative would be an outstanding opportunity to improve the scientific education in Europe in this area. It was decided that the next steps in this direction should be taken after the Marie Curie FP7 call has been published in July 2012.

4) It was planned to briefly discuss the usefulness of the proposed e-book on national RM regulatory rules and standards in Europe. However, due to the time constraints this point could not be discussed any more. It was decided that Reinhold Erben contacts Alexander Vos regarding the usefulness of such an e-book.

Assessment of the results and impact of the event on the future direction of the field

The participants unanimously agreed that the planned REMEDIC conference on regulations, rules and standards in regenerative medicine could have a large impact in this field. The kick-off meeting in Frankfurt was a big step in this direction, because it served as a platform to define a general outline of the planned meeting. Another important accomplishment of the kick-off meeting was the start of the initiative to establish a European Graduate School of Regenerative Medicine. If successful, the latter initiative could make an important contribution to improve the scientific education in Europe in this area in the future.

Final Meeting Agenda of the 4-hour kick-off meeting at Frankfurt Airport Centre, 11:00 – 15:00

1. Welcome and Opening

2. What is REMEDIC?

3. Brainstorming:
What are the needs?
How can we make a difference?
Format, structure, participants, and topics of the May 2013 conference
Date and venue of the May 2013 conference

4. European Graduate School of Regenerative Medicine

5. E-book on national RM regulatory rules and standards in Europe

6. Miscellaneous

7. Closing