



New Zealand 3, 4

APRIL 22 – 25, 2013

ISCT Conference Program

Sunday April 21, 2013

4:00pm - 7:00pm REGISTRATION Auckland Promenade

Monday Apr	il 22, 2013	Coffee and tea will be available prior to the start of the first morning sessions
7:00am – 7:00pm	REGISTRATION	Auckland Promenade
8:00am – 5:30pm	Global Regulatory Perspectives Workshop	New Zealand 1, 2
9:00am – 4:30pm	Flow Cytometry Workshop	Offsite at the Maurice Wilkins Centre
8:00am – 5:00pm	FACT Training Workshop Marlborough 2	FACT Training Breakout Session Marlborough 3
5:00pm – 7:00pm	Corporate Symposium Miltenyi Biotec (Refer to Co	orporate Guide for Details) New Zealand 3, 4
7:00pm – 7:30pm	Welcome Address	New Zealand 1, 2
7:30pm – 9:30pm	Welcome Reception	Auckland Room
ruesday Apri	ll 23, 2013	Coffee and tea will be available prior to the start
7:00am – 4:00pm	REGISTRATION STRATEGIES FOR COMMERCIALIZATION TRA	of the first morning sessions Auckland Promenade
	REGISTRATION	Auckland Promenade CCK 1 New Zealand 1, 2 Cell Therapies LAEY (AU) for cell therapy product characterization: r therapy products for commercialisation using

Janice Fogarty (AU) – Mesenchymal Stromal Cell Therapy
STRATEGIES FOR COMMERCIALIZATION TRACK 2

Richard Maziarz (US) - Perspectives on cell therapy reimbursement from the front lines of medicine

Jim Butler (AU) – The HTA imperative: Key issues in securing reimbursement

By the way, Who's Paying for All of This?

CHAIR: DAWN DRISCOLL (AU)

7:30am – 8:30am



Tuesda	ıv Apri	22. 201	3 continued
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8:45am – 9:00am **OPENING REMARKS** by Kurt Gunter

New Zealand 1, 2

PLENARY SESSION 1 – PRESIDENTIAL PLENARY PLURIPOTENT STEM CELLS New Zealand 1, 2

CHAIR: KURT GUNTER (US)

9:00am - 10:30am

SPEAKERS:

David Ma (AU) – Reprogramming somatic cells to the pluripotent state for use in cellular therapy Mahendra Rao (US) – Manufacturing stem cell derivatives for screening and therapy

Alan Davidson (NZ) - Modelling cystinosis with induced pluripotent stem cells

10:30am - 11:00am

COFFEE BREAK WITH EXHIBITS

Auckland Room

Epsom 1, 2, 3

ORAL ABSTRACT PRESENTATIONS 1

Mesenchymal Stem Cells

CHAIR: LUC SENSEBÉ (FR)

PRESENTERS:

11:00am - 12:15pm

Allan Dietz (US) – Data in support of the clinical use of adipose derived MSC: growth, storage, function and safety

Caroline Gargett (AU) – A tissue engineering construct comprising human endometrial mesenchymal stromal cells and polyamide/gelatin mesh evaluated in a preclinical animal model of pelvic organ prolanse renair.

Sze Chin (MY) – Intra articular injection of autologous bone marrow-derived mesenchymal stromal cells in patients with moderate to severe osteoarthritis

Steve Oh (SG) – Extracellular matrix free microcarrier cultures of human pluripotent stem cells induced by inhibition of rock-myosin II signaling

ORAL ABSTRACT PRESENTATIONS 2

Hematopoietic Stem Cells

CHAIR: EJ SHPALL (US)

PRESENTERS:

11:00am - 12:15pm

Marc Turner (UK) – Progress towards the cGMP production of pluripotent stem cell derived red blood cells **Alla Dolnikov (AU)** – GSK-3 β inhibition promotes T cell reconstitution and preserves naïve T cell phenotype in mice transplanted with human haematopoietic stem cells.

Ian McNiece (US) – Bone marrow versus PBPC for allogeneic stem cell transplant: defining the optimal graft Russell Cruz (US) – Infusion of CD19-directed/multivirus specific-cytotoxic T lymphocytes after allogeneic hematopoietic stem cell transplantation for B cell malignancies

Amit Khot (AU) – Low dose lenalidomide induction followed by autologous transplantation in untreated patients with myeloma is associated with adequate collection of haematopoietic and dendritic cell precursors and high response rates

ORAL ABSTRACT PRESENTATIONS 3

Marlborough 1, 2, 3

New Zealand 1, 2

Quality and Operations

CO-CHAIRS: DOMINIC WALL (AU) AND THOMAS LEEMHUIS (US)

PRESENTERS:

11:00am - 12:15pm

Robert Nordon (AU) – Mapping and modelling ex vivo cell culture processes directly from cell tracking data Patricia Distler (US) – Revisions to ISBT 128 nomenclature for cellular therapy

Mariele Viganò (IT) – Analytical procedures validation for good manufacturing practice (GMP) production of mesenchymal stem cells from different sources

Chih Wei (UK) – Regulatory blind spots in cellular therapy translation experience from Australia

Marc Turner (UK) – Establishment of a bank of blood donor derived Epstein Barr virus specific T cell lines for treatment of post-transplant lymphoproliferative disease.





APRIL 22 - 25, 2013

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STRATEGIES FOR COMMERCIALIZATION TRACK 2

New Zealand 3, 4

Risk in Cell Therapy Commercialization

CHAIR: CHRISTOPHER BRAVERY (UK)

11:00am - 12:15pm

SPEAKERS:

Ronnda Bartel (US) –Commercial strategies for ixmyelocel–T, a novel autologous therapy for severe, chronic cardiovascular disease

Miles Prince (AU) - Assessing Risk in Cell Therapy Clinical Trials

Lucy Foley (UK) -Considerations for the Widespread Adoption of Limbal Stem Cell Transplantation

LUNCH WITH EXHIBITS 12:15pm – 1:45pm

Auckland Room Corporate Tutorial

12:30pm - 1:30pm

Corporate Tutorial **GE** Healthcare

BioLife Solutions (Refer to Corporate Guide for Details) Corporate Tutorial **Corning Life Sciences**

(Refer to Corporate Guide for Details) Epsom 1, 2, 3

PLENARY SESSION 2 – NOVEL APPROACHES USING MSCs

CHAIR: EJ SHPALL (US)

(Refer to Corporate Guide for Details)

SPEAKERS:

1:45pm - 3:15pm

EJ Shpall (US) - Mesenchymal stem cells to enhance cord blood engraftment

Edwin Horwitz (US) – MSCs for Bone Regeneration: It's not what you think!

Paul Simmons (AU) – Mesenchymal Precursor Cells (MPC): A platform technology for multiple

therapeutic applications

QUALITY AND OPERATIONS TRACK 2

Marlborough 1, 2, 3

New Zealand 1, 2

Process Development

CHAIR: SHIRLEY BARTIDO (US)

1:45pm - 3:15pm

SPEAKERS: Julie Allickson (US) – Considerations for Tissue Engineering & Regenerative Medicine Product Development Prior to Clinical Trials

Allan Dietz (US) - Organizing the IND: Templates and Processes to Speed IND Preparation

Xiuyan Wang (US) – Large–Scale Clinical–Grade Retroviral Vector Production In iCELLis Nano Bioreactor

3:15pm – 3:30pm

COFFEE BREAK WITH EXHIBITS

Auckland Room

WORKSHOP 1

Tumor Vaccines and Beyond

SPEAKERS:

3:30pm - 5:00pm

Jonathan Serody (US) – Using Autologous Stem Cell Transplantation as a Platform for Building Tumor Vaccination

J H Frederik Falkenburg (NL) - Benefit and Risk of targeting HLA Class-II in the treatment of hematological malignancies

John Barrett (US) – Prevention of leukemic relapse after allogeneic stem cell transplantation with leukemia-specific T cells

WORKSHOP 2

Hot Topics in Haplo and Cord Transplant

3:30pm - 5:00pm

SPEAKERS:

Xiao-Jun Huang (CN) -Improving outcomes after Haploidentical SCT

Satoshi Takahashi (IP) - Strategies to improve the cord blood engraftment- a Japanese perspective Patrick Hanley (US) – Improving immune reconstitution after cord blood and haploidentical SCT



STRATEGIES FOR COMMERCIALIZATION TRACK 4 New Zealand 3, 4 **Unique Approaches in Cell Therapy Commercialization CHAIR:** DAVID RITCHIE (AU) SPEAKERS: 3:30pm - 5:00pm Paul Tan (NZ) - Taking the pig to market: LCT's regulatory and commercial journey so far Brian Salmons (SG) – Less can be more: reducing dose and increasing efficacy using encapsulated cells Robert Short (AU) – Making Cell Therapy Affordable and Accessible: An Introduction to the new Co-operative Research Centre for Cell Therapy Manufacturing (Australia) **QUALITY AND OPERATIONS TRACK 3** Marlborough 1, 2, 3 Validation/Verification/Qualification CHAIR: CAROLYN KEEVER-TAYLOR (US) 3:30pm - 5:00pm SPEAKERS: Carolyn Keever-Taylor (US) - Qualification, Validation, Verification. What, When, How? Martin Hildebrandt (DE) - Qualification of a facility - hints and pitfalls Lizette Caballero (US) - ISBT Labeling of Cellular Therapy Products: From Planning to Collection to Transplant MASTER CLASS 1 Marlborough 1, 2, 3 ISCT-ISBT Joint Session: Biobanking and Biomarkers SPEAKERS: Roy Jones (US) - Informatics to Optimize Stem Cell Transplantation (SCT) and Cell Processing Lab Function Michael Kalos (US) - Development and implementation of correlative studies for cell therapy trials Mickey Koh (SG/UK) - Biobanking: A treasure trove for cure 5:00pm - 6:00pm **MASTER CLASS 2** New Zealand 1, 2 **Access to Unproven Cell Therapies SPEAKERS:** Alok Srivastava (IN) – Stem Cells: From Clinical Trials to Standard of Care– How do we decide? Doug Sipp (|P) - Regulatory responses to the premature commercialization of 'stem cell' interventions Steve Wilton (AU) – Hypothesis driven research vs snake oil; validated outcomes, hope and hype for

Wednesday April 24, 2013

5:00pm – 6:30pm

neuromuscular diseases

Poster Session 1

Coffee and tea will be available prior to the start of the first morning sessions

New Zealand Foyer

wednesday i	of the first morning sessions
7:00am – 4:00pm	REGISTRATION Auckland Promenade
7:30am – 8:30am	TECHNICAL SESSION 1 Hands on Dendritic Cell Technology CO-CHAIRS: DEREK HART (AU) AND JAMES YOUNG (US)
7.30aiii — 8.30aiii	SPEAKERS: Derek Hart (AU) – Dendritic cell subsets in 2013 Rod Dunbar (NZ) – Dendritic cell antigen delivery – methodology in 2013 James Young (US) – Langerhans cells versus monocyte derived dendritic cells: challenges and opportunities
	STRATEGIES FOR COMMERCIALIZATION TRACK 5 Upstream Sourcing for Commercial Products New Zealand 3, 4
7:30am – 8:30am	CHAIR: KNUT NISS (US) SPEAKERS: Dominic Clarke (US) – Single–Use Technologies in Cell Therapy: Strategies for Implementation Ohad Karnieli (IL) – Challenges and possible solutions to overcome the gap in critical supply chain issues of new and evolving cutting edge technologies of cell therapy Ian Fitzpatrick (AU) – Upstream Processing of Cellular Therapies: Challenges and Solutions





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nesday April 24, 2013 continued

7:30am – 8:30am

QUALITY AND OPERATIONS TRACK 4

Marlborough 1, 2, 3

Sharing Paperwork that Actually Works

CHAIR AND FACILITATOR: MARTIN HILDEBRANDT (DE)

PLENARY SESSION 3 – T CELL IMMUNOTHERAPY

New Zealand 1, 2

CHAIR: HELEN HESLOP (US)

8:45am – 10:15am

SPEAKERS:

Stan Riddell (US) – Design of chimeric receptors and composition of T cell products for adoptive therapy Carl June (US) - Engineered T cells for cancer therapy

Malcolm Brenner (US) – Will Cellular Immunotherapies for Cancer Ever Become Standard of Care?

QUALITY AND OPERATIONS TRACK 5

Marlborough 1, 2, 3

Cellular Therapy Product Testing

CHAIR: ANNETTE TRICKETT (AU)

8:45am - 10:15am

SPEAKERS:

Pamela Clark (AU) - Optimised Microbial Screening for HPC

Christopher Tsai (TW) – Stem Cell Testing: Meeting the needs of clinical applications

Elaine Coustan-Smith (SG) - Flow Cytometry methods for product testing in NK cell therapy trials

10:15am -10:45am

10:45am - 12:15pm

COFFEE BREAK WITH EXHIBITS

Auckland Room New Zealand 1, 2

ORAL ABSTRACT PRESENTATIONS 4 Immunotherapy and Dendritic Cells

CHAIR: STEPHAN MIELKE (DE)

PRESENTERS:

Inge Jedema (NL) – Hematopoiesis-specific T-cells may contribute to GVHD reactivity by induction of collateral damage to non-hematopoietic tissues during an ongoing profound gvl reaction

Chrystal Louis (US) – A phase II study of carboplatin and docetaxel followed by Epstein-Barr virus specific cytotoxic T lymphocytes for refractory/relapsed EBV-positive nasopharyngeal carcinoma

Hermann Bohnenkamp (DE) – Automated in vitro generation of tri-virus-specific CD4+ and CD8+ T-lymphocytes for adoptive immunotherapy

Patrick Hanley (US) - Naïve t-cell-derived CTL recognize atypical epitopes of CMVPP65 with higher avidity than CMV-seropositive donor-derived CTL – a basis for treatment of post-transplant viral infection by adoptive transfer of T-cells from virus-naïve donors

Chun Ma (AU) - Prophylactic infusion of multi-virus specific T cells for management of viral reactivation and infection in patients post allogeneic hematopoietic stem cell transplantation (HSCT)

Minhtran Ngo (US) – An antigen presenting complex for the generation of broad-specificity effector T lymphocytes for the treatment of EBV-associated malignancies

ORAL ABSTRACT PRESENTATIONS 5

Epsom 1, 2, 3

Regenerative Medicine and Translational Process Development

CO-CHAIRS: ROBERT DEANS (US) AND OHAD KARNIELI (IL)

PRESENTERS:

10:45am - 12:15pm

Kong Then (UK) - Autologous cultivated oral mucosal epithelial cells transplantation (COMET) with amniotic membrane based sheets for severe ocular chemical injury

Sue Ngein Leow (MY) – Subretinal transplantation with human umbilical cord-derived mesenchymal stem cells delays retinal degeneration in royal college of surgeons rats

Jaroslav Michalek (CZ) – Stem cell therapy of osteoarthritis using stromal vascular fraction cells Audrey Varin (FR) – The CD200/CD200R axis: new control mechanism of bone remodeling

Inge Jedema (NL) – Production of leukemia-reactive T-cells via a good manufacturing practice procedure for treatment of patients with acute or chronic B-cell malignancies after allogeneic stem cell transplantation

STRATEGIES FOR COMMERCIALIZATION TRACK 6

New Zealand 3, 4

Clinical Themes Across Commercialization: Cord Blood Expansion Products

CO-CHAIRS: ROBERT NORDON (AU) AND CLAUDIA ZYLBERBERG (US)

10:45am - 12:15pm

Shelly Heimfeld (US) – Frozen, pre-expanded cord blood as an off-the-shelf universal blood stem cell source **Ian McNiece (US)** – The Role of Academia in Development of Cellular Therapy Products

Lynnet Koh (US) – Improving Stem Cell Software: Targeting Selectins for Homing and Engraftment of Cells in Regenerative Medicine



QUALITY AND OPERATIONS TRACK 6 Marlborough 1, 2, 3 Roundtable Debate: Pros and Cons in the Cellular Therapy Field 10:45am - 12:15pm **CHAIR: LYNN O'DONNELL (US)** 12:15pm - 1:45pm **LUNCH WITH EXHIBITS Auckland Room** 12:30pm – 1:30pm ANNUAL GENERAL MEETING New Zealand 1, 2 12:30pm - 1:30pm Corporate Tutorial kSep Systems (Refer to Corporate Guide for Details) Epsom 1, 2, 3 MMERCIAL PROGRESS IN REGENERATIVE MEDICINE New Zealand 1, 2 CHAIR: DAWN DRISCOLL (US) **SPEAKERS:** 1:45pm – 3:15pm Timothy Allsopp (US) – Commercial development of regenerative medicines: trials & tribulations Evan Snyder (US) – The rational use of cell-based therapies – viewpoint from a scientist who advises regulatory agencies Sharron Gargosky (US) - Orchestrating Autologous Dendritic Cell Therapy Clinical Trials Across 15 Countries **QUALITY AND OPERATIONS TRACK 7** Marlborough 1, 2, 3 **Challenging Quality Situations CHAIR: LIZABETH CARDWELL (US)** 1:45pm - 3:15pm PANELISTS: Cheryl Hutchins (AU), Vicki Antonenas (AU), Dhana Gounder (NZ), Martin Bleasdale (AU), Massimo Dominici (IT) **COFFEE BREAK WITH EXHIBITS** 3:15pm - 3:30pm **Auckland Room WORKSHOP 3** Regenerative Medicine for Cardiac and Neurological Disease **SPEAKERS: James Chong** (AU) – Cardiac Regeneration Using Cell Therapy Chris Bredeson (CA) – Autologous Hematopoietic Stem Cell Transplantation as a Paradigm for Immune Repair and Reinduction of Immune Tolerance – A Clinician's Perspective 3:30pm - 5:00pm **Bronwen Connor** (NZ) – Regenerating the Brain **WORKSHOP 4** New Zealand 1, 2 Immune Therapy for GVHD **SPEAKERS: Geoff Hill** (AU) – Cytokine modulation in transplantation: Mouse and man John Koreth (US) - Regulatory T cell homeostasis in GVHD - Role of Interleukin-2 STRATEGIES FOR COMMERCIALIZATION TRACK 7 New Zealand 3, 4 Approval and Post-Approval Experience **CHAIR: ANTONIO LEE (KR) Douglas Arm (US)** – Autologous Cell Therapy at the Point–Of–Care: Building a Global Business 3:30pm - 5:00pm Chul-Won Ha (KR) - CARTISTEM(R) - World's First Allogeneic Stem Cell Drug for OA: Clinical Results and Post-Approval Status Update Anish S. Majumdar (IN) – An open label, multicentric, dose-ranging Phase II clinical study for evaluating the safety and efficacy of pooled allogeneic bone marrow-derived mesenchymal stem cells for treating patients with critical limb ischemia due to Buerger's disease **QUALITY AND OPERATIONS TRACK 8** Marlborough 1, 2, 3 **Disaster Planning and Recovery** CHAIR: SUSY KIRWAN (NZ) SPEAKERS: 3:30pm - 5:00pm Cheryl Hutchins (AU) – Disaster Planning in a Cellular Therapy Facility – Experiences from the 2011 Brisbane Flood **Hemant Patel (NZ)** – The Christchurch Experience John Miller (US) - Medical Response to Marrow Toxic Injury Events: The Radiation Injury Treatment Network (RITN)



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Wednesday April 24, 2013 continued

MASTER CLASS 3

Mariborou

How to Run a Large GMP Facility

CHAIR: ADRIAN GEE (US)

5:00pm - 6:00pm

SPEAKERS:

Adrian Gee (US) – GMP Manufacturing in Texas – where Bigger is Expected to be Better

Bruce Levine (US) - Design and Operation of Two Cell Processing Sites Within the Hospital of the

University of Pennsylvania, or "Gentrification by Technology"

Dominic Wall (AU) – Good governance for good manufacturing – commercial and regulatory challenges

5:00pm - 6:30pm

7:00am - 3:00pm

Poster Session 2

New Zealand Foyer

7:00pm – midnight GALA – LOCATION: AUCKLAND WAR MEMORIAL MUSEUM

Thursday April 25, 2013

 Coffee and tea will be available prior to the start of the first morning sessions

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REGISTRATION

Auckland Promenade

Epsom 1, 2, 3

TECHNICAL SESSION 2

NK Cells

CHAIR: KATY REZVANI (US)

SPEAKERS:

Katy Rezvani (US) – Ex vivo expanded cord blood Natural Killer cells as a novel therapeutic for lymphoid malignancies

Dario Campana (SG) - NK cell therapy of cancer

7:30am - 8:30am

TECHNICAL SESSION 3

New Zealand 1, 2

Novel Cell Expansion Technologies

CHAIR: RAEWYN BROADY (CA)

SPEAKERS:

David DiGiusto (US) – In vitro expansion and in vivo evaluation of adult hematopoietic stem and progenitor cells

Juan Vera (US) – Optimized Manufacture of CAR–T Cells for Clinical Applications

Megan Levings (CA) – Expanding and tracking human regulatory T cells

STRATEGIES FOR COMMERCIALIZATION TRACK 8

New Zealand 3, 4

Downstream Logistics of Commercial Cell Products

7:30am - 8:30am

CHAIR: SHIRLEY BARTIDO (US)
SPEAKERS:

Kim Raineri (SG) - Packaging and Delivery of Cell Therapy Products by a CMO

Liz Cardwell (US) – Stability and Traceability of Cellular Therapy Products during Shipment

Morey Kraus (US) - Roadmap to Clinical Utility for Newborn Stem Cell Products

QUALITY AND OPERATIONS TRACK 9

Marlborough 1, 2, 3

BEACON Cell Therapy Bioprocessing Tools and Reagents Database

7:30am - 8:30am

CHAIR: LYNN O'DONNELL (US)

SPEAKERS:

Brian Poole (CA) – The Tools & Reagents Database – Past, Present and Future **Michelle Keir** (AU) – A User's Perspective

PLENARY SESSION 5 – ISCT–ASBMT JOINT SESSION: VIRUS SPECIFIC T CELLS New Zealand 1, 2

CHAIR: DAVID GOTTLIEB (AU) SPEAKERS:

8:45am – 10:15am

David Gottlieb (AU) – Rebuilding immunity to prevent infection after stem cell transplant

Ann Leen (US) – Extending the range and applicability of antigen specific T cells for viral infection

Richard O'Reilly (US) – The potential and limitations of HLA non–identical transplant donor and third party

 $donor\ derived\ virus-specific\ T-cells\ in\ stem\ cell\ and\ organ\ transplantation$



Thursday April 25, 2013 continued

QUALITY AND OPERATIONS TRACK 10

Marlborough 1, 2, 3

Cryobiology, Cryopreservation and Post-Thaw Process

CHAIR: PING LAW (SG)

8:45am - 10:15am

SPEAKERS:

Jason Acker (CA) - Cryobiology 101: The response of cell-based therapeutics to cryopreservation **Zbigniew M. Szczepiorkowski (US)** – Cryopreservation – when the function really matters... Shelly Heimfeld (US) – Cell Therapy Cryopreservation: Issues and Challenges with Stability Assessment and Post-thaw Processing

10:15am – 10:45am **COFFEE BREAK WITH EXHIBITS**

Auckland Room Epsom 1, 2, 3

ORAL ABSTRACT PRESENTATIONS 6

Nervous System Repair/Cardiovascular Regeneration

PRESENTERS

10:45am - 11:45am

Matthias Klugmann (AU) – AAV-based gene therapy approaches for the treatment of canavan disease Hossein Bahavarand (IR) - Transplantation of anterior-specified neural progenitors derived from human induced pluripotent stem cell improves the repair of the crushed optic nerve Nasser Aghdami (IR) - Phase III randomized clinical trial comparing the effects of autologous bone

marrow derived MNC and CD133 cells transplantation in ami patients during cabg

Kelly Ledford (US) – Potential atheroprotective effects of ixmyelocel-T cellular therapy

ORAL ABSTRACT PRESENTATIONS 7

New Zealand 3, 4

Gene Therapy

CHAIR: JOHN RASKO (AU) PRESENTERS

10:45am - 11:45am

10:45am – 11:45am

Bruce Levine (US) - Adoptive transfer of gene-modified T-cells engineered to express high-affinity TCR's for cancer-testis antigens NY-ESO-1 or LAGE-1, in multiple myeloma (MM) patients post autologous hematopoietic stem cell transplant (ASCT)

Saar Gill (US) - Effective targeting of primary human acute myeloid leukemia using ANTI-CD123 chimeric antigen receptor engineered T cells

Amit Khot (AU) – Autologous peripheral blood T lymphocytes transduced with an anti Lewisy chimeric receptor gene can be infused safely and persist in patients with Lewisy positive acute myeloid leukaemia Gunnar Kvalheim (NO) – Clinical experiences with therapeutic DC vaccines targeting autologous cancer stem cells in glioblastoma

QUALITY AND OPERATIONS TRACK 11

Marlborough 1, 2, 3

Worldwide Surveys on T-Cells and MSCs

CHAIR: SHANNON EAKER (US)

MODERATOR/PRESENTER: KNUT NISS (US)

Shannon Eaker (US) – ISCT T-cell Global Survey Results: Questionnaire to Identify Standard Methods in Reporting T-cell Cultures and Identification

Knut Niss (US) – The ISCT Survey on MSC Production Methods: a Global View

Bruce Levine (US), David DiGiusto (US), Austin Wang (TW), Jennifer Ho (TW)

REGULATIONS AROUND THE WORLD SESSION 1

New Zealand 1, 2

SPEAKERS:

Glenn Smith (TGA, Australia) - Regulation of Cell Therapies in Australia

Stewart Jessamine (MedSafe, New Zealand) - New Zealand's regulatory framework for cells and tissues Lee Lee Ong (Health Sciences Authority, Singapore) – Regulation of human cell– and tissue-based therapeutic products

Tetsuya Kusakabe (Pharmaceuticals and Medical Devices Agency, Japan) - Regulatory updates on Cellular and Tissue-based products in Japan

11:45am - 1:15pm **LUNCH WITH EXHIBITS**

Auckland Room

12:00pm - 1:00pm

10:45am - 12:15pm

Corporate Tutorial Elsevier (Cytotherapy) Corporate Tutorial **Charter Medical**

(Refer to Corporate Guide for Details) (Refer to Corporate Guide for Details) New Zealand 3, 4 Epsom 1, 2, 3



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Thursday April 25, 2013 continued

WORKSHOP 5 **GI Disorders**

New Zealand 3, 4

SPEAKERS:

Hootie Warren (US) – Dissecting and exploiting the autologous immune response to colorectal cancer Sarah Young (NZ) – Identification and activation of CD4 T cells from patients with colorectal cancer and Crohn's disease

1:15pm - 2:45pm

1:15pm - 2:45pm

Marian Sturm (AU) – Allogeneic Mesenchymal Stromal Cell Treatment for Biologic Refractory Crohn's Disease

WORKSHOP 6

Cell Therapies for Solid Tumors

SPEAKERS:

Michael Kershaw (AU) - Genetic redirection of T cells against the Lewis-Y tumor associated antigen Steve Grupp (US) - Adapting successful CAR therapy to solid tumors - can we move beyond CD19 Rajiv Khanna (AU) – Cellular immunotherapy for infectious complications and human malignancies: A new paradigm in personalized medicine

QUALITY AND OPERATIONS TRACK 12

Marlborough 1, 2, 3

Daily Technical Challenges Encountered by Cellular Therapy Laboratories: "When a good day turns bad... now what am I supposed to do?"

CHAIR: LIZETTE CABALLERO (US)

Panelists:

Lizette Caballero (US), Vicki Antonenas (AU), Thomas Leemhuis (US)

REGULATIONS AROUND THE WORLD SESSION 2

New Zealand 1, 2

SPEAKERS:

Younjoo Park (Korea FDA) - Korea Regulatory Framework on Cell Therapy Products Yi-Chu Lin (Taiwan FDA) – Regulatory Development of Cell Therapy Products in Taiwan

Paula Salmikangas (Finnish Medicines Agency) - Development and authorization of cell-based therapies in Europe

Liz Anne Gillham-Eisen (Health Canada) - The Regulation of Cellular Therapies in Canada Kimberly Benton (US FDA) - US FDA Regulatory Framework for Cell Therapy Products

2:45pm - 2:55pm

2:55pm - 4:25pm

1:15pm - 2:45pm

BEST POSTER AND ORAL ABSTRACT AWARDS PRESENTATION & EXHIBITOR PASSPORT WINNERS ANNOUNCEMENTS (Refer to Corporate Guide)

PLENARY SESSION 6 – GENE THERAPY

CHAIR: PETER BROWETT (AU)

SPEAKERS:

Steve Wilton (AU) – Therapeutic alternative splicing as a customized genetic therapy: hope and hype Gwendolyn Binder-Scholl (US) - TCR Engineered T Cell Therapy for Oncology Matt During (US) – Gene therapy, after years in the nursery is it finally of age?

QUALITY AND OPERATIONS TRACK 13

Marlborough 1, 2, 3

Small GMP Facility Management

2:55pm - 4:25pm

CHAIR: PING LAW (SG)

SPEAKERS:

Lynn O'Donnell (US) - 2013: A Space Odyssey - Quest for More or Making the Most of What You Have Ping Law (SG)- Who Is the Manager of a Small Facility: an Expert in Technology, Business or Regulatory Affairs?