2016 International Symposium for Recent Advances in Cell Therapy and 3rd Annual Meeting of Taiwan Association for Cell Therapy

October 28-29, 2016

Organized by
Taiwan Association for Cell Therapy
台北細胞醫療促進協會
Taipei Medical University
臺北醫學大學

Co-organized by
Center for Cell Therapy and Regeneration Medicine, Taipei Medical University
臺北醫學大學細胞治療與再生醫學研究中心

Sponsored by
College of Medicine, Taipei Medical University
臺北醫學大學醫學院
Office of Business Development, Taipei Medical University
臺北醫學大學事業發展處
Office of Research and Development, Taipei Medical University
臺北醫學大學研究發展處
Taipei Medical University-Joint Institutional Review Board (TMU-JIRB)
臺北醫學大學暨附屬醫院聯合人體研究倫理委員會
Ministry of Health and Welfare
衛生福利部
Ministry of Education
教育部
Ministry of Foreign Affairs, Republic of China (Taiwan)
中華民國外交部
Secretariat, Taipei City Government
臺北市政府秘書處

Venue
United Medical Back Building, 16F Lecture Hall, Taipei Medical University
臺北醫學大學醫學組合大樓後棟16F
Our esteemed guests and dear fellow members,

On behalf of the Taiwan Association for Cell Therapy (TACT), I heartily welcome you all to the “2016 Japan/Taiwan Forum for Cell Therapy and the 3rd Annual Meeting of TACT.” We are so delighted to see many familiar faces and appreciative of the new faces joining to enrich our discussion.

Cell therapy has gained traction among new medical treatments, as regenerative medicine and cancer immunotherapy received much attention in recent medicine progression. Japan has advanced technology and great network in developing cell therapy and often leads the world in this area of development. We are thrilled to have renowned scientists and executives of biotechnology companies in Japan to share their progression and achievement. Japanese companies including CellSeed, MEDINET, Cyfuse, FUKOKU, and Cellex will contribute to the presentation in the program.

In Taiwan, our efforts also bear some fruits. The collaboration among our government regulators, industry partners, and academicians has made great progression. There are increasing pre-clinical studies and clinical trials in cell therapy. You will hear the most update status of cell therapy clinical trials in Taiwan. Taiwanese biotechnology companies, such as EMO, Maria Von, Vectorite, UnicoCell, and Steminent, will also present their research findings and advancement.

This forum and meeting reflects the longstanding close collaboration between Taiwan and Japan. We hope that our TACT members will be inspired by the innovative technologies and clinical application shared by our Japan guests. We also wish to provide a platform for further collaboration between Japan and Taiwan, as well as among various stakeholders in the area of cell therapies.

Yours sincerely,

Yao-Chang Chen, M.D.
President, Taiwan Association for Cell Therapy
Dear colleagues and friends,

It is of great pleasure and honor to welcome you to the “2016 International Symposium for Recent Advances in Cell Therapy and 3rd Annual Meeting of Taiwan Association for Cell Therapy”, to be held at Taipei Medical University on October 28-29, 2016.

This year’s symposium features many distinguished international and domestic scientists and clinicians in the field of cell therapy. Our keynote lecture highlights Dr. Tasuku Honjo, the inaugural Tang Prize Laureate in Biopharmaceutical Science, whose discovery of PD-1 shaped the field of cancer immunotherapy. The keynote lecture will be followed by a series of significant presentations by our invited speakers to provide updates and insights on immunotherapy and stem cell medicine. Furthermore, as the translation from laboratory to clinics would not be possible without collaborative efforts from industry and government, we will have presentations dedicated to discussions of industrial perspectives and government regulations. Aside from oral presentations, we encourage you to visit the poster sessions and exhibition booths to meet new friends and learn about latest research advances and cutting-edge technologies.

This conference will present a perfect opportunity for representatives to mingle and possibly form new synergic bonds. We hope you will find this a rewarding and memorable experience at Taipei Medical University, and we look forward to seeing you in Taipei!

Yours sincerely,

Wen-Chang Chang, Ph. D.
Academician, Academia Sinica
Chairman, Board of Trustees
Chair Professor, Graduate Institute of Medical Sciences
Taipei Medical University
Taipei, Taiwan
Dear colleagues and friends,

We are most delighted to extend our warmest invitation to you to attend the upcoming “2016 International Symposium for Recent Advances in Cell Therapy and 3rd Annual Meeting of Taiwan Association for Cell Therapy”, to be held at Taipei Medical University, Taipei, Taiwan, on October 28-29, 2016.

Cell therapy has been a rapidly progressing field and offers tremendous potentials in cancer and regenerative medicine. The transition from bench to bedside, however, requires close communication and collaboration between academia, industry, and government. Accordingly, five aspects will be addressed in this forum: basic research, preclinical studies, clinical trials, industry, and regulations.

We are honored and delighted to have with us renowned scientists and scholars from prestigious institutions and corporations in Japan, Singapore, U.S.A., and Taiwan to share their expertise and experience in the applications of cell therapy. A poster session will also present latest findings in both basic and translational research from students, researchers, and clinicians. We are confident that this symposium will spark exciting exchanges and catalyze new collaborations between participants.

We hope you will come to enjoy this wonderful weekend with us in Taipei. We also welcome all the international guests and hope they will take this opportunity to appreciate the rich culture and explore the beautiful scenery of the city. With our warmest regards, we look forward to seeing you in Taipei in October, 2016.

Yours sincerely,

Yun Yen M.D., Ph. D., F.A.C.P.
President and Distinguished Professor
Taipei Medical University
Taipei, Taiwan
Dear colleagues and friends,

On behalf of Taipei Medical University Center for Cell Therapy and Regeneration Medicine (TMU-CCTRM), we are delighted to welcome you to the “2016 International Symposium for Recent Advances in Cell Therapy and 3rd Annual Meeting of Taiwan Association for Cell Therapy”, which will be held at Taipei Medical University, Taiwan, on October 28-29, 2016.

CCTRM is a new university-grade research center at TMU founded in response to the rapidly expanding field of cell therapy and regenerative medicine. Our goals are to integrate research resources between TMU facilities and promote international relations and industry-academic collaborations. To achieve this, we established a Good Tissue Practice (GTP) Core Laboratory that conforms to international regulations for manufacturing clinical-grade cells to be used in clinical trials. Last but not least, we organize and offer an International Ph.D. Program for Cell Therapy and Regeneration Medicine (commencing in Fall 2017) for bright and talented students wishing to embark on research into related fields, and we are currently accepting applications for the 2017-2018 academic year.

In line with our center’s missions, we are honored to contribute in co-organizing this year’s symposium, which brings together many leading experts in the fields of cancer immunotherapy and stem cell medicine from diverse backgrounds of basic and clinical research and industry. This will be a showcase of the most updated advances from around the world, and we expect there to be an exciting exchange between great scientific minds. For researchers, clinicians, business delegates, and students, this promises to be a fruitful opportunity you will not want to miss.

We welcome you to join us and be part of this stimulating scientific and cultural experience in Taipei. Hope to see you at the conference!

Yours sincerely,

Rita Yen-Hua Huang, Ph.D.
Distinguished Professor and Director
Department of Biochemistry and Molecular Cell Biology
Graduate Institute of Medical Sciences
International Ph.D. Program for Cell Therapy and Regeneration Medicine
College of Medicine
Center for Cell Therapy and Regeneration Medicine/GTP Laboratory
Taipei Medical University, Taipei, Taiwan
### 對象

陳耀昌 台灣細胞醫療促進協會理事長
張文昌 臺北醫學大學董事長/中央研究院院士
閻雲 臺北醫學大學校長

### 會議籌備組

**大會主席**

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<td>台灣細胞醫療促進協會理事長</td>
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<td>張文昌</td>
<td>臺北醫學大學董事長/中央研究院院士</td>
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<tr>
<td>閻雲</td>
<td>臺北醫學大學校長</td>
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**籌備委員會名單**

**黃彥華** 臺北醫學大學

- 醫學系生化學科特聘教授兼主任
- 細胞治療與再生醫學研究中心主任
- 細胞治療與再生醫學國際博士學位學程主任
- 台灣細胞醫療促進協會理事

**林泰元** 台灣細胞醫療促進協會秘書長

- 臺大醫學院藥理學研究所副教授

**吳友志** 臺北醫學大學細胞治療與再生醫學研究中心

- 教授兼主任
- 細胞治療與再生醫學國際博士學位學程主任

**林志翰** 臺北醫學大學暨附屬醫院聯合人體研究倫理委員會副執行長

**朱娟秀** 臺北醫學大學教務長

**何元順** 臺北醫學大學醫學系教授兼所長

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**李勝揚** 臺北醫學大學牙醫學系教授

**林建煌** 臺北醫學大學牙醫學系教授

**林俊茂** 臺北醫學大學生物醫學研究所

**林志翰** 臺北醫學大學暨附屬醫院聯合人體研究倫理委員會人體研究審查行政組組長
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施纯明  台北医学大学主任秘书/医学系生物化学科教授
区庆建  台北医学大学附设医院妇产科主任
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连吉时  台北市立万芳医院院长
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台北医学大学附设医院神经外科主任
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赖勇政  行政福利部双和医院副院长
简雄飞  台北医学大学附设医院副院长

2016 International Symposium for Recent Advances in Cell Therapy
3rd Annual Meeting of Taiwan Association for Cell Therapy

台北医学大学
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<td>林春元</td>
<td>台灣細胞醫療促進協會理事長 (召集人)</td>
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<td>楊淑卿</td>
<td>台灣細胞醫療促進協會秘書長</td>
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<tr>
<td>徐麗萍</td>
<td>臺大醫院外科系副教授</td>
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吳友志 臺北醫學大學細胞治療與再生醫學研究中心
助理研究員
吳玟欣 臺北醫學大學醫學系生化學科
熊兆男 臺北醫學大學醫學科技學院院經理
李美足 臺北醫學大學醫學系生化學科技正
羅翠勻 臺北醫學大學醫學系生化學科技士
藍佩琪 臺北醫學大學細胞治療與再生醫學研究中心
張可慧 臺北醫學大學醫學系生化學科
吳文文 台灣細胞醫療促進協會秘書

計畫申請組
黃彥華 臺北醫學大學 (召集人)
醫學系生化學科特聘教授兼主任
細胞治療與再生醫學研究中心主任
細胞治療與再生醫學國際博士學位學程主任
台灣細胞醫療促進協會理事
吳友志 臺北醫學大學細胞治療與再生醫學研究中心
助理研究員
吳玟欣 臺北醫學大學醫學系生化學科
藍佩琪 臺北醫學大學細胞治療與再生醫學研究中心
李美足 臺北醫學大學研發處研究推動中心主任
楊宗勳 臺北醫學大學研發處研究推動中心主任

現場工作人員
郭勇哲、賴思全、王曉峰、蘇鈺婷、高郁雯、邱伯涵、
甄沛勤、韓學薇、林宜衡、滕民豪、葉家亨、郭智嘉、
王苡茜、鄭紘偉、林柏興、凌祥曦、何芷芸、黃馨瑝、
翁顥珊
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The purpose of Taiwan Association for Cell Therapy (TACT) is to promote the Industry-Government-Academic cooperation for cell therapy; to advance the cell therapeutic technology and to accelerate education and industrial development in Taiwan.

The missions of TACT are:

1. to accelerate the development of cell therapeutic / medical technology in Taiwan;
2. to construct the platform of the Industry-Government-Academic cooperation for cell therapy in Taiwan;
3. to strengthen the communication of cell therapeutic / medical education of R&D in Taiwan;
4. to promoter the industrial development for cell therapeutic technology and products in Taiwan;
5. to update the regulation of cell therapy
Taipei Medical University (TMU), formerly known as Taipei Medical College (TMC), was founded on June 1, 1960 by Dr. Shui-Wang Hu, Dr. Cheng-Tien Hsu and other medical professionals and devoted educators. TMU is located on Wuxing Street in eastern Taipei.

Most of more than 30,000 TMU graduates serve in medical institutions and clinics, while many others are prominent figures in the fields of research, politics, and business. TMU has 7 colleges, 12 undergraduate schools and 14 graduate institutes as well as three affiliated hospitals - TMU Hospital, Wan Fang Hospital, and Shuangho Hospital. With approximately 3,000 beds, TMU is one of the largest health care systems and offers top-quality teaching, research and clinical services in the Taipei metropolitan area. We work continuously to improve the quality of teaching, research and clinical services with the goal of becoming a fully internationalized university that ranks in the top tier worldwide.

Together with its three affiliated hospitals, TMU promotes biomedical technology innovation and aims to study regenerative medicine and develop new cell therapies for clinical applications. **TMU Center for Cell Therapy and Regeneration Medicine** was founded with missions including integration of resources and research between TMU and its three affiliated hospitals, establishment of Good Tissue Practice (GTP) Core Laboratory and development of standard operating procedures for clinical-grade cell manufacturing, strengthening of international cooperation and facilitation of industry-academic collaboration, and cultivation of new talents through the International Ph.D. Program for Cell Therapy and Regeneration Medicine.
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<tr>
<th>Time</th>
<th>Session/Event</th>
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<tr>
<td>08:00~16:50</td>
<td>Registration</td>
<td>16F Conference Hall</td>
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<td>08:20~08:30</td>
<td>Opening Remarks</td>
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<td></td>
<td>TMU Board Chairman</td>
<td>Wen-Chang Chang, Ph.D., Academician (張文昌院士/董事長)</td>
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<td></td>
<td>TACT President</td>
<td>Yao-Chang Chen, M.D. (陳耀昌理事長)</td>
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<tr>
<td>08:30~08:30</td>
<td>Keynote Speaker: Cancer Immunotherapy by PD-1 Blockade</td>
<td>Tasuku Honjo, M.D., Ph.D. (本庶佑教授)</td>
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<td>Professor, Graduate School of Medicine, Kyoto University</td>
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<td>09:15~09:25</td>
<td>Group Photography</td>
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<td>09:45~10:30</td>
<td>Keynote Speaker: Mesenchymal Stem Cell-mediated Immune Therapies in Autoimmune Diseases</td>
<td>Song-Tao Shi, DDS, MS., Ph.D. (施松濤教授)</td>
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<td>Chair and Professor, Department of Anatomy &amp; Cell Biology, The Robert Schattner Center, University of Pennsylvania, School of Dental Medicine</td>
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<td>10:30~11:00</td>
<td>Application of Regulatory T Cells Induced by B Cells for Immune Modulation in Immunological Diseases</td>
<td>Bor-Luen Chiang, M.D., Ph.D. (江伯倫教授)</td>
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<td>Professor, Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University</td>
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<td>11:00~11:30</td>
<td>Personalized Cancer Immunotherapy</td>
<td>Kazuhiro Kakimi, M.D., Ph.D. (垣見和宏教授)</td>
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<td>Professor, Department of Immunotherapeutics, The University of Tokyo Hospital</td>
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<td>11:30~12:00</td>
<td>Next Generation MSC Therapy: MSC Exosome</td>
<td>Sai-Kiang Lim, M.D., Ph.D. (林賽娟教授)</td>
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<td>Director, Institute of Medical Biology Singapore</td>
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<td>TACT Annual Meeting (會員大會 / 16F)</td>
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<td>12:00~13:30</td>
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<td>13:30~14:00</td>
<td>Regenerative Medicine: Gene and Stem Cell Therapy for Lung Injury</td>
<td>Cheng-Wen Wu, M.D., Ph.D., Academician (吳成文院士)</td>
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<td>Founding President, National Health Research Institutes</td>
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<td>Corresponding Investigator, Institute of Biomedical Sciences Academia Sinica</td>
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<td>Academician, Academia Sinica</td>
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<td>14:00~14:30</td>
<td>Middle Ear Mucosal Regeneration by Nasal Mucosal Epithelial Cell Sheets Transplantation</td>
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### 14:30~14:50 Strategies Preventing Arrhythmogenesis in Cardiac Stem Cell Therapy

Patrick C.H. Hsieh, M.D., Ph.D. (謝清河教授)
Research Fellow & Professor, Institute of Biomedical Sciences, Academia Sinica, Taipei, Taiwan

### 14:50~15:10 Practice from Preclinical Study to Clinical Trial in TMU

Yen-Hua Huang, Ph.D. (黃彥華教授)
Distinguished Professor and Director, Department of Biochemistry and Molecular Cell Biology, Graduate Institute of Medical Sciences, College of Medicine, and Center for Cell Therapy and Regeneration Medicine, Taipei Medical University, Taiwan

### 15:10~15:30 Coffee Break

### 15:30~16:00 Rationales & Strategies for Targeting Tumor-Associated Carbohydrates for Cancer Immunotherapy

Alice L. Yu, M.D., Ph.D. Academician (陳鈴津院士)
Distinguished Chair Professor & Co-director, Institute of Stem Cell and Translational Cancer Research, Chang Gung Memorial Hospital at Linkou & Chang Gung University
Academician, Academia Sinica

### 16:00~16:30 Five-Year Follow-Up of Clinical Feasibilities Study of A Novel Biphasic Osteochondral Composite for Matrix-Associated Autologous Chondrocyte Implantation

Ching-Chuan Jiang, M.D., Ph.D. (江清泉教授)
Professor of Orthopaedic Surgery, Medical College, National Taiwan University

### 16:30~16:50 Hypoxic Culture of Mesenchymal Stem Cells: From Bench to Bedside

Shih-Chieh Hung, M.D., Ph.D. (洪士杰教授)
Distinguished Professor & Director, Institute of New Drug Development, China Medical University, Integrative Stem Cell Center, China Medical University Hospital

### 16:50~17:10 Development of Cellular Reprogramming and iPSC Technology as Personalized Medicine-based Platform: From Bench to Clinic Bedside

Shih-Hwa Chiou, M.D., Ph.D. (邱士華教授)
Chief, Stem Cell Center, Department of Medical Research, Taipei Veterans General Hospital
Genomic Center & Institute of Pharmacology, National Yang-Ming University, Taipei, Taiwan

### 17:10~17:30 Bioengineered Urogenital Organs

Shauh-Der Yeh, M.D., Ph.D. (葉劭德教授)
Director, Department of Urology Taipei Medical University Hospital
Assistant Professor, Graduate Institute of Clinical Medicine, Taipei Medical University

### 17:30~18:30 Poster Visit

### 18:30~20:30 Banquet (By Invitation Only)
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<td>Yao-Chang Chen, M.D. (TACT, Chair) 陳耀昌理事長</td>
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<td>Yun Yen, M.D., Ph.D. F.A.C.P. (TMU President) 閻雲校長</td>
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<td>Akihiro Shimosaka, Ph.D. (ACTO, Chair) 下坂皓洋主席</td>
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<tr>
<td>10:00~10:30</td>
<td>Group Photography / Coffee Break</td>
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<td>10:30~10:45</td>
<td>Guest Speech</td>
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<td>10:45~11:00</td>
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<td>Takuya Yokokawa (横川拓哉運営委員長)</td>
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<td>Forum for Innovative Regenerative Medicine. (FIRM)</td>
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<td>10:45~11:00</td>
<td>A Dream of &quot;Taiwan Stem Cell Team&quot;</td>
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<td>Yao-Chang Chen, M.D. (陳耀昌理事長)</td>
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<td>Professor, National Taiwan University, Taipei, Taiwan</td>
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<td>President, Taiwan Association for Cell Therapy (TACT)</td>
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<td>11:00~11:30</td>
<td>Regulatory Trends in Regenerative Medicine in Japan</td>
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<td>Yoshiaki Maruyama, Ph.D. (丸山良亮博士)</td>
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<td>Review Director, Office for Cellular and Tissue based Products</td>
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<td>Pharmaceuticals and Medical Devices Agency (PMDA), Japan</td>
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<tr>
<td>11:30~12:00</td>
<td>Current Status of Cell Therapy Clinical Trials in Taiwan</td>
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<td>Chih-Liu Lin, M.D. (林志六副執行長)</td>
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<td>Deputy Executive Director, Center for Drug Evaluation (CDE), Taiwan</td>
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<td>12:00~13:20</td>
<td>Lunch/Poster Visit</td>
<td>B1/1F</td>
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<td>13:20~13:40</td>
<td>Clinical Trial of Esophageal Epithelium Cell Sheets in Japan</td>
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<td>Setsuko Hashimoto, Ph.D. (橋本節子教授)</td>
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<td>13:40~14:00</td>
<td>Key Functions for Cell Therapies for Patients-Contract Cell Manufacturing Business</td>
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<td>Kunihiko Suzuki (鈴木邦彥副會長)</td>
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<td>Member of the Board, Vice Chairman, MEDINET Co., Ltd</td>
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<td>14:00~14:20</td>
<td>Kenzan Method: Scaffold-Free Three Dimensional Tissue Creation for Transplantation and Research</td>
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<td>Hitoshi Torii (鳥居仁執行長)</td>
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<td>Time</td>
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<td>14:20~14:40</td>
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<td>Ikki Horiguchi, Ph.D.</td>
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<td>14:40~15:00</td>
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<td>Junichi Masuyama, M.D., Ph.D.</td>
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<td>15:00~15:20</td>
<td>Coffee Break</td>
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<td>15:20~15:40</td>
<td>Session IV</td>
<td>Wann-Hsin Chen, Ph.D.</td>
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<td>Yen-Chung Chen, Ph.D. (陳彥聰資深研究員)</td>
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<td>16:00~16:20</td>
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<td>Celine Pang, Ph.D. (龐德玲博士)</td>
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<td>16:20~16:40</td>
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<td>James Tsai, Ph.D. (蔡嘉櫸總經理)</td>
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<td>16:40~17:00</td>
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<td>Kevin Ho (何智元業務發展經理)</td>
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<td>17:00~17:10</td>
<td>Closing Remarks</td>
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<td>TACT President Yao-Chang Chen M.D. (陳耀昌理事長)</td>
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<td>TMU Vice President Chien-Huang Lin, Ph.D. (林建煌副校長)</td>
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<td>17:10~18:00</td>
<td>Closed Door Discussion</td>
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<td>Moderator: Yao-Chang Chen M.D. (陳耀昌理事長)</td>
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<td>Chien-Huang Lin, Ph.D. (林建煌副校長)</td>
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<td>MOST (Ministry of Science &amp; Technology, Taiwan)</td>
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<td>19:00~21:00</td>
<td>Banquet/Awards Ceremony</td>
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Map Guidance

**Roads & Streets**
A. 220 Lane, WuXing Street
B. Wusung Street (WuXing Street)
C. 284 Lane, WuXing Street
D. 22 Alley, 284 Lane, WuXing Street

**Buildings**
1. Health Science Building
2. Auditorium
3. United Medical Building (Front Building)
4. United Medical Building (Back Building)
5. Oral Medicine Building
6. Instruction Building
7. Medical Laboratory Science and Biotechnology Building A
8. Medical Laboratory Science and Biotechnology Building B
9. Morphology Building
10. Gymnasium
11. Mushan Dormitory
12. First Building, Taipei Medical University Hospital
13. Second Building, Taipei Medical University Hospital
14. Third Building, Taipei Medical University Hospital

**Entrances**
1. University Entrance
2. Hospital Entrance
3. Ambulance Entrance
United Medical Back Building, 16F Lecture Hall

United Medical Back Building, B1 FL.
Transportation

TMU shuttle service
The school is located near MRT Taipei City Hall (Blue Line) and Liuzhangli (Brown Line) stations, and TMU provides shuttle services to both. Buses run every 15 minutes between the City Hall station and TMU (see route map), while the Liuzhangli shuttle bus runs every half an hour.

Public transit
Public transportation to TMU includes bus lines 266, 288, 226, 1, 235, 22, 33, Blue 5, and minibus 7.
Driving directions (自行開車)

高速公路
(國道3號) 由信義快速道路下來進入信義路，左轉松仁路，右轉松勤街，左轉松智路後直行過莊敬路約再300公尺，左側即可見臺北醫學大學校園。
(環東大道) 由基隆路下，直行往台北市政府方向，左轉松高路，右轉松智路。
TMU Wireless Setting

On campus SSID:
TMU-WLAN
TMU-wireless

Users from other Universities of Taiwan:
Username: your school email (include “@XXX.edu.tw”)
Password: as your school email’s password

Other Users
Username: TMU001 / Password: lqz658li
Username: TMU002 / Password: hnd187vg
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**Exhibition at 1F Lobby**

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16F-3 美商貝克曼庫爾特有限公司台灣分公司

16F-4 捷昇生物科技有限公司
Exhibitor at 1F Lobby

1F-1 英屬維京群島商勝澐國際股份有限公司台灣分公司
1F-2 艾瑞生醫股份有限公司
1F-3 宏騏實業股份有限公司
1F-4 萊富生命科技股份有限公司
Introduction of Moderator & Invited Speaker’s Brief
Curriculum Vitae
Abstract
Session I (October 28th 08:30-09:25)

Moderator

Wen-Chang Chang, Ph.D., Academician 張文昌院士

TMU Board Chairman
Chair Professor, Graduate Institute of Medical Sciences, College of Medicine, Taipei Medical University
National Chair Professor of the Ministry of Education
Emeritus Distinguished Chair Professor of National Cheng Kung University
Academician, Academia Sinica
E-Mail: wcchang@mail.ncku.edu.tw

Distinguished Research Award, National Science Council, Taiwan (1985-1989, 1991-1995)
Wu San-Lien Award in Medical Science, Wu San-Lien Award Foundation, Taiwan (1993)
Distinguished Research Award, Chinese Pharmacological Society, Taiwan (1994)
Glaxo-William Harvey Medical Award, Glaxo Co., Taiwan (1995)
Board Award, Chinese Education and Culture Foundation, Taiwan (1996)
Distinguished Scientist, specially contracted with National Science Council, Taiwan (1997-2003)
Science Academy Award, Ministry of Education, Taiwan (1998)
National Chair Professor, Ministry of Education, Taiwan (since 2001)
University Chair Professor of National Cheng Kung University (2001)
Merit NSC Research Fellow Award, Taiwan (2004)
Academician of Academia Sinica (2004)
APEX International Honor Society for Leadership, Honorary Member (2004)
K. T. Lee’s Science and Technology Chair, Honorary Scholar Award (2005)
Phi Tau Phi Scholastic Honor Society, Outstanding Achievement Award and Honorary Members (2006)
The 16th Annual Wang Ming-Ning Award (2006)
Distinguished Chair Professor of National Cheng Kung University (2007)
Emeritus Distinguished Chair Professor, National Cheng Kung University (2011/4)
Member of the Third World Academy of Sciences (2011/11)
K. T. Lee’s Science and Technology Chair, Chair Professor (2015)
Tasuku Honjo, M.D., Ph.D. 本庶佑教授

Professor,
Department of Immunology and Genomic Medicine,
Graduate School of Medicine, Kyoto University, Kyoto, Japan
Chairman, Board of Directors,
Shizuoka Prefectural University Corporation, Shizuoka, Japan
President,
Foundation for Biomedical Research and Innovation, Kobe, Japan
Email: Honjo@mfour.med.kyoto-u.ac.jp

AWARDS AND HONOR:

1981  Noguchi Hideyo-Memorial Award for Medicine
1982  Asahi Prize
1984  Osaka Science Prize
1984  Kihara Prize of the Japanese Genetics Society
1985  Erwin von Bälz Prize
1988  Takeda Medical Prize
1991-96  Fogarty Scholar-in-residence at NIH
1992  Behring-Kitasato Prize
1994  Uehara Prize
1996  The Imperial Prize and the Japan Academy Prize
2000  Award “Persons of Cultural Merit” by Japanese Government
2001  Foreign Associate of U.S. National Academy of Sciences
2003  Member of Leopoldina (The German Academy of Natural Scientists)
2004  Leading Japanese Scientists in Emerging Research Fronts (Thomson)
2005  Member of Japan Academy
2012  Robert Koch Prize
2013  Order of Culture, Japan
2014  Tang Prize, Biopharmaceutical Science Award
2014  William B. Coley Award
2014  JCA-CHAAO Award
2015  Richard V. Smalley, MD Memorial Award
2016  Kyoto Prize
2016  The Keio Medical Science Prize
CANCER IMMUNOTHERAPY BY PD-1 BLOCKADE

Tasuku Honjo

Department of Immunology and Genomic Medicine, Graduate School of Medicine, Kyoto University, Kyoto, Japan

Abstract

PD-1, a negative coreceptor expressed on antigen-stimulated T cells and B cells, seems to serve as a ‘rheostat’ of the immune response. The molecular mechanisms of the functions of PD-1, in conjunction with the mild, chronic and strain-specific autoimmune phenotypes of PD-1-deficient mice, suggest that immunoregulation by PD-1 is rather antigen specific and is mainly cell intrinsic. Such unique properties make PD-1 a powerful target for immunological therapy, with highly effective clinical applications for cancer treatment.

In fact, immune checkpoint blockade with anti-PD-1 has revolutionalized cancer therapy as it has many advantages over the other treatments; (a) applicable to almost all types of cancer at any stages; (b) long duration; and (c) weak side-effects. It is most likely that anti-PD-1 will be the first choice of cancer treatment in a near future. The striking effects of anti-PD-1 depend on three basic principles; (a) the immune system can recognize mutated cancer antigens (b) the diversity of the immune repertoire is much larger than variations generated by mutations in tumor cells, and (c) the immune system is tolerized in tumor patients by excessive negative regulations of the immune system. I will provide historical perspective how we reached the new innovation of cancer treatment and discuss future perspective.
Session II (October 28th 09:45-12:00)

Moderator

Leroy F. Liu, Ph.D., Academician 劉昉院士

Vice President,
Taipei Medical University
Academician,
Academia Sinica, Taiwan
Professor,
Department of Pharmacology, Rutgers-Robert Wood Johnson Medical School

Email: lliu88@yahoo.com

Recent Selective Publications:


Session II (October 28th 09:45-12:00)

Moderator

Po-Huang Lee, M.D., Ph. D. 李伯皇教授

Professor and Physician,
Department of Surgery, National Taiwan University Hospital

Email: pohuang1115@ntu.edu.tw

Professor Lee graduated from the National Taiwan University (NTU), College of Medicine in 1974, and the Medical Science Graduate Institute of Clinical Medicine, NTU in 1986. He received his surgical residency training in the National Taiwan University Hospital (1975-1979) and fellowship training in liver transplantation in the University of Pittsburgh (1986-1987). Professor Lee is a Visiting Professor of Surgery and former Chairman of Department of Surgery, School of Medicine, National Taiwan University. He also served as the former president of Taiwan Transplantation Society, Taiwan Society of Digestive Surgery, Taiwan Surgical Society, the Asian Surgical Association, and the Vice President of the International Society for Digestive Surgery. He retired from National Taiwan University in Feb 2013 and was appointed as Emeritus Professor in August. Currently Professor Lee is the Distinguished Chair Professor of the College of Medicine of I-Shou University, the Chief Executive Officer of E-Da Medical Group, and Chairman, Committee of Medicine and Biomedical Technology, E-United Group in Taiwan. His major research interests are liver transplantation, liver regeneration and surgical oncology in liver surgery. He has more than 500 publications related to kidney and liver transplantation and liver surgery for hepatic malignancies.
Songtao Shi, D.D.S., Ph.D. 施松涛教授
Chair and Professor,
Department of Anatomy & Cell Biology,
The Robert Schattner Center,
University of Pennsylvania, School of Dental Medicine,
Philadelphia, US

Email: songtaos@dental.upenn.edu

Recent Selective Publications:
MESENCHYMAL STEM CELL-MEDIATED IMMUNE THERAPIES IN AUTOIMMUNE DISEASES

Sogntao Shi, DDS, MS, PhD
University of Pennsylvania, Philadelphia, US

Abstract
Mesenchymal stem cells (MSCs) are multipotent postnatal stem cells capable of regenerating mineralized and non-mineralized tissues and interplaying with various immune cells. MSCs are widely used to treat a variety of autoimmune diseases, such as graft versus host disease, diabetes, rheumatoid arthritis, autoimmune encephalomyelitis, inflammatory bowel disease, systemic lupus erythematosus and multiple sclerosis. However, detailed mechanism by which MSC transplantation (MSCT) offers effective immune therapies is not fully understood. Our recent studies showed that MSCs use multiple mechanisms to interplay with the recipient cells to ameliorate disease phenotypes. MSCs are capable of inducing recipient activated T cell apoptosis via Fas/Fas ligand pathway to trigger macrophage to take debris of apoptotic T cells, resulting in an elevated TGF level and immune tolerance in systemic sclerosis. In addition, exosomes secreted by donor MSCs during MSCT may provide functional cell components and miRNA, thereby rescuing recipient impaired MSCs or immune cells via a reuse mechanism. Thus, our findings demonstrate that MSCT rescues recipient MSC function through a donor cellular component or miRNA reuse mechanism that serves to regulate epigenetic cascade.
Recent Selective Publications:


APPLICATION OF REGULATORY T CELLS INDUCED BY B CELLS
FOR IMMUNE MODULATION IN IMMUNOLOGICAL DISEASES

Bor-Luen Chiang
Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University

Abstract
In the past several years, our team has focused on exploring the characteristics of a certain subpopulation of regulatory T cells induced by B cells. We have initially found that LAG3 molecule might play the critical role in the functions of Treg-of-B cells. Further, the results also demonstrated that Foxp3 and IL-10 were not necessary for the development and functions of Treg-of-B cells. All these results suggested that these Treg-of-B cells are different from the conventional naturally occurring regulatory T cells (nTreg cells) and inducible type 1 regulatory T cells (Tr1 cells). The regulatory T cells described in our study could be the novel subset of the regulatory T cells, which might open the brand new approaches for the pathway of immune regulation. In the past three years, we have analyzed these Treg-of-B cells with the methods of microarray and quantitative RT-PCR and identified a variety of candidate genes and molecules. We have applied these Treg/B cells for the treatment of several animal model of immunological diseases such as asthma, collagen-induced arthritis and inflammatory bowel disease. All the data suggested that Treg/B cells could alleviate disease severity of these immunological diseases. From our results, it is suggested that relatively large number of regulatory T cells could be induced with our approaches, which could make it easier for the potential application. In addition, novel genes or molecules identified in the study could become the target molecules for the future development of immune target therapy as well.
Kazuhiro Kakimi, M.D., Ph.D. 垣見和宏教授

Project Professor, 
Department of Immunotherapeutics, 
The University of Tokyo Hospital 
E-mail: kakimi@m.u-tokyo.ac.jp

Recent Selective Publications:
PERSONALIZED CANCER IMMUNOTHERAPY

Kazuhiro Kakimi

Department of Immunotherapeutics, the University of Tokyo Hospital

Abstract
Since the anti-PD-1 monoclonal antibodies nivolumab and pembrolizumab were approved for the treatment of NSCLC, robust and durable responses have been observed, but only 20~30% of patients responded to the therapy. Although the expression of PD-L1 or the number of tumor neoantigens was reported to correlate with treatment outcome, better predictive biomarkers for distinguishing between those patients who will respond to therapy and those who should be offered alternative treatments is warranted.

Anti-cancer immunity is a dynamic process described as a Cancer-Immunity Cycle; different steps in the cycle by which tumors escape immunosurveillance are likely to be different patient by patient. Therefore, we propose to construct an immunogram for each patient in order to better understand the individual patient’s immunological status and to clarify the steps where the anti-cancer response is blocked. Recently, we defined the “Immunogram for the Cancer-Immunity Cycle” using NGS data and were able to visualize the status of potential anti-tumor immune responses within the tumor. Three immunogram patterns were observed in lung cancer patients: T-cell-rich, T-cell-poor and intermediate. The T-cell-rich pattern was characterized by gene signatures of abundant T cells, Tregs and MDSCs, checkpoint molecules and immune-inhibitory molecules in the tumor, suggesting the presence of anti-tumor immunity dampened by an immunosuppressive microenvironment. The T-cell-poor phenotype reflected lack of anti-tumor immunity, inadequate DC activation, and insufficient antigen presentation in the tumor. Immunograms for both the adenocarcinoma patients and the non-adenocarcinoma patients included both T cell-rich and T cell-poor phenotypes, suggesting that histology does not necessarily reflect the cancer-immunity status of the tumor.

Future immunotherapy needs to be personalized in terms of the identification of immunosuppressive mechanisms as well as target antigens and integrated with immune regulatory strategies. The patient-specific landscape of the tumor microenvironment can be appreciated using immunograms as integrated biomarkers, which may thus become a valuable resource for optimal personalized immunotherapy.

Keywords: neoantigen, cancer-immunity cycle, immunogram
Lim Sai Kiang, M.D., Ph.D. 林賽娟教授

Research Director,
A*STAR Institute of Medical Biology
Director,
Graduate Affairs, A*STAR BMRC

E-mail: saikiang.lim@imb.a-star.edu.sg

Recent Selective Publications:


NEXT GENERATION MSC THERAPY: MSC EXOSOME

Sai Kiang Lim, PhD

A*STAR Institute of Medical Biology, Singapore

Abstract
Mesenchymal stem cells (MSCs) are currently the leading stem cell type in clinical trials and in scientific publications. Their use to treat a wide range of diseases was predicated on their potential to differentiate into many cell types. However, observations from animal studies and clinical studies generally suggest that MSCs exert their therapeutic efficacy through their secretion. Recently, it was discovered that Extracellular Vehicles (EVs) mediate many of the MSC therapeutic activity. EV is a collective terms for secreted bi-lipid membrane vesicles carrying proteins and RNA, and it include exosomes, microvesicles, apoptotic bodies etc. Exosomes are 50-150nm EVs. MSC exosomes were used purified and shown to be efficacious in reducing reperfusion injury in a mouse model of myocardial ischemia/reperfusion injury. Since then, MSC exosomes were reported to be efficacious against many diseases. This talk will describe the discovery and isolation of MSC exosomes, the possible mechanism of action and the implications for future development of MSC therapy.

Keywords: Mesenchymal stem cells, exosomes, therapy
Session III (October 28th 13:30-15:10)

Moderator

Wen-Chang Chang, Ph.D., Academician 張文昌院士

TMU Board Chairman
Chair Professor, Graduate Institute of Medical Sciences, College of Medicine, Taipei Medical University
National Chair Professor of the Ministry of Education
Emeritus Distinguished Chair Professor of National Cheng Kung University
Academician, Academia Sinica

E-Mail: wcchang@mail.ncku.edu.tw

Distinguished Research Award, National Science Council, Taiwan (1985-1989, 1991-1995)
Wu San-Lien Award in Medical Science, Wu San-Lien Award Foundation, Taiwan (1993)
Distinguished Research Award, Chinese Pharmacological Society, Taiwan (1994)
Glaxo-William Harvey Medical Award, Glaxo Co., Taiwan (1995)
Board Award, Chinese Education and Culture Foundation, Taiwan (1996)
Distinguished Scientist, specially contracted with National Science Council, Taiwan (1997-2003)
Science Academy Award, Ministry of Education, Taiwan (1998)
National Chair Professor, Ministry of Education, Taiwan (since 2001)
University Chair Professor of National Cheng Kung University (2001)
Merit NSC Research Fellow Award, Taiwan (2004)
Academician of Academia Sinica (2004)
APEX International Honor Society for Leadership, Honorary Member (2004)
K. T. Lee’s Science and Technology Chair, Honorary Scholar Award (2005)
Phi Tau Phi Scholastic Honor Society, Outstanding Achievement Award and Honorary Members (2006)
The 16th Annual Wang Ming-Ning Award (2006)
Distinguished Chair Professor of National Cheng Kung University (2007)
Emeritus Distinguished Chair Professor, National Cheng Kung University (2011/4)
Member of the Third World Academy of Sciences (2011/11)
K. T. Lee’s Science and Technology Chair, Chair Professor (2015)
Session III (October 28th 13:30-15:10)

Moderator

Shinn-Zong (John) Lin, MD, PhD, FAAAS, FNAI, IFAANS, CPI 林欣榮教授

Superintendent, Hualien Tzu Chi Hospital, Taiwan
Professor of Neurosurgery, Tzu Chi Medical University, Taiwan.
Fellow of American Association for the Advancement of Science (AAAS)
Fellow of American Association of Neurological Surgery (AANS)
Charter Fellow of National Academy of Inventors (NAI)
E-Mail: shinnzong@yahoo.com.tw

Recent Selective Publications:


Recent Selective Publications:


REGENERATIVE MEDICINE: GENE AND STEM CELL THERAPY
FOR LUNG INJURY

Cheng-Wen Wu

Distinguished Chair Professor, National Yang-Ming University, Taipei, Taiwan

Abstract
Lung is a vital organ with highly complex architectural structure and contains a variety of cell populations. Lung diseases, such as acute respiratory distress syndrome (ARDS) or chronic obstructive pulmonary disease (COPD), are both major public health problems but currently without any effective pharmacologic approach for the treatment. Stem cell therapy based on transplantation of in vitro propagated stem/progenitor cells has been proposed as a potential solution to restore lung functions. However, due to the complexity of cell source and lung microenvironment, whether transplanted cells have differentiated for reconstitution of airway/alveolar epithelium were questioned. Furthermore, safety issues have raised concerning the use of stem cells in vivo.

Gene therapy has long been considered as a promising approach for the treatment of a variety of diseases. Although past studies using viral vectors in human has been hampered due to adverse effects and safety issues, recent clinical trials have shown remarkable therapeutic benefits and an excellent safety record of gene therapy with improved vector designs. Our lab has focused on in vivo gene delivery of stemness genes in somatic lung epithelial cells using PEI nanoparticles for lung injury treatment. In mouse model of elastase-induced emphysema, we found that the transient gene delivery of BMI-1 in alveolar epithelial cells post-injury induced efficient regeneration of alveolar epithelium and improved pulmonary function. The regenerated regions showed normal alveolar epithelial phenotype and extracellular matrix components, without the symptoms of neoplasia. Furthermore, the treatment enriched the population of slow-cycling cells that appeared after injury. The BMI-1 target cells were further sorted and cultured in vitro, which formed colonies within a week. Whether these cells may undergo an in vivo reprogramming process and transiently acquire the stemness property for tissue regeneration remains to be further clarified by gene expression and epigenetic profile analyses.

In summary, our study suggests that in vivo delivery of stemness genes in somatic cells in pathologic loci is a feasible approach for tissue regeneration. The target cells could proliferate and differentiate more efficiently due to the native identity and microenvironment. Such approach also avoids the complexities of in vitro propagating stem/progenitor cells resulting from differences in cell source and culture conditions. In vivo gene delivery may hold promise for the future treatment of lung diseases such as ARDS or COPD.
Kazuhisa Yamamoto, M.D., Ph.D. 山本和央教授
Assistant professor,
Department of Otorhinolaryngology, Jikei University School of Medicine, Tokyo
E-mail: kyamamoto1109@gmail.com

Recent Selective Publications:
MIDDLE EAR MUCOSAL REGENERATION BY NASAL MUCOSAL EPITHELIAL CELL SHEETS TRANSPLANTATION

Kazuhisa Yamamoto

Department of Otorhinolaryngology, Jikei University School of Medicine, Tokyo, Japan

Abstract

Recurrence of cholesteatoma is mainly caused by poor mucosal regeneration in the middle ear cavity and mastoid cavity, and changes such as granulation tissue formation can occur, which impair gaseous exchange in the middle ear cavity. If middle ear mucosa can be preserved and the rapid postoperative regeneration of mucosa on the exposed bone surface can be achieved after middle ear surgery, surgical treatment for otitis media including cholesteatoma can be potentially improved, and the physiological function of middle ear can be recovered. Conventional canal wall up tympanoplasty often results in a lack of mucosal regeneration in the resected area of the mastoid cavity and changes such as granulation tissue formation occur. In particular, mucosal regeneration in a poorly pneumatized mastoid cavity is extremely difficult. To overcome these limitations, we developed a novel method combining canal wall up tympanoplasty and autologous epithelial cell sheet transplantation for postoperative regeneration of the middle ear mucosa.

We obtained the approval of the ethics committee of our institution and the Ministry of Health, Labor, and Welfare. In the clinical research, we endoscopically removed an approximately 10 × 10-mm² nasal mucosal tissue from her inferior concha. Tissue-engineered autologous nasal mucosal epithelial cell sheets were fabricated by culturing the harvested cells using keratinocyte culture medium (KCM) containing autologous serum for 26 days in an aseptic environment in a good manufacturing practice (GMP)-compliant cell processing facility (CPF). The cultivated cell sheets were transplanted, during canal wall up tympanoplasty, onto the exposed bony surface of the attic of the tympanic and mastoid cavities where the mucosa was lost.

We have performed this procedure on five patients with middle ear cholesteatoma. All patients showed a favorable postoperative course, with no adverse events or complications, and the post transplanted hearing results also remained good.

Keywords: Mucosal regeneration, Cell sheet, Cholesteatoma, Tympanoplasty, Nasal mucosa
Patrick C.H. Hsieh, M.D., Ph.D. 謝清河教授

Research Fellow and Professor,
Institute of Biomedical Sciences, Academia Sinica
Institute of Medical Genomics and Proteomics, National Taiwan University & Hospital

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Recent Selective Publications:

Abstract
Despite significant advances in the treatment of ischemic heart disease, it remains the leading cause of mortality worldwide. Undoubtedly, methods for regenerating the injured human heart are urgently needed and whilst exciting progress has been made from utilizing stem cell therapy for cardiac regeneration, several major challenges still remain. In particular, one major safety issue is the occurrence of potentially life-threatening ventricular arrhythmias after cell therapy. Several drivers may be responsible for this, ranging from the potential inherent arrhythmogenicity of delivered stem cells to that of the underlying ischemic myocardium. Therefore, it is imperative to thoroughly assess the risk-to-benefit ratio of such treatments prior to the clinical application. As such, despite the considerable progress made in stem cell therapy over the past decades, many obstacles still lie ahead.

Keywords: Cardiac regeneration, stem cell therapy, arrhythmia
Recent Selective Publications


**Abstract**

Clinical use of cells and/or stem cells is current potential treatment targeting on diseases of unmet medical needs. To facilitate the future promising of cell therapy in Taipei Medical University (TMU), we have established university-grade Center for Cell Therapy and Regeneration Medicine (TMU CCTRM) and GTP Lab to speed-up preparation of clinical grade cells and stem cells and promote cell/stem cell translational medicine and cell therapy clinical trial. Our main efforts will focus on cancer treatment and regeneration medicine using immune cells (T cell and NK cells), blood stem cells, mesenchymal stem cells, and drug screening of cancer stem cells; and, the disease-specific induced pluripotent stem cells (disease iPS cells). We hope to strengthen the international cooperation with experts in basic research, preclinical animal study, clinical translational medicine, and industry development in the future. For the future incubation of high-grade experts in field, we have been approved by Ministry of Education for the “International PhD Program for Cell Therapy and Regeneration Medicine (IPCTRM)” from 2017. In this talk, the practice of preclinical study to clinical trial for novel peripheral small blood stem cells and mesenchymal stem cells will be discussed.
Session IV (October 28th 15:30-17:30)

Moderator

Chii-Ruey Tzeng, M.D. 曾啟瑞教授
Professor and Chairman,
Department of Obstetrics and Gynecology
Taipei Medical University
E-Mail: tzengcr@tmu.edu.tw

Recent Selective Publications

Session IV (October 28th 15:30-17:30)

Moderator

Oscar Kuang-Sheng Lee M.D., Ph.D. 李光申教授
Distinguished Professor, Institute of Clinical Medicine,
Director, Stem Cell Research Center,
National Yang-Ming University
Professor, Department of Orthopaedics and Traumatology,
Taipei Veterans General Hospital
Clinical Professor, School of Medicine,
National Defense Medical Center
E-mail: DAV47@tpech.gov.tw

Recent Selective Publications


Alice L. Yu, M.D., Ph.D. Academy 陈鈴津院士

Distinguished Chair Professor & Co-director,
Institute of Stem Cell and Translational Cancer Research, Chang Gung
Memorial Hospital at Linkou & Chang Gung University
Academician, Academia Sinica
E-Mail: aliceyu@cgmh.org.tw

Awards
2016  Academician, Academia Sinica, Taiwan;
2016  Excellence in Technology Transfer Award 2016 from Federal Laboratory Consortium, USA
2011  The 55th Academic Award from the Ministry of Education
2009  The 19th Wang Min-Ning Memorial Award for Outstanding Contribution to the Development Medical Science and Technology, National Health and Society
2001  Recipient of the Year 2000 “Key to Life” Award from the Leukemia & Lymphoma Society

Recent Selective Publications
RATIONALES & STRATEGIES FOR TARGETING TUMOR-ASSOCIATED CARBOHYDRATES FOR CANCER IMMUNOTHERAPY

Alice L. Yu

Distinguished Chair Professor & Co-director, Institute of Stem Cell and Translational Cancer Research, Chang Gung Memorial Hospital at Linkou & Chang Gung University Genomics Research Center, Academia Sinica.

Abstract

Until recently, all approved cancer immunotherapeutics target proteins but not glycans. The approval of Unituxin, a chimeric anti-GD2 antibody, ch14.18 for the treatment of high-risk neuroblastoma by US FDA and European Commission in 2015 marks the first new agent targeting a glycolipid molecule, thereby widening the net of potential pharmaceutical targets. It is also the first agent approved for therapy aimed specifically for neuroblastoma. This was largely based on the pioneer work of Dr. Yu and her leadership during the entire course of ch14.18 development, from preclinical studies all the way through the final randomized phase III clinical trial. Her recent studies focused on another glycan, Globo H, which is the most prevalent cancer-associated antigens. Her group showed that Globo H and its precursor, Gb5 (SSEA3) are present in breast cancer stem cells. They further provided the first evidence that Globo H-ceramide (GHCer) acts as an immune checkpoint by suppressing T and B cell immune responses via downregulation of Notch1 signaling. GHCer is also incorporated into endothelial cells, enhancing angiogenesis. Clinically, Globo H+ breast cancer specimens contained Globo H+ tumor infiltrating lymphocytes, and higher vessel density than Globo-H- tumors. Mechanistic investigations linked its angiogenic effects to its binding to TRAX, thereby releasing PLCb1 from TRAX to trigger Ca2+ mobilization. Thus, GHCer plays triple roles in serving as a cancer antigen (including breast cancer stem cells), as an immune checkpoint and as an angiogenic factor, thereby propelling the ongoing multi-national phase II/III clinical trial of Globo H vaccine in breast cancer. The results showed significant prolongation of progression free survival and overall survival in those patients who generated significant anti-Gbloo H antibody responses. In addition to Globo H vaccine, bispecific antibody and CAR-T cells directed against Globo H are ongoing in collaboration with the Development Center of Biotechnology in Taiwan.
Recent Selective Publications


FIVE-YEAR FOLLOW-UP OF CLINICAL FEASIBILITIES STUDY OF A NOVEL BIPHASIC OSTEOCHONDRAL COMPOSITE FOR MATRIX-ASSOCIATED AUTOLOGOUS CHONDROCYTE IMPLANTATION

Ching-Chuan Jiang¹, Hongsen Chiang¹, ChangHsun Hsieh¹, Chia-Jung Tsai¹

¹Department of Orthopaedic Surgery, National Taiwan University Hospital

Abstract
Ten patients with symptomatic osteochondral lesions at femoral condyles were treated by replacing the pathological tissue with autologous chondrocyte-laden biphasic osteochondral composite. Outcome of repair was examined by KOOS at 3, 6, 12, 24, 36 and 60 months postoperatively, second-look arthroscopic needle-biopsy was done at 12 months. The primary outcome parameter was the postoperative change of KOOS at 1, 3 and 5 years; and the secondary outcome parameter was the regeneration of cancellous bone and hyaline cartilage at the repair site which was evaluated by C/T scan at 3 years and MRI scan at 3 and 5 years follow-up. Mean KOOS was compared with paired t-test.

No patient experienced serious adverse events. The mean KOOS in the “function, sports and recreational activities” were significantly higher than the pre-operative at any time of follow-up. The subchondral lesions became smaller over three and five years. At twelve months, gross appearance of the repair site under arthroscopy showed full-filling of the grafted site, with the surface of regenerate cartilage flush with the surrounding native joint surface. Microscopic examination of the regenerate tissue showed formation of hyaline cartilage.

Summary: The five years follow-up result of chondrocyte implantation with the novel biphasic matrix showed successful regeneration of hyaline cartilage and partial cancellous bone repair of the osteochondral lesion. The construct was feasible for chondrocyte implantation to treat such lesion in the femoral condyle.

Keywords: autologous chondrocyte implantation, biphasic osteochondral composite
Shih-Chieh Hung, M.D., Ph.D. 洪士杰教授

Distinguished Professor & Director,
Department of New Drug Development, China Medical University
Integrative Stem Cell Center, China Medical University Hospital
E-mail: hung3340@gmail.com

Recent Selective Publications:


3. FY-Chiu, SP-Lin, Y-Wang, SY-Kao, SC-Hung*. Rb maintains quiescence and prevents premature senescence through up-regulation of DNMT1 in mesenchymal stem cells. Stem Cell Reports, 3(6):975-86, 2014 (Cell Press Journal)


5. CC-Tsai, PF-Su, YF-Huang, TL-Yew, (洪士杰) SC-Hung*. Oct4 and Nanog directly regulate Dnmt1 to maintain self-renewal and undifferentiated state in mesenchymal stem cells. Molecular Cell, 47: 169–182, 2012 (IF: 15.280; Rank: 4/290) suggested and recommended by Faculty 1000-Prime.


HYPOXIC CULTURE OF MESENCHYMALE STEM CELLS:
FROM BENCH TO BEDSIDE

Shih-Chieh Hung

Distinguished Professor & Director, Department of New Drug Development, China Medical University; Integrative Stem Cell Center, China Medical University Hospital
Adjunct Research Fellow, Institute of Biomedical Sciences, Academia Sinica
Founding consultant, TaiwanBio Therapeutics

Abstract
Human bone marrow-derived mesenchymal stem cells (MSCs) have emerged as a promising tool for clinical application. Cultivation of MSCs under hypoxic conditions, the normal physiological status of bone marrow, represents a new platform of MSCs expansion for clinical applications. In a long term culture, hypoxia can inhibit senescence, increase the proliferation rate and enhance differentiation potential along the different mesenchymal lineages. Hypoxia also modulates the paracrine effects of MSCs, causing upregulation of various secretable factors, including the vascular endothelial growth factor and IL-6, and thereby enhances wound healing and fracture repair. Hypoxia also plays an important role in mobilization and homing of MSCs, primarily by its ability to induce stromal cell-derived factor-1 expression along with its receptor, CXCR4. After transplantation into ischemic limb, an environment combined of hypoxia and serum deprivation, can lead to apoptosis or cell death, which can be overcome by the hypoxic preconditioning of MSCs.

Recently, we have demonstrated the application of MSCs expanded under hypoxic conditions for treatment of a variety of diseases, including bony defect, tendon healing, osteoarthritis, hindlimb ischemia, graft versus host disease, and acute hepatic failure. We have filed a clinical trial and was approved by Taiwan Food & Drug Admiration (TFDA). In the current project, bone marrow MSCs were isolated from allogenic healthy donors, expanded under hypoxic conditions, and applied for Phase I/II a study in treating 18 recipients with critical limb ischemia, including placebo, low dose and high dose groups. We currently enrolled and treated more than 10 patients with the longest follow-up for more than 12 months. All of these patients tolerated the treatment very well. No treatment-related adverse events were reported. Some patients reported the improvement of skin color, hair and snail in the affected limbs.

Keywords: mesenchymal stem cells, basic studies, translational medicine, clinical trials, critical limb ischemia
Shih-Hwa Chiou, M.D., Ph.D. 邱士華教授

Section Chair,
Division of Basic Research, Department of Medical Research,
Taipei Veterans General Hospital
Professor,
The Institute of Pharmacology / The Institute of Clinical
Medicine & Gemonic Center, National Yang-Ming University,
Taiwan
E-mail: shchiou@vghtpe.gov.tw

Recent Selective Publications:
*: Corresponding author


DEVELOPMENT OF CELLULAR REPROGRAMMING AND IPSC TECHNOLOGY AS PERSONALIZED MEDICINE-BASED PLATFORM: FROM BENCH TO CLINIC BEDSIDE

Shih-Hwa Chiou¹,²,³

¹Professor, Institute of Pharmacology, School of Medicine, National Yang-Ming University;
²Section Chair, Department of Medical Research, Taipei Veterans General Hospital, Taipei, Taiwan
³Adjunct Researcher, Genomics Research Center, Academia Sinica, Taiwan

Abstract
The development of induced pluripotent stem cells (iPSCs) has opened a new era for stem cell research. How to quickly, efficiently, and safely produce specific-lineage differentiation from pluripotent-state cells and iPSCs is still an open question. To overcome this critical obstacle, we performed proteomic analysis to find that Parp1, a key factor for DNA repair, plays a crucial role in regulating the efficiency of cellular reprogramming. Furthermore, the generation of patient- or disease-specific iPSCs therefore holds promising potential for the drug industry and regenerative medicine. Following this concept with using iPSC technology, we have reprogrammed T cells from patients with dry type aged macular degeneration (AMD) into induced pluripotent stem cells (iPSCs) and differentiated them into RPE cells that were used as an expandable platform for investigating pathogenesis of the AMD and in-vitro drug screening. Moreover, we demonstrated a plasma treated and laminin coated PDMS film that can enhance the attachment, sustain the survival, and facilitate the functional maturation of iPSC-differentiated retinal pigment epithelial cells (dRPE) seeded on it. The dRPE/PDMS-PmL implant was able to enhance the response to light stimuli in vivo. Taken together, our findings provide the pre-clinical examinations for the prospective clinical application of Human iPSCs, including dRPE/PDMS-PmL subretinal implant, in treating aging degeneration diseases like AMD.

Keywords: induced pluripotent stem cells; iPSC; aged macular degeneration.
Shauh-Der Yeh, M.D., Ph.D.  葉劭德教授

Director,
Department of Urology, Taipei Medical University Hospital
Assistant Professor,
School of Medicine and Graduate Institute of Clinical Medicine
Taipei Medical University
E-mail: d8602003@tmu.edu.tw

Recent Selective Publications:


BIOENGINEERED UROGENITAL ORGANS

Shauh-Der Yeh

Department of Urology, Taipei Medical University Hospital

Abstract
People loss their kidney, bladder, prostate, or testis due to cancer, trauma, or chronic illness. The failure in urogenital organs impair life quality, induce infertility or reduce survival. End-stage kidney failure could be managed by renal transplant; however, the source of donor kidney is a global challenge. After renal transplantation, patients face the problem of rejection and toxicity of immune agents. Bioengineered patient-specific kidneys can be an ideal source of healthy kidneys with minimal risk of immune rejection. Several cell-based strategies were applied to this unresolved issues. The common strategies included repopulation of natural scaffolds, de novo generation of organs from iPS cells, and the creation of human organs in the embryos of other mammalian species. Three dimensional culture and 3D cell printing provide another approach to fabricate human organs. Human bioengineered kidney with tubular epithelium and glomerulus-like structure can be generated in vitro. The problem of vascularization is still the unsolved issue in organoid formation strategies. 3D bioengineered human prostate were generated by stromal-epithelial coculture strategy. Patient-specific bioengineered prostate can be considered to improve ejaculatory and urinary function after different prostatectomy.
Moderator

Akihiro Shimosaka, Ph. D. 下坂皓洋主席
President & CEO,
ZeroBio Co., Ltd. Tokyo, Japan
BioOne Corporation Tokyo, Japan
Director,
Research & Development Division
Research Foundation for Community Medicine,
Utsunomiya, Japan
President,
Asian Cell Therapy Organization (ACTO)
E-mail: sams@zero-bio.com
ashimo@post0.mind.ne.jp
shimosaka@bioone.co.jp

Recent Selective Publications:

1. Liang DC, Shih LY, Chai HT, Chen SH, Liu HC, Shimosaka A. The synergistic effect of thrombopoietin in erythropoiesis with erythropoietin and/or IL-3 from umbilical cord blood cells of premature neonates. Pediatric Hematol Oncol. 2002 Sep; 19(6): 399-405


Session I (October 29th 10:30-11:00)

Moderator

Chung-Liang Chien, Ph.D. 錢宗良教授

Professor,
Department of Anatomy and Cell Biology,
College of Medicine, National Taiwan University
E-mail: chien@ntu.edu.tw

Recent Selective Publications:


Takuya Yokokawa is a Manager for special mission in Healthcare Business Development, FUJIFILM Corporation, and has been working for regenerative medicine business since 2013.

He joined FUJIFILM in 1985 and had developed photographic materials for twenty years. After the photographic products R&D, he moved to the pharmaceutical R&D and was the first general manager for Pharmaceutical and Healthcare Research Laboratories of FUJIFILM from 2009 to 2013.

He has been the head of steering committee of “Forum for Innovative Regenerative Medicine”, the industrial association in Japan since 2014.

Education:

He had obtained his MS degree in the Graduate School of Polymer and Textile of Technology from Tokyo Institute of Technology.
JAPANESE REGENERATIVE MEDICINE INDUSTRIAL ASSOCIATION FIRM

Takuya Yokokawa

Abstract
FIRM was established in 2011, at the starting there were only 14 companies, since then, it has grown dramatically and now there are about 200 companies from various kinds of industries and businesses. It is important to establish the industry association from the early stage of industrialization to communicate with academies, governments, regulatory agencies and industries associations abroad to collaborate strategically. I will talk about the Japanese Regenerative Medicine Industrialization update and next challenge.
Yao-Chang Chen, M.D. 陳耀昌理事長

Professor Emeritus of Hematology,
National Taiwan University Hospital Taipei, Taiwan
President,
Taiwan Association for Cell Therapy (TACT)
Vice President,
Asian Cell Therapy Organization (ACTO)
E-mail: ycchenmd@ntu.edu.tw

Recent Selective Publications:

8. Shang-Yi Huang, Chih-Hsin Yang, and Yao-Chang Chen. Arsenic trioxide therapy for relapsed acute promyelocytic leukemia: a useful salvage therapy. Leukemia and Lymphoma, 2000; 38:283-293. (Corresponding Author)
A DREAM OF TAIWAN STEM CELL (MSCS) TEAM

Yao-Chang Chen, M.D.

Abstract

1. MSCs:
   ´alike drug store
   ´alike a generic drug
   ´may be used in wide spectrum of disease therapy
2. Current status in Taiwan:
   ´many MSCs companies
   ´but just one single product (MSCs)
   ´clinical trials might be duplicated
   ´products very expensive
3. Anticipated benefits of one integrated MSCs team in Taiwan.
   ´save money?
   ´better and uniform quality control?
   ´may serve the domestic patients with lower cost?
   (More popularly used, not just for rich patient)
4. Provide MSCs for public use in case of catastrophe (national MSC bank?)
5. How to achieve this goal?
Session II (October 29th 11:00-12:00)

Moderator

Shiow-Ing Wu, Ph.D. 吳秀英副署長
Deputy Director General,  
Food and Drug Administration,  
Ministry of Health and Welfare, Taiwan

E-mail: shiow@fda.gov.tw

1982-1985  Dentist, Taipei Medical University Hospital.  
Teaching Assistant, School of Dentistry, Taipei Medical University.
1985-1988  Trainee, Field Epidemiology Training Program, Department of Health, Taiwan
1989-1991  Section Assistant, National Institute of Preventive Medicine, Department of Health, Taiwan
1991-1993  Specialist, Bureau of Health Promotion and Protection, Department of Health, Taiwan
1994-1997  Section Chief, Bureau of Communicable Disease Control, Department of Health, Taiwan
1997-2000  Section Chief, Department of Health, Taipei City Government.
2000-2003  Superintendent, Taipei City STD Control Center.
2003-2005  Chief Secretary, Department of Health, Taipei City Government.
2005-2010  Deputy Director General, Bureau of Health Promotion, Department of Health, Taiwan.
Dr. Gau started leading the Center for Drug Evaluation (CDE) as Chief Executive Director on April 1, 2011. CDE was established by Department of Health (DOH, now MOHW) in 1998, to assist the technical evaluation for market approval of drugs and medical devices.

Dr. Gau received her Ph.D. degree in Pharmaceutics from the School of Pharmacy, University of Wisconsin-Madison, USA, in 1992, after that she returned to the School of Pharmacy, National Taiwan University (NTU) as a faculty member. During Aug. 1996 to July 2000, she was appointed as the Director of the Department of Pharmacy, NTU Hospital, one of the largest university-affiliated medical centers in Taiwan.

Prior to joining CDE, Dr. Gau served for DOH (now MOHW) as an expert in many Committees, specializing in the evaluation of new drug application, assessment of drug safety, and accreditation of teaching hospital. Dr. Gau had led a project for several years to establish the National ADR Reporting System in Taiwan initiated in 1998. Dr. Gau was appointed as the Deputy Executive Director of CDE from June 2006 to Aug. 2009 and as a researcher in Food and Drug Administration, Ministry of Health and Welfare (MOHW) from March 2011 to June 2014.

Dr. Gau’s researches focus on the use of claim database of the National Health Insurance program of Taiwan to study the prescription pattern of drug utilization, the adherence of drug usage to the professional practice guidelines, and the association of adverse reactions and clinical outcomes with the drug used. She has published more than sixty research papers in the fields of pharmaceutical sciences and drug safety in internationally recognized medical journals.
Yoshiaki Maruyama, Ph.D. 丸山良亮博士

Review Director,
Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency, Japan
E-mail: maruyama-yoshiaki@pmda.go.jp

Recent Selective Publications:

Abstract

In Japan, the regulatory reform was carried out to improve access to the new therapeutic innovation in regenerative medicine. The Pharmaceuticals and Medical Devices Act (PMD Act) (the revised Pharmaceutical Affairs Law) was enacted on 25 November 2014, which enables early patient access to promising therapies, using conditional and time-limited approval scheme (as “accelerated approval”) for regenerative medical product review. The scope of regenerative medical products is considered to be mainly products satisfying unmet medical needs.

Human cellular and tissue-based products (hCTPs) are derived from the processing of autologous or allogeneic human cells and tissue, using the serum or other raw materials derived from human/animal components. Due to the non-uniform quality of CTPs reflecting individual heterogeneity of raw materials, quality control strategy for products manufactured, such as specifications (a set of acceptance criteria and analytical procedures) for the final products, quality control of raw materials, verification of the suitability of the manufacturing process, maintenance of consistency, and proper quality control of intermediate products, is extremely important in quality assurance. Also, such an early access scheme would raise the issues of GMP type quality validation, due to the limited experience of batches and timeline for regulatory process. Risk-based scientific evaluation should be applied to achieve patient protection.

This presentation will give a short introduction to Japan regulatory framework and the current challenges to facilitate product development.
Chih-Liu Lin, M.D. 林志六副執行長

Deputy Executive Officer,
Center for Drug Evaluation, Taiwan

E-mail: cllin051@cde.org.tw

2013.6-3013.9  Deputy Executive Officer, Taiwan Joint Commission on Hospital Accreditation, Taiwan
2009.4-2011.3  Partner, Macrolaw Law Office, Taipei, Taiwan
2006.2-2009.3  Director, Division of Clinical Sciences, Center for Drug Evaluation, Taiwan
2002-2012      Adjunct Lecturer, National Yang-Ming University
2000.7-2006.1  Senior Medical Reviewer, Division of Clinical Sciences, Center for Drug Evaluation, Taiwan
1999-2000  Executor, Taiwan Bio-Medical Law Office, Taipei, Taiwan
1992-1998  Attending Visiting Staff, Orthopedic Department, Taipei Municipal Yang-Ming Hospital, Taiwan
CURRENT STATUS OF CELL THERAPY CLINICAL TRIALS IN TAIWAN

Chih-Liu Lin

Deputy Executive Director, Center for Drug Evaluation Taiwan

Abstract
Cell therapy is an advanced technology which brings new challenges to both regulatory body and biotech companies. Existing regulatory rules for pharmaceutical products may not be fully applied to cell therapy products. Besides making new regulatory guidelines, it is also important to have a more efficient communication mechanism because many of the cell therapy development are initiated by small biotechnology company or investigator who might not have sufficient resource to know or fulfill regulatory requirement. In this presentation, we will introduce the recent progress of cell therapy regulations and the impact on the development in Taiwan.
Session III (October 29th 13:20-15:00)

Moderator

Shiaw-Min Hwang, Ph.D. 黃效民博士

Chief Technology Officer,
U-Neuron Biomedical Inc., Taipei, Taiwan
Senior Scientist,
Bioresource Collection and Research Center, Food Industry Research and Development Institute, Hsinchu, Taiwan
E-mail: hsm@firdi.org.tw

Recent Selective Publications:


Session III (October 29th 13:20-15:00)

Moderator

Setsuko Hashimoto, Ph.D. 橋本節子博士
President & CEO,
CellSeed Inc.
E-mail: shashimoto@cellseed.com

PROFESSIONAL EXPERIENCES

• Hoechst Japan Ltd. (April 1984 – March 1991)
• Pharmacia Biotech K.K. (October 1993 - June 1998)
• Bio-Business Bridge Co. Ltd. (July 2008 – 2015)
• Invest in Sweden Agency (ISA, currently Business Sweden) and the Embassy of Sweden in Japan (February 2009 – December 2014)
• CellSeed Inc. (April 2014 – May 2014)
• CellSeed Inc. (June 2014 – present)

AWARDS

Setsuko Hashimoto, Ph.D. 橋本節子博士
President & CEO, CellSeed Inc.
E-mail: shashimoto@cellseed.com

PROFESSIONAL EXPERIENCES

• Hoechst Japan Ltd. (April 1984 – March 1991)
• Pharmacia Biotech K.K. (October 1993 - June 1998)
• Bio-Business Bridge Co. Ltd. (July 2008 – 2015)
• Invest in Sweden Agency (ISA, currently Business Sweden) and the Embassy of Sweden in Japan (February 2009 – December 2014)
• CellSeed Inc. (April 2014 – May 2014)
• CellSeed Inc. (June 2014 – present)

AWARDS


CLINICAL TRIAL OF ESOPHAGEAL EPITHELIUM CELL SHEETS IN JAPAN

Setsuko Hashimoto
President & CEO, CellSeed Inc.

Abstract
CellSeed Inc. offers an innovative and versatile technology in regenerative medicine: cell sheet engineering. Cells grown to confluency on the unique cultureware (UpCell®) coated with temperature-responsive polymers can be detached from the surface just by lowering the temperature but without enzyme digestion. The sheets with intact cells can be used for various therapeutic applications in regenerative medicine to treat patients with diseases that cannot be treated with the conventional therapies.

Endoscopic Submucosal Dissection (ESD) has become popular for the early phase of the esophageal cancer. The stricture formation of the esophageal duct after ESD is one of drawbacks of ESD. Medical doctors at Tokyo Women’s Medical University have developed a new therapy using cell sheets prepared from the patient’s oral mucosa to prevent the stricture. Positive results were obtained in the clinical research conducted in Japan and in Sweden with total 30 patients. A special device to support cell sheet transplantation was also developed.

CellSeed Inc. sponsors development to obtain product licenses both in Japan and Europe. A clinical trial of esophageal epithelium cell sheets and the device (CLS2702C/D) has been started at National Cancer Research Centers and Tokyo Women’s Medical University in Japan. The latest status of the study will be shared.

Keywords: Regenerative medicine, cell sheet, temperature-responsive polymer, esophageal cancer, ESD
Kunihiko SUZUKI (born in 1959) has more than 30 years’ business experiences with various types of private sector organizations, such as Oil Company, Investment Bank, Commercial Bank and Biotechs. In Mar 2006, he joined MEDINET Co., Ltd., a company specializing in cell manufacturing and related services in immuno-cell therapy for cancer patients and also acting as a Contract Development and Manufacturing Organization for both private and public sectors such as hospitals, clinics, academia, conducting their activities under “The Act on Pharmaceuticals and Medical Devices” and “The Act on the Safety of Regenerative Medicine”.

In respect of the public activities, he has been serving as Vice Chairman at FIRM (Forum for Innovative Regenerative Medicine) since Jun 2014 and to date.
KEY FUNCTIONS FOR CELL THERAPIES FOR PATIENTS

— CONTRACT CELL MANUFACTURING BUSINESS

Kunihiko Suzuki

Member of the Board, Vice Chairman, MEDINET Co., Ltd.

Abstract
Under new regulatory framework in Japan, which consists of “Pharmaceuticals and Medical Devices Act (PMD Act)” and “The Act on the Safety of Regenerative Medicine (RM Safety Act)”, there are two ways for patients to access to the medical technologies, which will be provided by either “regenerative medical products” under PMD Act or “medical treatments” under RM Safety Act.
MEDINET as a Contract Development and Manufacturing Organization will support in the investigational product for clinical trials for the development of “regenerative medical products”, which will be conducted by corporates and medical doctors, and also will make contract manufacturing of commercial production for the regenerative medical product after its market authorisation.
In addition, MEDINET will play a role as an outsourcee of cell manufacturing for “specified cell products” under RM Safety Act for clinical researches and medical practices at hospitals and clinics.
The business model in the above and its practical issues should be discussed in the session, which might be the case to be considered for commercialization/industrialization of regenerative medicine and cell therapies in future.
Hitoshi Torii, 鳥居仁執行長

Executive Officer, Corporate Officer, Business Development, Cyfuse Biomedical K.K.
E-mail: Hitoshi.torii@cyfusebm.com

- Cyfuse Biomedical K.K., Tokyo, Japan (2014 ~ present)
  - Director of Finance and Operations, Director of Corporate Planning and Business Development (June 2014 ~ Present), interim CEO (July 2016 ~ October 2016)
  - Member of Board of Directors

- Tecan Japan Co., Ltd., Kawasaki, Japan (2009 ~ 2014)
  - Head of Commercial and General Manager, Representative Director (November 2011 – February 2014)
  - CFO and Head of Operations, Representative Director (August 2010 – November 2011)
  - CFO (October 2009 – July 2010)

- Aqumen Biopharmaceuticals K.K., Fukuoka, Japan (2007 ~ 2009)
  - Director of Corporate Planning (August 2007 – April 2009)

- Novartis Pharma K.K., Tokyo, Japan (2000 ~ 2007)
  - Head of Business Development and Licensing Finance Japan (June 2006 – August 2007)
  - Head of Development Finance Japan (January 2004 – May 2006)

  - Assistant Senior Researcher, Tsukuba Technology Center, and Exchange Scientist, Sandoz Agro Inc. (Gilroy, CA)

- ADVANCE CO. LTD., Tokyo, Japan 1989 ~ 1991)
  - Project researcher, Drug Delivery Center

  - Researcher, Technical Research Center
KENZAN METHOD: SCAFFOLD-FREE THREE DIMENSIONAL TISSUE CREATION FOR TRANSPLANTATION AND RESEARCH

Hitoshi Torii¹, Hideki Kizawa¹, Koichi Nakayama²

¹Cyfuse Biomedical K.K.; ²Professor, Saga University

Abstract
Cyfuse is working on the novel technology to create scaffold-free three dimensional tissues. This technology, Kenzan method, invented by Dr. Nakayama at Saga University, enables us to create functional tissues by utilizing cells’ natural capability to self-reorganize their relative locations and to create own living environment. This method uses spheroids as building blocks for the larger tissue, assembles them on needle array to support fusions of spheroids and to allow good accesses to nutrients and oxygen during the critical period of the spheroid fusion. Because the created tissue does not contain exogenous scaffold materials or biomaterials, but is formed by only cells and own-produced extracellular matrix, it has advantages to avoid undesired interactions caused by biomaterials and to reduce associated regulatory hurdles. Cyfuse and our collaborators in Japan and the US have been developing functional tissues such as blood vessel, liver, heart and others with this technology. Some progresses and examples of our current collaborations and researches will be presented.

In order to practice the method in research laboratories, we have developed the 3D bioprinter, Regenova®. Regenova® is a state-of-the-art robotic system that enables fully automated fabrication of three-dimensional artificial tissues from living cells.

Our goal is to facilitate innovative therapeutic approaches through our new tissue creation technology to make regenerative medicine a reality for patients around the world.

Keywords: 3D tissue, bioprinter,
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Recent selective publications:

1. Ikki Horiguchi and Yasuyuki Sakai, Serum replacement with albumin-associated lipids prevents excess aggregation and enhances growth of induced pluripotent stem cells in suspension culture, Biotechnol Prog., 32(4), 1009-1016, 2016.


4. Ikki Horiguchi, Mohammad M Chowdhury, Yoji Tabata, Yasuyuki Sakai, Proliferation, morphology, and pluripotency of mouse induced pluripotent stem cells (iPSCs) in three different types of alginate beads for mass production., Biotechnol Prog., 30(4), 896-904, 2014
DEVELOPING O-SHAPE VESSELS FOR STABLE SUSPENSION-BASED MASS PRODUCTION OF HUMAN INDUCED PLURIPOTENT STEM CELLS

Ikki Horiguchi¹, Ikumi Suzuki², Takamasa Sato³, Takashi Morimura⁴, Takao Yoshida⁵, Yasuyuki Sakai⁶

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Abstract
Suspension culture is one of the most promising approaches to obtain the enough number of human induced pluripotent stem cells (hiPSCs) for clinical applications. However, hiPSCs are sensitive to shear stress of medium flow and hard to grow up from single hiPSC in suspension condition even with ROCK inhibitor. In addition, they tend to adhere each other and form aggregates. In existing culture vessels, floating cells migrate into a center and bottom of the vessel with moderate rotary shaking condition, which is known as “Einstein’s tea leaves paradox”. This migration causes excess aggregation and low growth ratio in a batch. Therefore stronger agitation than hiPSC can survive is required for hiPSC suspension culture in existing culture vessels. In this study, in order to avoid the problem derived from the paradox, we developed a novel O-shape cell culture vessel with two different sizes of petri dishes. According to a particle distribution test by suspending Cytodex 1 microbeads within rotary shaking vessels, they were well distributed with lower shaking speed than existing rotary shaking vessels. Suspension culture with mild agitation condition (20 mL of Essential 8 medium within 100 mm dish on 45 rpm rotary shaking) showed that O-shape vessels obtained uniform aggregates from single cell suspension without unacceptable over-aggregation. We also developed an O-shape culture bag as a closed culture vessel and hiPSCs were successfully cultured in the O-shape bag. Now we are trying to optimize the detailed shape and shaking conditions for stable iPSC production.

Keywords: iPSC Cells, Suspension Culture, Aggregation, O-shape Vessel
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Recent Selective Publications:


BEFORE AND AFTER THE ENFORCEMENT OF THE ACT FOR
REGENERATIVE MEDICINE IN JAPAN:
FROM A VIEW OF A CLINIC

Junichi Masuyama, M.D., Ph.D.

New city Osaki clinic, Cellex Corporation

Abstract
In Japan, the Act for regenerative medicine was enforced in November, 2014, and after a year, it was entirely applied to not only advanced medicine using iPS or stem cells but also cellular immunotherapy for cancer. Different from the former 2 cell types, the cellular immunotherapy, viewed as part of medical practice, has been provided to cancer patients in great many clinics without laws and regulations till 2014. Because of no regulations, the clinics do not necessarily need to verify and report the safety and the efficacy of their immunotherapy.

After the Act was enforced, each clinic needs their procedures to be reviewed by special committee for regenerative medicine and must report all procedures conducted in their cellular immunotherapy, and furthermore its safety and efficacy to the Ministry of Health and Welfare every year. The duty should be fitted to the aim that trustworthy cell products are provided to patients. However, we now wonder if we really could get out of the gray zone before 2014.

As a medical practitioner in this field, I will mention a personal view as for the issues that should be discussed to achieve the goal that is to provide valid cell products in cellular immunotherapy.

Keywords: The Act for regenerative medicine, Japan, cell therapy
Moderator

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Recent Selective Publications:


Session IV (October 29th 15:20-17:00)

 Moderator

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 Recent Selective Publications:

Shing-Mou Lee, Ph.D. 李幸懋博士

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1. **Current Good Tissue Practice (cGTP) 2003 Workshop**, International Society for Cellular Therapy
2. Medical Laboratory Accreditation Standard-ISO 15189 Training
3. Training Workshop on Biomedical Laboratory Practice
4. **Executive Programs of Technology Management**, Graduate Institute of Technology and Innovation Management, National ChengChii University, Taiwan (2000.2~2000.4)
5. **The Intellectual Property Training Program** at the Georgetown University Law Centre, Asia Pacific Legal Institute, Washington D.C., USA (2000.7.5~2000.7.28)
CONTRACT MANUFACTURING AND TESTING SERVICES FOR
THERAPEUTIC CELL-BASED PRODUCT

Shing-Mou Lee, Ph.D.

Abstract
EMO Biomedicine Corporation (www.emobio.com) was founded in Taipei, Taiwan in 2004. In order to be the world leading company in the field of cellular therapy, EMO has developed necessary platform technologies related to manufacturing and analysis for therapeutic cell-based products. Since 2004, EMO has been providing comprehensive cell-based bioassays and Contract Research Services to local and global clients, including pharmaceutical and biotech companies. In 2011, EMO started to provide Contract Manufacturing Service of cell-based products to cell therapy companies and hospitals.

Accredited Lab for Contract Testing Services
EMO established a quality management system specific for cell-based products characterization, to comply with international standards. In June 2007, EMO obtained the Certificate of Accreditation as a “Testing Laboratory” from Taiwan Accreditation Foundation (TAF), in compliance with ISO/IEC 17025:2005. EMO’s accredited testing scope includes Cell-based Products, Cell Culture Supernatant and Whole Blood. Through the ILAC-MRA (International Laboratory Accreditation Cooperation - Mutual Recognition Arrangement), TAF’s accreditation is bilateral recognized by 71 economies and 86 accreditation organizations. Furthermore, in November 2009, EMO also obtained the certificate of accreditation as a qualified “Drugs and Cosmetics Testing Laboratory” from Taiwan FDA.

Contract Manufacturing service - Cell-Based Products
After inspection by Taiwan FDA in 2010, EMO started to offer Contract Manufacturing Service of cell-based products to support local and overseas clients who lack GTP/GMP compliant facilities and quality management systems. Existed testing services accompanied with manufacturing service, EMO offers a complete service system, including manufacturing and product characterization, for cell therapy clients. In June 2013, EMO was qualified as a contract research organization for pharmaceuticals by Ministry of Economic Affairs and we expect to provide the best service to all clients for accelerating development of cellular therapy.
Yen-Chung Chen, Ph.D. 陳彥聰博士

E Research Fellow,
Maria Von Med-Biotechnology Co., LTD
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Recent Selective Publications:


CURRENT STATUS AND FUTURE DEVELOPMENT OF SKIN-DERIVED MESENCHYMAL CELL THERAPY

Yen-Chung Chen¹, Chia-Wen Chien¹, Mei-Yue Huang¹

¹Maria Von Med-Biotechnology Co., LTD

Abstract
Skin is one of the major tissue sources used in applications of regenerative medicine fields. Skin-derived mesenchymal cells (fibroblasts) has been widely used in treating various symptoms, such as reducing age-related folds and wrinkles, repairing diabetic wounds and ulcers, speeding up wound healing process in severely burned patients, facilitating recessive dystrophic epidermolysis bullosa wound healing, treating vocal fold scars, Achilles tendinitis, and gingival recession.

Maria Von Med-Biotechnology Co. Ltd. has been using skin-derived mesenchymal cells in treating skin defects, the successful completion of our phase I clinical trial has ensured the safety of our cellular biologics. Maria Von conducted two clinical trials in 2016, a phase II study of autologous skin-derived mesenchymal cells for the treatment of moderate to severe nasolabial fold wrinkles in adults, and a phase I study of allogeneic skin-derived mesenchymal cells in treating epidermolysis bullosa, respectively. In addition, our recent research results showed that skin-derived mesenchymal cells are multipotent and have the self-renewal ability. Accordingly, other than using skin-derived mesenchymal cells in skin defect treatment, Maria Von is looking forward to conducting various clinical studies, aimed to discover more potential applications.

Keywords: skin-derived mesenchymal cell, fibroblast, skin defect treatment
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Recent Selective Publications:

   Telomere-binding and Stn1p-interacting activities are required for the essential function of

   Design and synthesis of class-selective activity probes for protein tyrosine phosphatases. J Proteome
   Res. 1, 35-40.

   Exposure of single-stranded telomeric DNA causes G2/M cell cycle arrest in Saccharomyces

   Dictyostelium gnt15 encodes a protein with similarity to LARGE and plays an essential role in

   Classification of LARGE-like GlcNAc-transferases of Dictyostelium discoideum by phylogenetic

   Costars, a Dictyostelium protein similar to the C-terminal domain of STARS, regulates the actin
DEVELOPMENT OF IMMUNOCELL THERAPY PLATFORMS

IN VECTORITE

Celine Pang, Ph. D.

Vectorite Biomedical Inc.

Abstract
Vectorite is a clinical stage biopharmaceutical company providing cell-banking service and developing novel cellular immunotherapies based on three unique and complementary platforms – Targeted Immune Effector (TIE) platform, High Purity NK technology and next-generation chimeric antigen receptor (CAR) T cell technology. Our goal is to revolutionize cancer treatment by exploring the new possibilities of immunotherapy.

EBV/CMV-TIE is a T cell therapy designed to treat EBV or CMV reactivation after allogeneic hematopoietic stem cell transplantation (HSCT), and was evaluated in Phase 1 clinical trials proceeding in China. Encouraging early results showed that our approach has remarkable potential to improve HSCT outcomes through immune system recovery. In addition, High Purity NK technology is designated to generate high purity CD3 CD56+ NK cells for both hematological cancers and solid tumors treatment and improving the quality of life for patients. To date, CAR-T therapies have been shown to be effective in certain blood cancers. Vectorite intends to develop next-generation CAR-T cell technology platform to establish new approaches to treatment of various cancers, including hematological cancers and solid tumors-addressing huge unmet medical needs.

Keywords: skin-derived mesenchymal cell, fibroblast, skin defect treatment
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- *Arrangement and leadership in collaboration between Institute of Biochemistry and Molecular Biology in NTUCM and Institute of Biomedical Science in University of Tokyo and University of Kyoto.
FROM AUTOLOGOUS TO ALLOGENEIC:

BUSINESS'S POINT OF VIEW

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¹R&D Manager, UnicoCell Biomed Co., Ltd.; ²President, UnicoCell Biomed Co., Ltd.

Abstract
Upon the several types of stem cell resources, autologous and allogeneic transplantation procedures have their own distinct process and associated with specific benefits and risks. In spite of the clinical and medical inquiry, regulatory and financial issues should be taken into account when building an allogeneic cell banking system. Updated guidelines of donor eligibility and resources of allogenic cells have been released by FDA in 2007 and TFDA in 2015, which benefits a great deal. However, a gap from bench works to industry and the gap between regulatory and execution would be a challenge. Also, the insight of cost-effectiveness and economic benefits yield from allogenic cell therapy is also expected.

For a long while, autologous cell source is well accepted and comforting with its safety and efficacy. Once allogeneic cell transplantation conquers the issues of safety and efficacy, it would bring advantages in several ways like massive production and public obligee. In comparison of autologous transplantation is more likely a customized medical service, allogeneic cell products could be a wild applications for more ones. Research publications inspired us that allogeneic mesenchymal stem cells (MSCs) are ideal for various application of cell therapy like treating inflammatory diseases and tissue repair. Furthermore, their immunosuppressive properties and low immunogenicity shows promising of MSCs in cell-based therapy. Therefore, accompany with the advantages are few more tribulations which we are putting efforts in, for example, overcome the issue of human species and then building up a well-connected industrial chain of material supply and cold-chain transportation under a mature regulatory monitoring.

Keywords: allogeneic, cell therapy
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Professional experiences: SBI focuses on new drug development of allogeneic adipose-derived mesenchymal stem cells.
Abstract
Steminent Biotherapeutics Inc. (SBI) aims to translate stem cell sciences to stem cell treatments for unmet and underserved medical needs. Focusing on clinical development of adipose-derived mesenchymal stem cells (AdMSCs), we have established an end-to-end technology platform from stem cell manufacturing to clinical development in neurodegenerative diseases, musculoskeletal diseases, metabolic disorders and acute symptoms.