Program

Scale-Up and Manufacturing of Cell-Based Therapies III

January 5 – 9, 2014
San Diego, CA, USA

Conference Chairs:

Chris Mason
University College London

Greg Russotti
Celgene Cellular Therapeutics

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Sunday, January 5, 2014

18:00 – 19:30	Conference check-in (Bayview Foyer)
19:30 – 20:30	Welcome Reception (Bayview Terrace)

NOTES

- Audiotaping, videotaping and photography of presentations are strictly prohibited.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
- Technical sessions will be in Bayview I/II. Poster sessions will be in Bayview III.
- Meals will be in the Regatta Pavilion. The banquet on Wednesday will be in Mission II/III.
- Be sure to check your contact information on the Participant List in this program and make any corrections to your name/contact information online. A corrected copy will be sent to all participants after the conference.
- Speakers – Please leave at least 5 minutes for questions and discussion. Be available for discussion during meals and social periods

Monday, January 6, 2014

08:00 – 09:30	Breakfast
09:00 – 09:45	Conference check-in (Bayview Foyer)
09:45 – 09:55	Welcome Conference Chairs ECI Liaison (Barry Buckland)
09:55 – 10:00	Introduction to Plenary 1
10:00 – 11:00	**Plenary 1** **Stem Cells for Tissue and Organ Regeneration** Mahendra Rao, National Institutes of Health, USA **Session 1: Procurement, Handling and Processing of Tissue** Chairs: Gary du Moulin (Genzyme) Glyn Stacey (UK Stem Cell Bank, NIBSC)
11:00 – 11:25	**Three decades of human tissue banking: Lessons learned for developers of cell therapy products** Silvia Chen (invited), LifeNet Health, USA
11:25 – 11:50	**Material matters in cell therapy product development** Nicole Provost (invited), Biotechnology Consultant and USP BB2 Expert Committee Member, USA
11:50 – 12:10	**Human-derived raw materials: Controlled, consistent collections enable successful manufacturing of cell-based regenerative medicine products** Thomas V. Ramos, HemaCare Corporation, USA
12:10 – 12:30	**Ultra scale-down approach to membrane separation procedure of human cells for therapy; effect of cell concentration on cell loss** Maria Fernanda Masri, University College London, United Kingdom
12:30 – 14:00	Lunch **Session 2: Shipping, Storage, Handling Product in Clinic and Delivery to Patient** Chairs: Shelly Heimfeld (Fred Hutchinson Cancer Research Center) Dolores Baksh (Organogenesis)
14:00 – 14:25	**Implementation of cell- and gene therapy for clinical application: Impact of clinical requirements on the development** Volker Scherhammer (invited), Apceth GmbH & Co. KG
14:25 – 14:45	**Multistem – Overcoming the logistical hurdles of a multi country trial** Ronald W. Fedechko (invited), Pfizer, USA
14:45 – 15:05	**Expanded cord blood stem cells: would you like those fresh or frozen?** Ian Nicoud, Colleen Delaney (invited), Fred Hutchinson Cancer Research Center, USA
15:05 – 15:35	Coffee break *Sponsored by Lonza Bioscience*

Monday, January 6, 2014 (continued)

15:35 – 15:40	Introduction to Plenary 2
15:40 – 16:30	**Plenary 2** **Raman spectroscopy to non-invasively monitor cell differentiation and nutrient limitation responses in culture** James Piret, University of British Columbia, Canada
16:30 – 18:10	**Poster Snapshots**
18:30 – 20:00	Dinner
20:00 – 22:00	**Poster Session and Social Hour** (with desserts) Chairs: Peter Fuhrken (Cellular Dynamics International) Josh Leonard (Northwestern University)

Tuesday, January 7, 2014

07:30 – 09:00	Breakfast
	Session 3: Process Development Challenges for Allogeneic Products Chairs: Paula Alves (IBET) Ben Fryer (Betalogics)
09:00 – 09:25	**Learning from history and planning for the future - scale up of cell therapies for commercialization** Anthony Davies (invited), Capricor
09:25 – 09:50	**Process development and scale-up of an allogeneic cell therapy product** Koki Lilova (invited), Janssen Research & Development, Johnson and Johnson
09:50 – 10:10	**Robust cell manufacturing platforms integrated with novel proteomic and metabolomic tools to streamline the design of cardiac stem cell therapies** Margarida Serra, ITQB-UNL/IBET, Portugal
10:10 – 10:30	**Metabolic consequences of defined media in pluripotent stem cell cultures** Christian M. Metallo, University of California, San Diego, USA
10:30 – 10:50	**Scalable expansion of human induced pluripotent stem cells in xeno-free microcarriers** Maria Margarida Diogo, Technical University of Lisbon, Portugal
10:50 – 11:20	Coffee break *Sponsored by Sartorius Stedim North America*
11:20 – 11:25	Introduction to Plenary 3
11:25 – 12:25	**Plenary 3** **TBA** Gabor Forgacs, University of Missouri & Modern Meadow, USA
12:30	Boxed lunches available
13:00 – 14:20	**Session 4: Cell Therapy Manufacturing And Implementation Solutions** Lunch Session: 4 talks - 20 min each
13:00 – 13:20	**Enabling allogeneic cell based product manufacturing transition from R&D to industrialization. Case study by Promethera Biosciences, a Cell Therapy Company** Sarah Snykers, Promethera Biosciences, Belgium
13:20 – 13:40	**Cell processing facility with automated culture system based on the flexible modular platform** Masahiro Kino-oka, Osaka University, Japan
13:40 – 14:00	**Scalable expansion and harvest solutions for allogeneic stem cells** Daniel Kehoe, EMD Millipore Corporation, USA
14:00 – 14:20	**Development of a scalable manufacturing process for bone-marrow derived HMSC's in a low-shear single-use bioreactor system** Daniel Giroux, PBS Biotech, Inc., USA

Tuesday, January 7, 2014 (continued)

14:20 – 15:00	Networking / Free time
15:00 – 15:05	Introduction to Plenary 4
15:05 – 15:55	**Plenary 4** **TBA** Mark Post, Maastricht University & Cultured Beef, The Netherlands **Session 5: Process Development Challenges for Immunotherapies** Chairs: Mark Angelino (Bluebird Biotech) Isabelle Riviere (MSKCC)
15:55 – 16:20	**TBA** Brian Hampson, Progenitor Cell Therapy, USA
16:20 – 16:50	Coffee Break *Sponsored by GE Healthcare*
16:50 – 17:15	**Process improvements for engineered T-cell manufacture to enable near-term commercialization** Gwen Binder (invited), Adaptimmune
17:15 – 17:35	**Development of a bioreactor process for the production of NK-92 cells for allogeneic immunotherapies** Ricardo Baptista, Centre for Commercialization of Regenerative Medicine (CCRM), Canada
17:35	**Free Evening /Dinner on your own**

Wednesday, January 8, 2014

07:30 – 08:30	Breakfast
	Session 6: Scale-up of Cell Therapy Processes Chairs: Michael Kallos (University of Calgary) Chris Hewitt (Loughborough University) Tom Brieva (Celgene Cellular Therapeutics)
08:30 – 08:55	**Physical characterisation of the microbioreactor 'ambr' and Implications for animal and stem cell culture** Alvin Nienow (invited), Loughborough University, University of Birmingham, United Kingdom
08:55 – 09:20	**Evolution of a scale-down model for generation of HIV-1 based Lentiviral vectors for use in ex-vivo manufacturing of cell therapy products** Robert Kutner (invited), Bluebird Bio, USA
09:20 – 09:40	**Expansion and harvest of human mesenchymal stem cells from microcarriers in a stirred-tank bioreactor** Qasim A. Rafiq, Loughborough University, United Kingdom
09:40 – 10:00	**Scalable suspension culture technologies to enable robust stem cell biomanufacturing** Todd C. McDevitt, Georgia Institute of Technology, USA
10:00 – 10:20	**The development of a clinical manufacturing process for the *ex vivo* expansion of umbilical cord blood derived haematopoietic stem cells** Elizabeth Csaszar, Centre for Commercialization of Regenerative Medicine (CCRM), Canada
10:20 – 11:00	Coffee break *Sponsored by Celgene*
	Session 7: Analytics and Product Characterization Chairs: Jeffrey Karp (MIT) Mark Lowdell (Royal Free Hospital)
11:00 – 11:25	**Innovating preclinical drug discovery and human cell therapy** Steven Minger (invited), GE Healthcare, USA
11:25 – 11:50	**Automating process control by using innovative label-free quantitative imaging** Philip Mathuis (invited), Ovizio Imaging Systems, Germany
11:50 – 12:10	**Downstream processing of therapeutic cells - high-throughput process development for cell separation in aqueous two-phase systems** Sarah Nagel, Karlsruhe Institute of Technology, Germany
12:10 – 12:30	**A metabolic approach to optimizing human mesenchymal stem cell expansion in cell therapy** Teng Ma, Florida State University, USA
12:30 – 12:50	**Lysine deacetylase (KDAC) enzyme activity in cell differentiation** Teresa A. DeLuca, Northwestern University, USA

Wednesday, January 8, 2014 (continued)

12:50 – 13:10	**Human mesenchymal stem cells: Characterization and potency** Alexander K. C. Chan, Loughborough University, UK
13:10 – 14:30	Lunch
14:30 – 16:00	Free time / Networking
	Session 8: Tissue Engineering, New Technologies and Tools Chairs: Todd McDevitt (Georgia Institute of Technology) Devyn Smith (Neucentis)
16:00 – 16:25	**Molecular engineering of synthetic microenvironments for stem cell culture** David Schaffer (invited), University of California at Berkeley, USA
16:25 – 16:50	**Cell therapy scale-out: Parallel iPSC manufacture and differentiation for the delivery of immunomatched cell therapies** Emile Nuwaysir (invited), Cellular Dynamics International
16:50 – 17:10	**Dynamic transcription factor activity profiles and inferred networks reveal key regulatory interactions during megakaryocytic and erythroid differentiation of bipotent progenitor cells** William M. Miller, Northwestern University, USA
17:10 – 17:30	**Using novel non-invasive imaging as a process analytical tool for cell based therapy manufacturing** David Smith, Loughborough University, United Kingdom
17:30 – 17:50	**Process development strategies to enable large scale fabrication of scaffold-less 3D ligament constructs for ACL reconstruction** Michael J. Smietana, University of Michigan, USA
17:50 – 18:00	**Presentation of ECI Award for Scale-up and Manufacturing of Cell Based Therapies to Bob Nerem, Georgia Institute of Technology**
18:00 – 19:00	**Award Lecture** **The challenge ahead: Cell-based therapies and the translation of bench-top research into products and clinical therapies** Bob Nerem, Georgia Institute of Technology, USA
19:30 – 21:30	Conference Banquet
21:30 – 23:00	Social Hour / Poster Session

Thursday, January 9, 2014

08:00 – 09:30 Breakfast and departures

Poster List

1. **The development of scale-up bioreactor system for human induced pluripotent stem cell stirred suspension culture**
   Masanori Wada, ABLE Corporation, Japan

2. **mRNA transfection in cell therapy: A step in vitro, a leap in vivo**
   Kelvin S. Ng, Brigham & Women's Hospital, Harvard Medical School, USA

3. **A scalable modeling approach for the design and operation of a continuous fluidized-bed centrifuge for cell concentration and washing**
   John C. Gaut, Celgene Cellular Therapeutics, USA

4. **Development of a harvest process for stirred tank microcarrier culture of therapeutic placental-derived cells**
   David Hsiung, Celgene Cellular Therapeutics, USA

5. **Cell culture medium characterization and optimization by Design of Experiments (DOE) for the production of a placental-derived cellular therapy**
   Andrea L. Nordberg, Celgene Cellular Therapeutics, USA

6. **Large scale ex vivo generation of red blood cells from human umbilical cord blood-derived hematopoietic stem cells**
   Rajarajeswari Sivalenka, Celgene Cellular Therapeutics, USA

7. **Cell selection in cellular therapy and other large-scale industrial cell purification settings**
   Ruud Hulspas, Cytonome/ST, LLC, USA

8. **T lymphocytes expanded in the WAVE bioreactor maintain a healthy phenotype**
   Michelle Janas, GE Healthcare UK Limited, United Kingdom

9. **Development of a subculture equipment for a mass cell production in automated 3-dimensional tissue fabrication system (Tissue Factory)**
   Toyoshige Kobayashi, Hitachi, Japan

10. **Novel human dopaminergic 3D in vitro model for pre-clinical assessment of gene therapy strategies**
    Paula M. Alves, IBET and ITQB-UNL, Portugal

11. **Highly functional hepatic spheroids: Synergistic roles of microencapsulation and 3D configuration for differentiation of hepatic cells**
    Paula M. Alves, IBET/ITQB-UNL, Portugal

12. **Evaluation of microcarrier-based suspension cultures for human mesenchymal stem/stromal cells**
    Cláudia Lobato da Silva, Instituto Superior Técnico, Universidade de Lisboa, Portugal

13. **Serum-free media development for ex vivo expansion, differentiation, and cryopreservation of human mesenchymal stem/stromal cells**
    Annie Ngo, Irvine Scientific, USA

14. **Establishment of biological activity assays to qualify and reliably measure key growth factors derived from animal component free processes**
    Ryan G. Linfield, Irvine Scientific, USA

15. **Process development and scale-up of an allogenic cell therapy product**
    Kostadinka (Koki) Lilova, Janssen R&D, USA

16. **Low temperature cell pausing: An alternative cell preservation method for use in cell therapies**
    Thomas Heathman, Loughborough University, United Kingdom

17. **Systematic development of a process control system for the manufacture of human mesenchymal stem cells on microcarriers**
    Thomas Heathman, Loughborough University, United Kingdom

18. **Informing value driven cell therapy new product development**
    Mark J. McCall, Loughborough University, United Kingdom

19. **Immunoaffinity aqueous two-phase systems with pegylated CD133 antibodies for the potential recovery of stem cells**
    Marco Rito-Palomares, Tec de Monterrey, Mexico

20. **The quality stability for human epithelial cell sheet after transportation by air**
    Toshiyuki Owaki, Tokyo Women's Medical University, Japan

21. **Allogeneic cell therapy bioprocess economics and optimization: Single-use volume reduction technologies**
    Sally Hassan, University College London, United Kingdom

22. **Induced pluripotent stem cell processing for drug discovery platforms: Process economics and optimisation**
    Michael Jenkins, University College London, United Kingdom

23. **Using a Design of Experiment (DoE) approach to optimise pluripotent stem cell differentiation for subsequent manufacturing**
    Iwan T. Roberts, University College London, United Kingdom

24. **IPS derived photoreceptor production in an agitated suspension culture system**
    Vishal Sharma, University College London, United Kingdom

25. **Comparison of filtration and centrifugation for cryoprotectant removal from thawed cell suspensions**
    Rui Tostoes, University College London, United Kingdom

26. **Purification challenges for whole cell therapies: The isolation of photoreceptor precursors for treatment of retinal dystrophy**
    Ben Weil, University College London, United Kingdom

27. **Rice Bran Extract (RBE) as supplement for Mescenchymal Stem Cells (MSCs)**
    Satoshi Terada, University of Fukui, Japan

28. **A parallel bioreactor system for investigating metabolic pathway changes during iPSC reprogramming**
    Yonatan Lipsitz, University of Toronto, Canada

29. **Towards scalable production and cryopreservation of functional iPSC-derived cardiomyocytes**
Cláudia Correia, IBET/ITQB-UNL, Portugal

30. **Towards a robust and scalable bioprocess for the expansion of human pluripotent stem cells**
Cláudia Correia, IBET and ITQB-UNL, Portugal

31. **The development of laminar flow-based suspension culture system for human iPS cells and the application to the cardiac tissue engineering**
Katsuhisa Matsuura, Tokyo Women's Medical University, Japan

32. **Ultra scale-down approach to membrane separation procedure of human cells for therapy: Effect of cell concentration on cell loss**
Fernanda Masri, University College London, United Kingdom

33. **Concentration and harvest of hepatic progenitor stem cells using the integrity**
Fabien Moncaubeig, ATMI LifeSciences, Belgium

34. **Generating aligned vascular networks via a scalable process**
Jacob Ceccarelli, University of Michigan, USA

35. **Decoding human cardiac stem cell proteomic profiles towards the design of efficient therapies for cardiac repair**
Margarida Serra, IBET/ITQB-UNL, Portugal

36. **Designing scalable and clinical-grade filtration-based strategies for the downstream processing of human mesenchymal stem cells**
Margarida Serra, ITQB-UNL/IBET, Portugal

37. **Statistical analysis of process consistency for allogeneic cardiosphere-derived cells**
Brandon J. Burton, Capricor Inc., USA