

Monday, November 6		Tuesday, November 7		Wednesday, November 8	
Room 1	Room2	Room1	Room2	Room 1	
9:00	Opening Remarks	9:00-10:20		9:00-11:00	9:00
	9:10-9:50 <b>Plenary Session I</b> Chair Shuichi Taniguchi	<b>Plenary Session II</b>  Chair Akihiro Shimosaka		<b>Regenerative Therapy</b>  Chair Koichi Nakayama	
	9:50-10:10 Coffee Break	10:20-10:30 Coffee Break			
10:00	10:10-12:30 <b>CAR Therapy</b>  Chair Takanori Teshima	10:30-12:00 <b>Asian Report</b>  Chair Akihiro Shimosaka		11:00-12:00 <b>Pricing Issue</b>	11:00
11:00					
12:00		12:10-13:10 <b>Luncheon Seminar 3</b> Chair Koichi Akashi  LSI Medience		12:00-12:30 <b>ACTO Report</b>	12:00
	12:40-13:40 <b>Luncheon Seminar 1</b> Chair Koji Kato Medical Affairs, Novartis Pharma K.K.	12:40-13:40 <b>Luncheon Seminar 2</b> Chairs Keiya Ozawa/Tokiko Nagamura Human Life Cord Japan Inc.		Closing Ceremony	
13:00					
	13:45-15:15 <b>Gene Therapy</b>  Chair Keiya Ozawa	13:15-15:15 <b>Regulatory Session I</b>  Chairs Yoshiaki Maruyama Kiyoshi Okada		13:30-14:00 Technical Seminar SHIBUYA CORPORATION	
14:00				14:10-14:40 Technical Seminar CellSeed Inc.	
				14:50-15:20 Technical Seminar Miltenyi Biotec	
15:00					
	15:15-15:30 Coffee Break	15:15-15:30 Coffee Break			
16:00	15:30-17:00 <b>Immune Cell Therapy</b>  Chair Shuji Terai	15:30-16:30 <b>Regulatory Session II</b> Chairs Yoshiaki Maruyama Kiyoshi Okada		15:30-16:00 Technical Seminar Etta Co.Ltd.	
				16:10-16:40 Technical Seminar Minaris Regenerative Medicine	
17:00		16:30-17:00 <b>Regulatory Session Round Table Discussion</b>			
	17:10-18:10 <b>Evening Seminar</b> Chair Koji Kato	17:00-17:45 <b>Best Poster abstract short presentation Award Ceremony</b>			
18:00	AbbVie GK / Genmab K.K.				

Monday, November 6, 2023

[Room 1]

Plenary Session 1 9:00-9:50

Chair: **Shuichi Taniguchi** (Director of Hamanomachi Hospital)

**Willem Fibbe** (Leiden University Medical Centre (LUMC), Netherlands)

*Immune signatures in aGvHD: A tool to guide immune-suppressive treatment?*

CAR Therapy 10:10-12:30

Chair: **Takanori Teshima** (Hokkaido University)

**Koji Izutsu** (Chief of Department of Hematology, National Cancer Center Hospital, Tokyo, Japan)

*Role of CD19-directed CAR-T for B-cell lymphomas and its clinical development in Japan*

**Yoshiyuki Takahashi** (Nagoya University Graduate School of Medicine, Department of Pediatrics)

*PiggyBac transposon-mediated Chimeric Antigen Receptor-T Cell therapy*

**Linda Hanssens** (Miltenyi Biotech)

*Development of Novel CD20 and CD19 Targeting Tandem Chimeric Antigen Receptor, in Patients with Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma*

**Peggy Lu** (Medical Executive President of Lu Daopei Hospital and Lu Daopei Institute of Hematology)

*The Challenge of CD7 CAR-T Therapy in Treating T Cell Malignancies*

**Yongxian Hu** (Chief physician in Bone Marrow Transplantation Center)

*Allogeneic CAR-T cells for Hematological Malignancies*

**Hideki Goto** (Division of Laboratory and Transfusion Medicine, Hokkaido University Hospital)

*Real-world data of tisagenlecleucel in Japanese diffuse large B-cell lymphoma patients*

Luncheon Seminar 1 12:40-13:40 cosponsored by Medical Affairs, Novartis Pharma K.K.

Chair: **Koji Kato** (Department of Medicine and Biosystemic Science, Kyushu University Faculty of Medicine)

**Yu Yagi** (Department of Oncology, Tokyo Metropolitan Cancer and Infectious Disease Center, Komagome Hospital, Tokyo, Japan)

*Real-World Experience of CAR T-cell therapy for the treatment of Large B cell lymphoma in Japan*

## Gene Therapy 13:45-15:15

Chair: **Keiya Ozawa** (Jichi Medical University)

**Suradej Hongen**

**Shin-ichi Muramatsu** (Division of Neurological Gene Therapy, Center for Open Innovation, Jichi Medical University)

*Adeno-associated virus vector-based gene therapies*

**Naoya Sato** (Director, Corporate Development Department, AnGes, Inc., Tokyo, Japan)

*OMNI™ Technology Platform: Genome Editing Solution to Make Any Gene Targetable Technology Platform: Genome Editing Solution to Make Any Gene Targetable*

**Chae-Ok Yun** (Dept. of Bioengineering, School of Engineering, Hanyang University, Seoul, Korea)

*Functionalizing oncolytic adenovirus with nanomaterial-based delivery systems*

## Immune Cell Therapy 15:30-17:00

Chair: **Shuji Terai** (Niigata University)

**Ren Jun** (Professor and Director, Center of Clinical Oncology, Fudan University Pudong Medical Center, Shanghai, China)

*New Adoptive T cell Immunotherapy triggered by hyperthermia*

**Rishu Takimoto** (Deputy-director, Clinical Research and Trial Center, Seta Clinic Group, Tokyo, Japan)

*Safety evaluation of immune-cell therapy for malignant tumor in Cancer Immune-cell Therapy Evaluation Group (CITEG)*

**Juichi Masuyama** (New City Osaki Clinic, Tokyo, Japan)

*Correlation between immunological changes and prolonged survival induced by NK cell-based immunotherapy*

**Tokiko Nagamura** (The Institute of Medical Science, The University of Tokyo (IMSUT))

*Umbilical cord tissue banking as a source of immunotherapy and regenerative medicine*

Evening Seminar 17:10-18:10 cosponsored by AbbVie GK / Genmab K.K.

Chair: **Koji Kato** (Department of Medicine and Biosystemic Science, Kyushu University Faculty of Medicine)

**Daisuke Ennishi** (Associate Professor, Department of Hematology and Oncology, and Center for Comprehensive Genomic Medicine, Okayama University Hospital)

*Therapeutic approaches targeting microenvironment of relapsed and refractory Diffuse Large B-cell Lymphoma (DLBCL) ~ focusing on newly available bispecific antibody ~*

[Room 2]

Luncheon Seminar 2 12:40-13:40 cosponsored by Human Life Cord Japan Inc.

Chairs: **Keiya Ozawa** (Jichi Medical University)

**Tokiko Nagamura** (The Institute of Medical Science, The University of Tokyo (IMSUT))

**Tokiko Nagamura** (The Institute of Medical Science, The University of Tokyo (IMSUT))

*Immunological influence of serum-free manufactured umbilical cord-derived mesenchymal stromal cells for steroid-resistant acute GVHD and COVID-19-ARDS*

**Willem Fibbe** (Leiden University Medical Centre (LUMC), Netherlands)

*Progress in biology, engineering and clinical application of Mesenchymal Stromal Cells*

Tuesday, November 7, 2023

[Room 1]

Plenary Session 2 9:00-10:20

Chair: **Akihiro Shimosaka** (ACTO chair)

**Yasuhiro Fujiwara** (Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA))

*Regulatory Aspects of Cell and Gene Therapy Product*

**Yuichiro Ukon**

(Medical Technical Officer, Office for Promotion of Regenerative Medicine Research and Development, Research and Development Division, Health Policy Bureau, Ministry of Health, Labour and Welfare, Japan)

*Act on the Safety of Regenerative Medicine and the Direction in the Amendment*

Asian Report 10:30-12:00

Chair: **Akihiro Shimosaka** (ACTO chair)

**Mickey Koh** (Clinical Director-Oncology and Haematology, St George's Hospital and Medical School, London, UK Programme Director-Cell and Gene Therapy Facility, Health Sciences Authority, Singapore)

*The Landscape of Cell Therapy in Singapore*

**Suradej Hongen**

**Kaiyan Liu** (Department of Hematology, Peking University People's Hospital Chairman, Ethics Review Committee, Peking University People's Hospital)

**Hee-Je Kim** (Department of Hematology, Catholic Hematology Hospital, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea)

*Cell-Based Immunotherapy: Experience of Catholic Hematology Hospital in Korea*

**Keiya Ozawa** (Jichi Medical University)

*New subprogram of AMED (Japan Agency for Medical Research and Development): Core Center for Regenerative Medicine and Cell and Gene Therapy*

**Chia-Ning Shen** (President, Taiwan Association for Cellular Therapy)

*Current Status of Cell-Based Therapeutic Development in Taiwan*

**Luncheon Seminar 3 12:10-13:10** cosponsored by LSI Medicine

Chair: **Koichi Akashi** (Kyushu University)

**Yoshikane Kikushige** (Center for Cellular and Molecular Medicine, Kyushu University Hospital)

*TIM-3 in human acute myeloid leukemia; its therapeutic application and clinical significance in allogeneic hematopoietic stem cell transplantation*

**Regulatory Session 13:15-15:15**

Chairs: **Yoshiaki Maruyama** (Director Office of Cellular and Tissue-based Products Pharmaceuticals and Medical Devices Agency, JAPAN)

**Kiyoshi Okada** (Osaka University)

**Kellathur Srinivasan** (Roche Pharma Technical Regulatory Policy for APAC based in Singapore)

*Harmonisation and Convergence for Advanced Therapy Medicinal Products – a Global Perspective*

**Piyanan Boonprasert** (Medicines Regulation Division, Thailand Food and drug administration, Nonthaburi, Thailand Pharmacist-Regulator)

*The Current Regulation of Advanced Therapy Medicinal Products in Thailand*

**Yueh-Tung, Tsai** (Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW))

*Regulatory Updates for Regenerative Medicine in Taiwan*

**Maria Christina Gali** (Retired from Istituto Superiore di Sanità, Roma, Italy and is now a freelance consultant in gene and cell therapy production and development)

*EUROPEAN REGULATORY FRAME FOR ADVANCED THERAPY MEDICINAL PRODUCTS: AN UPDATED OVERVIEW*

**Regulatory Session 15:30-16:30**

Chairs: **Yoshiaki Maruyama** (Director Office of Cellular and Tissue-based Products Pharmaceuticals and Medical Devices Agency, JAPAN)

**Kiyoshi Okada** (Osaka University)

**Kyoung Suk Choi** (Senior Scientific Officer Cell and Gene Therapy Products Division National Institute of Food and Drug Safety Evaluation

Ministry of Food and Drug Safety Republic of Korea)

*Regulatory Landscape of Advanced Biological Products in Korea*

**LU Jiaqi** (Senior Reviewer Center for Drug Evaluation (CDE), NMPA)

*Cellular therapy products in China: Current regulation and challenges*

**Rusdy Ghazali Malueka** (Member of Indonesia Stem Cell and Cell-based Therapy Development University of Gadjah Mada/Dr. Sardjito General Hospital)

*Regulation of stem cells and other cell-based therapies in Indonesia*

**Shinichi Noda** (Deputy Review Director, Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency(PMDA) Srinivasan)

*Experience of 10th anniversary Regenerative Medical Products in JAPAN*

Wednesday, November 8, 2023

[Room 1]

Regenerative Therapy 9:00-11:00

Chair: **Koichi Nakayama** (Professor Department of regenerative medicine and Biomedical Engineering, Faculty of medicine, Saga University)

**Masato Sato** (Department of Orthopaedic Surgery, Tokai University School of Medicine)

*Regenerative Therapy for Osteoarthritis of the Knee Using Cell Sheets*

**Takayasu Ohtake** (Vice president Director of Regenerative Medicine, Center for Cell Therapy & Regenerative Medicine, Shonan Kamakura General Hospital, Kamakura, Japan)

*A clinical trial of comprehensive regenerative treatment for acute and chronic kidney injury by autologous G-CSF-mobilized peripheral blood-derived CD34+ cell administration.*

**Ryosuke Ikeguchi** (Department of Rehabilitation, Kyoto University Hospital, Kyoto, Japan)

*Peripheral nerve regeneration by Bio 3D nerve conduit using a bio-3D printer*

**Ryousuke Hirota** (Department of Orthopaedic Surgery, Sapporo Medical University School of Medicine, Department of Neural Regenerative Medicine, Research Institute for Frontier Medicine, Sapporo Medical University School of Medicine)

*Bone Marrow-Derived Mesenchymal Stem Cell Therapy for Spinal Cord Injury: Current Status and Future Prospects*

**Jaeseung Lim** (Adjunct Professor Dept. of Health Industry, SookMyung Women's University Chief Executive Officer & Chief Scientific Officer (Founder) Cellatoz Therapeutics, Inc)

*The real regeneration of cartilage by human Muscular Skeletal Stem Cells (hMSSC)*

**Koichi Nakayama** (Professor Department of regenerative medicine and Biomedical Engineering, Faculty of medicine, Saga University)

*Scaffold-free Bio-3D Printing for Solid organ fabrication.*