

ISCT Miami 2008 Program

Registration Hours:

Friday, May 16th • 3:00 pm – 7:00 pm

FRIDAY, MAY 16

3:00pm – 7:00pm

Registration Riverfront Lobby Central

SATURDAY, MAY 17

6:45am - 7:00pm	Registration Riverfront Lobby Central	
7:30am – 12:00pm	Flow Cytometry Workshop (Additional Registration Fee Required) Orchid BCD The content of this workshop is not CME accredited	
	Chair: Krishna Komanduri, MD, Associate Professor of Medicine, Dept. of Stem Cell Transplantation and Cellular Therapy, University of Texas M.D. Anderson Cancer Center	
	7:30am – 8:00am	Continental Breakfast
	8:05am - 8:10am	Introduction and Brief Overview. Krishna Komanduri, MD
	8:10am - 8:40am	Using flow cytometry to characterize immune reconstitution in clinical stem cell transplantation recipients. Krishna Komanduri, MD
	8:40am - 9:10 am	The functional analysis of NK cells after cord blood transplantation. Mike Verneris, M.D, Assistant Professor of Pediatrics, Division of Hematology-Oncology and Blood and Marrow Transplantation, University of Minnesota Medical School
	9:10am - 9:25am	Coffee Break
	9:25am - 9:55am	Avidity grading of antigen-specific CD8+ T cell populations with coreceptor-mutated pMHCI tetramers. Professor David A Price, MD PhD, Cardiff University Medical School, Cardiff, UK
	9:55am - 10:25am	Polyfunctional analysis of perforin producing human CD8 T cells Michael R. Betts, PhD, Assistant Professor, Department of Microbiology, University of Pennsylvania
	10:25am - 10:40am	Coffee Break
	10:40am - 11:10am	Flow cytometric characterization of therapeutic dendritic cells. Dr. Michel Gilliet, Assistant Professor of Immunology, M.D. Anderson Cancer Center
	11:10am - 11:40am	Flow cytometric analysis of mesenchymal cells Ian K. McNiece, PhD, Professor, Director Experimental and Clinical Therapies, Stem Cell Institute, University of Miami
	11:40am - 11:55am	Panel discussion/Q&A (All speakers)
	11:55am - 12:00pm	Acknowledgments/closing remarks (Krishna Komanduri, MD)
8:00am - 5:00pm	FACT Inspectio	n & Accreditation Training Workshop (Pre-Registration required through FACT) Visit: www.factwebsite.org
7:30pm – 9:30pm	WELCOME RECEPTION Riverfront Hall	
3:00pm – 10:00pm	Advisory Board Meeting Orchid BCD	

SUNDAY, MAY 18

6:45am - 7:00pm Registration Riverfront Lobby Central Technical **Technical Technical Technical Technical** Breakfast 4
Riverfront Hall - South **Breakfast 2** Breakfast 1 Orchid BCD **Breakfast 3 Breakfast 5** Hibiscus Gardenia Jasmine A road to a cure: MRD as a Clinical Incorporation **Environmental** Cord Blood challenges in the Surrogate and of ISBT 128 into Cell Monitoring - Practical Transplantation and Therapy Laboratory Approaches manufacturing of Integration into **Graft Engineering** allogeneic islet cells **Clinical Trials** Systems Chair: Chair & Speakers: 7:30am - 8:30am Lizette Caballero, BSc, Elizabeth Shpall, MD, MD Chair & Speaker: Chair: Chair: Elina Linetsky, M.Sc., MT, University of Miami Robert Sutherland, MSc, Fran Rabe, University MT, Florida Hospital Anderson Cancer Center University of Toronto Cancer Institute Joanne Kurtzberg, of Minnesota Speakers: MD. Duke University Speakers: Speaker: Speakers: Gerrit Schuurhuis, PhD, Federico Rodriguez, MT Medical Center Joel Szust, DVM, CPTC, Stella Larsson, MD. (ASCP) SBB, Blood Speaker: Karolinska University CTOP, University of Miami Vriie Universiteit Systems Laboratories Colleen Delaney, MD, MSc, James Reuben, MD, MD Aisha Khan, MS, MBA, Hospital Linda Sledge, RN, Duke Doris Herrmann, PhD, Fred Hutchinson Cancer University of Miami Anderson Cancer Center **GMP** Unlimited Research Center University Medical Center 9.00am - 6:00pm **Exhibits** Riverfront Hall **Welcome and Opening Remarks** 8:45am - 9:00am Donna E. Shalala, President, University of Miami Regency Ballroom PLENARY SESSION 1 - DIABETES Regency Ballroom Chair: Camillo Ricordi, MD, Director Diabetes Research Institute, University of Miami peakers: Overview: Camillo Ricordi, MD, Director Diabetes Research Institute, University of Miami 9:00am - 10:30am Developments in Clinical Trials: José Oberholzer, MD, Director, Cell Transplantation, University of Illinois at Chicago Cutting Edge Research and Future Directions: Olle Korsgren, MD, PhD, Professor of Cell Transplantation, Rudbeck Laboratory, Uppsala University Hospital 10:30am - 10:45am Coffee Break Riverfront Hall **Oral Abstract Presentations 2 Hibiscus** Oral Abstract Presentations 1 Jasmine 10:45am - 12:15pm Hematopoietic Stem Cells 1 **Immunotherapy & Dendritic Cells** 12:15pm - 1:30pm Box Lunch Riverfront Hall PLENARY SESSION 2 - CARDIOLOGY R Chair: Joshua Hare, MD, Chief of Cardiology, Director Stem Cell Institute, University of Miami Speakers: Overview: Joshua Hare, MD, Chief of Cardiology, Director Stem Cell Institute, University of Miami 1:30pm - 3:00pm Developments in Clinical Trials: Stefan Janssens, MD, PhD, Principal Investigator, Center for Transgene Technology and Gene Therapy, Katholieke Universiteit Leuven Cutting Edge Research and Future Directions: Annarosa Leri, MD, New York Medical College 3:00pm - 3:30pm Coffee Break Riverfront Hall Workshop 4 Workshop 2 Workshop 1 Workshop 3 Workshop 5 Orchid BCD Riverfront Hall - South Financing for Cell How to Integrate Risk Management 1: Infectious and Tumor-Mesenchymal Stromal **Therapy Companies** Biomarkers into Overview of Risk Specific Cellular Cells: Universal Donor Therapy **Clinical Development** Management for Cell Therapy? Chairs: Lee Buckler, BEd, Programs; What Strategies in Chair: Chair: LLB, Progenitor Cell are the Regulations **Cellular Therapy** Elizabeth Shpall, MD, MD Jacques Galipeau. Therapy, LLC MD FRCPC, Lady and Implications Anderson Cancer Center Chair: Dawn Driscoll, MBA PhD, Chair & Speaker: Davis Institute for for Therapeutic Victoria Lake RAC 3:30pm - 5:00pm Driscoll Consulting Krishna Komanduri, MD. Medicine Research Fred Hutchinson Cancer **Applications** Speaker: MD Anderson Cancer Center Speakers: Research Center Leonide Saad, Proteus Chair & Speaker: Speakers: Pranela Rameshwar, PhD, Speakers: Venture Partners Panteli Theocharous, Catherine Bollard, MD, New Jersey Medical Asiya Imam, PhD, CQA, Eric Faulkner, RTI Health BSc, MSc, PhD, J&J Baylor College of Medicine Donald G. Phinney, PhD, **BD** Biosciences Pharmaceutical R&D Solutions Laurence Cooper, MD, MD Tulane University Karen Nichols, ESQ, RAC, Robert Deans, PhD, Speakers: Anderson Cancer Center ViaCell, Inc. Uma Prabhakar, PhD, Athersvs Inc. Donna R. Rill, BS, MT Frederic Hammel, MSc. Centocor, Inc. (ASCP), Opexa Therapeutics Bettina Heidecker, MD. TxCell SA University of Miami 5:00pm - 6:00pm Poster Session 1 Riverfront Hall 7:30pm - 10:00pm **Committee Meetings**

MONDAY, MAY 19

6:45am - 7:00pm Registration Riverfront Lobby Central **Technical** Technical **Technical** Technical Workshop 6 **Breakfast 6 Breakfast 7 Breakfast 8 Breakfast 9** (7:30 am - 9:00 am)Orchid BCD Riverfront Hall - South **Practical Qualification** Review of the New EU/ **Epitope Identification Gene Transfer into Emerging Techniques EMEA Cell and Tissue** and Validation for Measuring and Mapping **Immune Effectors** Regulations **Epigenetic Change and** Chair: Chair: Chairs & Speakers: Cytogenetic Stability Michelle Sugrue, MS, Chairs: Ann Leen, PhD, Baylor Allan Dietz, PhD, MT (ASCP)SBB, in Adherent Adult College of Medicine Mayo Clinic Ineke Slaper-Cortenbach University of Florida Catherine Bollard, MD, Speaker: PhD, University Medical Stem Cells 7:30am - 8:30am Sabrina Mogle, Baylor College of Medicine Shands Cancer Center Center Utrecht Chair: ProImmune Inc. Speakers: Speaker: Panteli Theocharous, BSc, Robert Deans, PhD, Lizabeth Cardwell, Lisa Butterfield, PhD. MSc, PhD, Johnson & Athersys, Inc. MT(ASCP), MBA University of Pittsburgh Johnson Pharmaceutical Speakers: School of Medicine Karen Snow, BS, R&D Uma Lakshmipathy, PhD, (ASCP)BB, CLS(NCA)I, Speaker: Invitrogen Massachusetts Paul Williamson, MD. Ulrich Hoffmueller, PhD, General Hospital J&J. The Stem Cell MBA, Epiontis GmbH Internal Venture, Giovanni Migliaccio. Istituto Superiore di Sanità 9.00am - 6:00pm **Exhibits** Riverfront Hall PLENARY SESSION 3 - CANCER Regency Balli Chair: Eli Gilboa, PhD, Head Immunobiology and Immunotherapy Program, University of Miami 9:00am - 10:30am sakexs: Overview: Stanley Riddell, MD, Member, Program in Immunology, Fred Hutchinson Cancer Research Center Developments in Clinical Trials: Carl June, MD, Director, Translational Research, University of Pennsylvania, Abramson Cancer Center Cutting Edge Research and Future Directions: Luca Gattinoni, Research Fellow, National Cancer Institute 10:30am - 11:00am Coffee Break Riverfront Hall **Oral Abstract Presentations 4 Hibiscus** Oral Abstract Presentations 3 Jasmine 11:00am - 12:30pm Mesenchymal & Tissue Stem Cells 1 Commercialization, Legal & Regulatory Affairs & Lab Practices ISCT AGM Regency Ballroom 12:30pm - 1:30pm Box Lunch Riverfront Hall **PLENARY SESSION 4 – IMMUNOTHERAPY** Chair: Eckhard Podack, MD, Chair of Microbiology and Immunology, University of Miami Speakers: Overview: Tom Malek, PhD, Professor and Vice Chair of Immunology and Microbiology, University of Miami 1:30pm - 3:00pm Developments in Clinical Trials: Robert Levy, PhD, Professor of Microbiology / Immunology and Medicine, University of Miami, School of Medicine Cutting Edge Research and Future Directions: Ana Izcue, PhD, Powrie Group, CIU, Sir William Dunn School of Pathology, University of Oxford 3:00pm - 3:30pm Coffee Break Riverfront Hall Workshop 8 Workshop 9 Workshop 11 Workshop 7 Workshop 10 Jasmine Orchid BCD Hibiscus Riverfront Hall - South Gardenia Use of Hematopoietic Cell Therapy Bench-**How to Select And** Species Specific **Gene Therapy Manage Contractors** Differences in MSCs: Stem Cells for to-Bedside - Early Chair & Speaker: Stage Set Up and Vendors How Do You Do Bruce Levine, PhD, **Induction of Tolerance** From Pre-Clinical Director, University Preclinical Studies? Chair: Chair: of Pennsylvania to Phase I Joyce Frey-Vasconcells, Chair: John Jackson, PhD, Speakers: PhD, Pharmanet Consulting Edwin Horwitz, MD, PhD, University of Nebraska Chair: 3:30pm - 5:00pm Jeffrey Medin ,PhD, Speakers: Children's Hospital of Medical Center David McKenna, MD, Ontario Cancer Institute Robert Preti, PhD, Philadelphia Speaker: University of Minnesota Frederic Bushman, PhD, Progenitor Cell Camillo Ricordi, MD. Medical Center University of Pennsylvania Therapy, LLC University of Miami Speaker: Robert Perry, MSc, William Beschorner, MD, Janice Davis-Sproul, MAS, Athersys, Inc. MT(ASCP), Johns Hopkins Ximerex, Inc. Harry E. Carmitchel, Medical Institutions Osiris Therapeutics Stewart Craig, PhD, Progenitor Cell Therapy, LLP 5:00pm - 6:00pm Poster Session 2 Riverfront Hall 6:30pm - 7:30pm **EXECUTIVE COMMITTEE & SPONSOR RECEPTION** 7:30pm **GALA DINNER**

TUESDAY, MAY 20

6:45am – 5:00pm

Registration Riverfront Lobby Central

Technical Breakfast 10

Jasmine

Banking Cord Blood: How to Maintain Quality from Deposit through Withdrawal

Chairs & Speakers: Liana Harvath, PhD, Biologics Consulting Group, Inc. Ellen Areman, MS, SBB (ASCP), Biologics Consulting Group, Inc.

Technical Breakfast 11

Hibiscus

Immunological Evaluation of Patients Before and After Allogeneic Stem Cell Transplantation

Chair: Paul Moss, University Hospital Birmingham NHS Trust

Technical **Breakfast 12** Orchid BCD

How to Start an MSC Research Program

Chair & Speaker: Armand Keating, MD, FRCP(C), Princess Margaret Hospital

Technical Breakfast 13 Riverfront Hall - South

Perspectives on Leveraging the Accreditation Process to Prepare Your Facility for **Regulatory Inspections**

Chair: Darin Weber, PhD, Biologics Consulting Group, Inc. Speakers:

Nancy Collins, PhD, University of Toledo Mary Beth Fisk, MT, CTBS, CQA, South Texas Blood & Tissue Center Aisha Khan, MS, MBA, University of Miami

8:30am - 1:30pm

7:30am - 8:30am

Exhibits Riverfront Hall

PLENARY SESSION 5 - NEURAL DISEASES Regency Ballroon

Chair: W. Dalton Dietrich, III, PhD, Scientific Director of the Miami Project, University of Miamii

Overview: W. Dalton Dietrich, III, PhD, Scientific Director of the Miami Project, University of Miamii Developments in Clinical Trials: Gary Steinberg, MD, PhD, Chairman, Department of Neurosurgery, Stanford University School of Medicine Cutting Edge Research and Future Directions: Clive Svendsen, PhD, Professor, Anatomy and Neurology, University of Wisconsin-Madison

10:00am - 10:30am

8:30am - 10:00am

Coffee Break Riverfront Hall

Oral Abstract Presentations 5 Jasmine 10:30am - 12:00pm

Mesenchymal & Tissue Stem Cells 2 & Cell and Tissue Evaluation

Oral Abstract Presentations 6 Hibiscus Hematopoietic Stem Cells 2 & Gene Therapy

12:00pm - 1:00pm

1:00pm - 2:30pm

2:30pm - 4:00pm

Box Lunch Riverfront Hall

Workshop 12

Jasmine

In vivo Pharmacology and Toxicology for Cell Therapy

Chair: Lily Li, Therakos Speakers: David Pepperl, PhD, Biologics Consulting Group, Inc. Carl June, MD, University of Pennsylvania

Joseph Frank, MD, National

Institutes of Health

Workshop 13 Orchid BCD

Immune Status in Cancer: **Towards Immune** Reconstitution

Chair & Speaker: Stanimir Vuk-Paylovic. PhD, Mayo Clinic College of Medicine Speakers:

Roshini Abraham, Ph.D., D(ABMLI), Mayo Clinic Svetomir Markovic, MD, PhD, Mayo Clinic

Workshop 14

Hibiscus

Stem Cell Aging

Chair: John Jackson, PhD, University of Nebraska Medical Center Speakers:

Barbara O'Kane, PhD, University of Nebraska Bonnie Blomberg, PhD, University of Miami

Workshop 15

Riverfront Hall - South

Chair:

Germany

Rapid Generation of Antigen Specific T Cells

Paul Moss, University Hospital Birmingham NHS Trust Speaker: Dirk Busch, MD, Technical University of Munich, Germany Jeffrey S. Miller, MD, University of Minnesota

Cancer Center Tobias Feuchtinger, MD, University Children's Hospital, Tuebingen,

Workshop 16

Gardenia

Risk Management 2: Application to Cell Therapy Manufacturing Chair & Speaker:

Lynn O'Donnell, PhD, OSU James Cancer Hospital & Research Institute Speakers: Olive Sturtevant, MT, SBB, SLS, MHP, Dana-Farber Cancer Institute William Janssen, PhD, Moffitt Cancer Center

PRESIDENTIAL PLENARY SESSION R

Chair: Shelly Heimfeld, PhD, ISCT President, Associate Member, Director of Cellular Therapy and Cell Processing Facilities, Fred Hutchinson Cancer Research Center

Frederick Applebaum, MD, Director, Clinical Research Division Member, Fred Hutchinson Cancer Research Center Pascal Goldschmidt, MD, Senior Vice President for Medical Affairs and dean, Miller School of Medicine, University of Miami

WEDNESDAY, MAY 21 (ADDITIONAL FEE REQUIRED)

ISCT 2008 Post-Conference Session – Global Regulatory Perspectives Hibiscus The content of this workshop is not CME accredited 8:00am - 8:30am **Opening Remarks** 8:30am - 8:45am Burger, MD, Advanced Cell & Gene Therapy - USA Session I: Emerging Regulatory Environments Chair: Kurt C. Gunter, MD, Medical Director, Cellular Therapy, Hospira Inc – USA 8:45am - 10:15am Speakers: Dr. Mickey Koh: Vice Director of Center for Transfusion Medicine, Health Science Authority, Singapore • Dr. Der-Yuan Wang, Chief, Section of Blood Products & In Vitro Diagnostics, Bureau of Food and Drug Analysis, Taiwan • Dr. Yuji Heike, National Cancer Center, Tokyo, Japan 10:15am - 10:30am **Coffee Break** Session II: Preclinical Development of Regenerative Therapies Chaix: Dominic Wall, PhD, Peter MacCallum Cancer Centre - Australia 10:30am - 12:00pm Speakers: Mercedes Serabian, OCTGT/DCEPT FDA/CBER • Professor Ming Hao Zheng, PhD, DM, FRCPath, Director, Centre for Orthopaedic Research, Perth Australia • Dr Ralf Sanzenbacher, Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines, Germany 12:00pm - 12:30pm Lunch ession III: Novel Advanced Cell Therapies Chair: Scott Burger MD, Advanced Cell & Gene Therapy - USA 12:30pm - 2:00pm Speakers: Dr. Kimberly Benton, OCTGT/DCGT FDA/CBER • Dr. Christoph Gaissmaier, Author: Guidelines from the German Society of Surgery (Deutsche Gesellschaft für Chirurgie) on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production. • Dr. Giovanni Migliaccio, Head, Section of Gene and Cell Therapy, Dept. of Cell Biology and Neuroscience, Istituto Superiore di Sanità, Rome, Italy) 2:00pm - 2:15pm **Coffee Break** Chair: Ineke Slaper-Cortenbach, PhD, University Medical Center Utrecht - The Netherlands 2:15pm - 3:45pm Speakers:. Thomas Brégeon, DG SANCO, Brussels • Dr. Peta O'Connell, Scientific Evaluator-Cell Therapies, Blood and Tissues Unit, Office of Devices, Blood and Tissues, TGA, Australia 3:45pm - 4:00pm **Closing Remarks**

Plenary, Workshop and Technical Breakfast Speakers & Chairs

- Roshini Abraham, PhD, D(AMBLI), Mayo Clinic
- Frederick Applebaum, MD, Fred Hutchinson Cancer Research Center
- Ellen Areman, MS, SBB(ASCP), Biologics Consulting Group, Inc.
- · William Beschorner, MD, Ximorex, Inc.
- Bonnie Blomberg, PhD, University of Miami
- Catherine Bollard, MD, Baylor School of Medicine
- · Lee Buckler, BEd, LLB, Progenitor Cell Therapy, LLC
- Dirk Busch, MD, Technical University Munich
- · Frederic Bushman, PhD, University of Pennsylvania
- Lisa Butterfield, PhD, University of Pittsburgh School of Medicine
- Lizette Caballero, BSMT(ASCP), Florida Hospital Cancer Institute
- Lizabeth Cardwell, MT(ASCP), MBA, RAC
- Harry E. Carmitchel, Osiris Therapeutics
- · Nancy Collins, PhD, University of Toledo
- Laurence Cooper, MD, PhD, MD Anderson Cancer Center
- Stewart Craig, PhD, Progenitor Cell Therapy, LLP
- Janice Davis-Sproul, MAS, MT(ASCP)SBB, Johns Hopkins Medical Institutions

- · Robert Deans, PhD, Athersys, Inc.
- Colleen Delaney, MD, MSc, Fred Hutchinson Cancer Research Center
- · Dalton Dietrich, PhD, University of Miami
- Allan Dietz, PhD, Mayo Clinic
- Dawn Driscoll, MBA, PhD, Driscoll Consulting
- · Eric Faulkner, RTI Health Solutions
- Tobias Feuchtinger, MD, University Children's Hospital, Tuebingen, Germany
- Mary Beth Fisk, MT, CTBS, CQA, South Texas Blood & Tissue Center
- · Joseph Frank, MD, National Institutes of Health
- Joyce Frey-Vasconcells, PhD, Pharmanet Consulting
- Jacques Galipeau, MD, Lady Davis Institute for Medical Research
- Luca Gattinoni, MD, National Cancer Institute
- Eli Gilboa, PhD, University of Miami
- Pascal Goldschmidt, MD, University of Miami
- Frederic Hammel, MSc, TxCell SA
- · Joshua Hare, MD, University of Miami
- Liana Harvath, PhD, Biologics Consulting Group, Inc.
- Bettina Heidecker, MD, University of Miami