

A central green rectangular area contains the text of the summit. This area is flanked by two vertical columns of three fluorescence microscopy images each. The images on the left show cells with red, green, and purple fluorescence. The images on the right show cells with blue, red, and red fluorescence.

**European
Interdisciplinary
Summit
on Cell-Based ATMPs**

May 02 – 03, 2013
Billrothhaus
Vienna, Austria



www.esf-remedic2013.org

WELCOME

Dear Colleagues,

On behalf of the Steering Committee of REMEDIC, I cordially invite you to attend the first **European Interdisciplinary Summit on Cell-Based ATMPs** to be held at the Billrothhaus in Vienna, Austria, from May 02 - 03, 2013.

The meeting is supported by the Research Networking Programme REMEDIC (REgenerativeMEDICine) funded by the European Science Foundation.

The 2-day **European Interdisciplinary Summit on Cell-Based ATMPs** will bring together leading academic experts in the field of cell-based Advanced Medicinal Therapy Products, European and national regulators, company representatives, representatives of tissue banks, but also young scientists. The meeting will provide a forum for the in-depth assessment and discussion of the challenges involved in the development, application and marketing of cell-based ATMPs in this dynamic and fast moving field. Special emphasis will be placed on regulatory issues and safety models.

Sincerely,

Reinhold G. Erben, MD, DVM
Chair of REMEDIC

President & Chair

Prof. Reinhold G. Erben
Institute of Physiology, Pathophysiology & Biophysics,
Dept. of Biomedical Sciences,
University of Veterinary Medicine, Vienna (A)

Vice Chairs

Prof. Gerjo van Osch
Department of Orthopaedics & Department of Otorhinolaryngology,
Erasmus University Medical Center, Rotterdam (NL)

Prof. Frank Luyten
Laboratory for Skeletal Development and Joint Disorders,
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SCIENTIFIC PROGRAMME

Thursday, May 2, 2013

09.00-09.10 Welcome Address

Reinhold G. Erben, Chair of REMEDIC
Maria Manuela Nogueira, ESF Representative

09.10-10.10 EU Research Agenda, Interdisciplinarity & Education

Chairs: Ana Pego, Porto (P)
Reinhold G. Erben, Vienna (A)

09.10-09.40 Arnd Hoeveler, Brussels (B)
*The EU research agenda in cell therapy:
opportunities and challenges*

09.40-10.10 Mário Barbosa, Porto (P)
*Integrative Training in Biomaterials: how to deal
with complexity using simple tools*

10.10-10.40 Coffee Break

10.40-12.10 Treatment Algorithms and Reimbursement

Chairs: Wilfried Dalemans, Leuven (B)
Frank Luyten, Leuven (B)

10.40-11.10 Freddy Cornillie, Leiden (NL)
TNF blockers in Rheumatoid Arthritis: a case study

11.10-11.40 Mark Charny, Worcester (UK)
*What sort of evidence do you need to secure optimal
reimbursement?*

11.40-12.10 Panel discussion (chairs, speakers, audience)

SCIENTIFIC PROGRAMME

Thursday, May 2, 2013

12.10-13.30 Lunch Break

12.30-13.30 ESF Steering Committee Meeting

13.30-15.00 Manufacturing Challenges

Chairs: Gudrun Tiedemann, Rostock (GER)
Alexander Vos, Maastricht (NL)

13.30-14.00 Dieter Hauwaerts, Leuven (B)

ChondroCelect manufacturing: from ground zero to commercial supply

14.00-14.30 Cedric Volanti, Maastricht (NL)

Manufacturing challenges from academic to phase clinical trials

14.30-14.45 Ioannis Papantoniou, Leuven (B)

Linking decoupled bioprocess design to tissue-engineered construct quality attributes: a stairway to robust manufacturing for tissue engineering

10'+5'

14.45-15.00 Cornelia Kasper, Vienna (A)

Optimization of process parameters for stem cell expansion and differentiation

10'+5'

15.00-15.15 Frauke Stähler, Rostock (GER)

Point-of-Care (PoC) systems - an option for stem cell manufacturing in hospitals?

10'+5'

15.15-15.45 Coffee Break

Thursday, May 2, 2013

15.45-18.15 Non-Clinical Models. Strengths and Limitations

Chairs: Reinhold Erben, Vienna (A)
Gerjo van Osch, Rotterdam (NL)

-
- 15.45-16.15 Mary McElroy, Edinburgh (UK)
Preclinical models and the safety assessment of cell-based regenerative mtherapies
-
- 16.15-16.45 Michaela Kneissel, Basel (CH)
Strength and weaknesses of preclinical animal models for drug discovery: examples from musculoskeletal research'
-
- 16.45-17.00 Hamish Simpson (UK) 10'+5'
Preclinical models for bone and cartilage repair
-
- 17.00-17.15 Daniela Zwolanek, Vienna (A) 10'+5'
Model for cell tracking in immunocompetent hosts
-
- 17.15-17.30 Anna Theresa Hofmann, Vienna (A) 10'+5'
Establishment of an ischemic excision wound model in the rat
-
- 17.30-17.45 Liesbet Geris, Liège (B) 10'+5'
In silico models for framing and taming the complexity of cell-based regenerative therapies
-
- 17.45-18.00 Linda Howard, Galway (IRL) 10'+5'
Probing the interaction between stem cells and the host
-
- 18.00-18.15 Basem Abdallah, Odense (DK) 10'+5'
In vitro stem cell models for identifying novel therapeutic targets for enhancing bone formation

19.30-22.30 Reception at the Town Hall

The Mayor of Vienna invites the participants of the congress to enjoy a cocktail reception in the splendid town hall of Vienna.

SCIENTIFIC PROGRAMME

Friday, May 3, 2013

09.00-10.30 Safety models/Tumorigenesis (long-term safety)

Chairs: Michaela Kneissel, Basel (CH)
Beatriz Silva Lima, Lisbon (P)

09.00-09.30 Beatriz Silva Lima (P)
State-of-the-art in safety testing of cell-based ATMPs

09.30-10.00 Richard Moriggl, Vienna (A)
Tumour-host interaction, lessons from tumour biology

10.00-10.30 Panel discussion (chairs, speakers, audience)

10.30-11.00 Coffee Break

11.00-12.15 Ethics and Economy

Chairs: Kris Dierickx, Leuven (B)
Frank Luyten, Leuven (B)

11.00-11.30 Annelien Bredenoord, Utrecht (NL)
Returning results in translational research: the ethics reconsidered

11.30-12.00 Kris Dierickx, Leuven (B)
Ethical aspects of biobanks

12.00-12.15 Panel discussion (chairs, speakers, audience)

12.15-13.30 Lunch Break

SCIENTIFIC PROGRAMME

Friday, May 3, 2013

13.30-15.30 Clinical studies and Quality Assurance

Chairs: Gustav Steinhoff, Rostock (GER)
Katarina LeBlanc, Stockholm (S)

13.30-14.00 Gustav Steinhoff, Rostock (GER)
*Development of Cardiac Stem Cell Therapies-
PERFECT Phase III Study*

14.00-14.30 Martina Schüssler-Lenz, Langen (GER)
Clinical studies-regulatory view

14.30-15.00 Dominique Pioletti (CH) 10'+5'
*Progenitor Fetal Cell Therapy as a Platform for
Clinical Applications in Musculoskeletal Tissue Engineering*

15.00-15.15 Ulrike Ruch (GER) 10'+5'
*Cardiac stem cell registry - the basis for
standardization and quality assurance*

15.15-15.30 Anthony Hollander, Bristol (UK) 10'+5'
*Stem cells for torn cartilage: Forging a path into the
clinic*

15.30-16.00 Coffee Break

SCIENTIFIC PROGRAMME

Friday, May 3, 2013

16.00-17.30 Roadmap 2020 for ATMPs

Panel discussion with participants from academia, companies, and regulatory authorities

Panel members: Frank Luyten, Leuven (B), Gustav Steinhoff, Rostock (GER), Katarina LeBlanc, Stockholm (S), Eduardo Bravo, Leuven (B), Michaela Kneissel, Basel (CH), Alexander Vos, Maastricht (NL), Martina Schüssler-Lenz, Langen (GER), Beatriz Silva Lima, Lisbon (P)

Examples for successful product development:

16.00-16.15 Christian Homsy, Mont-Saint-Guibert (B)
Cardio 3 Biosciences "*CHART-1 Study*"

16.15-16.30 Wilfried Dalemans, Leuven (B)
"*ChondroCelect: from 2000 till 2009/2012 towards 2020*"

16.30-17.30 Panel discussion

17.30-17.35 Closing

01

GMP-Grade Human Platelet Lysate for Cell Therapy

K. Plöderl^{1,2}, **A. Lindenmair**^{3,2}, **F. Hildner**^{1,2}, **A. Peterbauer-Scherb**^{1,2}, **H. Redl**^{3,2},
S. Hennerbichler-Lugscheider^{1,2}, **C. Gabriel**^{1,2}

¹Red Cross Blood Transfusion Service of Upper Austria, Linz, Austria, ²Austrian Cluster for Tissue Regeneration, Austria, ³Ludwig Boltzmann Institute for Experimental and Clinical Traumatology, Vienna, Austria

02

From bench to bedside with a full thickness autologous skin substitute for healing therapy resistant ulcers – taking into account the new legislation on the use of ATMPs

S. Gibbs^{1,2,3}, **M. Breetveld**¹, **E.M. de Boer**¹, **C. van Montfrans**¹, **R.J. Schepers**²

¹VU university Medical Centre, ²A-Skin BV, ³Academic Centre for Dentistry (ACTA) Amsterdam, The Netherlands

03

A phase I clinical trial for maxillary bone augmentation with adipose stem cells and calcium phosphate scaffolds; an intra-operative ATMP concept

M.N. Helder^{1,2}, **H.J. Prins**^{2,3}, **C.M. ten Bruggenkate**^{1,2,3}, **J.R. Overman**^{2,3},
J. Klein-Nulend^{2,3}, **T.H. Smit**^{1,2}, **E.A.J.M. Schulten**^{1,2,3}

¹VU University medical center, Dept. of Orthopedics, Amsterdam

²Centre for Translational Regenerative Medicine, VU University, Amsterdam

³Academic Center for Dentistry Amsterdam, University of Amsterdam & Vrije Universiteit, Amsterdam, The Netherlands

04

Analysis of CD34+/CD133+ progenitor cells in bone marrow suitable for application in the therapy of critical limb ischemia

J. Mlynárová¹, **P. Musil**¹, **A. Klepanec**², **J. Maďarič**², **M. Viňanský**³, **J. Kyselovič**¹

¹Faculty of Pharmacy, Comenius University, Bratislava, Slovakia,

²The National Institute of Cardiovascular Diseases, Bratislava, Slovakia,

³Glaston Ltd., Bratislava, Slovakia

05

Off-the-shelf cord blood mesenchymal stem cell bank

T. Montemurro, C. Lavazza, M. Viganò, M. Barilani, B. Baluce, V. Boldrin, V. Parazzi, S. Budelli, E. Ragni, E. Montelatici, R. Giordano, L. Lazzari
 Cell Factory, Cell Therapy and Cryobiology Unit, Fondazione Ca' Granda IRCCS, Milano, Italy

06

β1 Integrin Mediates Attachment of MSC to Cartilage and Bone *In Vitro*

D. Zwolanek¹, M. Flicker¹, E.R. Balmayor¹, G. Lepperdinger², G.van Osch^{3,4}, R.G. Erben¹

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²Extracellular Matrix Research, Institute for Biomedical Aging Research, Austrian Academy of Sciences, Innsbruck, Austria

³Department of Orthopaedics, Erasmus MC University Medical Center Rotterdam, The Netherlands

⁴Department of Otorhinolaryngology, Erasmus MC University Medical Center Rotterdam, The Netherlands

SPEAKERS & CHAIRS

- Abdallah** Basem M., Asst.Prof., Molecular Endocrinology Lab. ,KMEB, Clinical Institute, University of Southern Denmark, Odense (DEN)
- Barbosa** Mario, Prof, Univ. of Porto, Instituto de Engenharia Biomedica, Porto (P)
- Bredenoord** Annelien L., Asst. Prof., UMC Utrecht, Julius Center, Department of Medical Ethics, Utrecht (NL)
- Charny** Mark, Dr., Translucency Ltd., Worcester (UK)
- Cornillie** Freddy, Janssen Biologics BV, Director Immunology, Leiden (NL)
- Dalemans** Wilfried, Dr., TiGenix NV, Leuven (B)
- Dierickx** Kris, Prof., KU Leuven, Faculty of Medicine, Centre for Biomedical Ethics and Law, Leuven (B)
- Erben** Reinhold, Prof., Chair of REMEDIC, University of Veterinary Medicine, Institute of Physiology, Pathophysiology & Biophysics, Dept. of Biomedical Sciences, Vienna (A)
- Geris** Liesbet, Prof, KULeuven/Univ. of Liege, Skeletal Biology and Engineering Research Center, Leuven (B)
- Hauwaerts** Dieter, Dr., TiGenix NV, EU Manufacturing Director, Leuven (B)
- Hoeveler** Arnd, Prof., European Commission, Directorate-General for Research & Innovation, Head of unit "Advanced Therapies and systems medicine, Brussels (B)
- Hofmann** Anna Theresa, Dr., LBI Trauma, Vienna (A)
- Hollander** Anthony, Prof., University of Bristol, Arthritis Research UK, Professor of Rheumatology and Tissue Engineering, Bristol (UK)
- Homsy** Christian, Mr., Cardio3 BioSciences S.A., Chief Executive Officer, Mont- Saint-Guibert (B)
- Howard** Linda, Dr, National University of Ireland, Regenerative Medicine Institute, M.Sc. in Regenerative Medicine Course Director, Senior Stem Cell Investigator, Galway (IRL)
- Kasper** Cornelia, Prof. Dr., BOKU, Department for Biotechnology, Vienna (A)
- Kneissel** Michaela, Dr., CTM, Musculoskeletal Disease Area, Novartis Institutes for Biomedical Research, Basel (CH)
- LeBlanc** Katarina, Prof., Karolinska Institute, Department of Laboratory Medicine, Stockholm (S)

SPEAKERS & CHAIRS

- Luyten** Frank, Prof., KU Leuven, Skeletal Biology & Engineering Research Center, Leuven (B)
- McElroy** Mary, Dr., Preclinical Safety Assessment, Discovery Model Services, Edinburgh (UK)
- Moriggl** Richard, Univ. Doz. DI. Dr., Ludwig-Boltzmann Institute of Cancer Biology, Vienna (A)
- Nogueira** Maria Manuela, Dr, Scientific Review group for the Biomedical Sciences, Senior Science Officer , Strasbourg (F)
- Papantoniou** Ioannis, Prof., KULeuven, Skeletal Biology and Engineering Research Center, Leuven (B)
- Pêgo** Ana Paula, Dr., Institute of Biomedical Engineering (INEB), Laboratory of Biomaterials, University of Porto, Porto (P)
- Pioletti** Dominique, Prof., Ecole Polytechnique Federale de Lausanne, Lausanne (CH)
- Ruch** Ulrike, Dr., University Medicine Rostock, Reference and Translation Center for Cardiac Stem Cell Therapy, Rostock (GER)
- Schüssler-Lenz** Martina, Dr., Paul-Ehrlich-Institute, Langen (GER)
- Silva Lima** Maria Beatriz, Prof., Faculty of Pharmacy, University of Lisbon, Department Pharmacological Sciences, Lisbon (P)
- Simpson** Hamish, Prof., University of Edinburgh, School of Orthopaedics, Edinburgh (UK)
- Steinhoff** Gustav, Prof.Dr., University of Rostock, Director, Rostock (GER)
- Tiedemann** Gudrun, Dr., University of Rostock, Reference and Translation Center for Cardiac Stem Cell Therapy, Rostock (GER)
- van Osch** Gerjo, Prof., Erasmus Univ. Medical Center Rotterdam, Department of Orthopaedics and Department of Otorhinolaryngology , Rotterdam (NL)
- Volanti** Cedric, Dr., Pharmacell Maastricht (NL)
- Vos** Alexander, PhD, Pharmacell, Maastricht(NL)
- Zwolaneck** Daniela, Fr, University of Veterinary Medicine, Institute for Physiology, Pathophysiology and Biophysics, Vienna (A)

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