

2023

ATC抗體藥物暨第18屆前瞻生醫新知研討會

Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

Time May 26-27, 2023

Venue National Biotechnology Research Park C201



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

Welcome Message

Dear distinguished guests, ladies and gentlemen,

On behalf of the organizing committee, it is my pleasure to welcome you to the 10th Antibody Therapeutic Conference (ATC): Extended Applications of Antibodies, to be held on May 26th-27th, 2023 at the National Biotechnology Research Park in Taipei, Taiwan.

In recent years, the field of antibody therapeutics has experienced significant growth, particularly with regard to treatment of cancer, immune-mediated diseases and infectious diseases. At the forefront of this growth, several types of immunotherapies, including antibody-mediated tumor regression, checkpoint blockade, antibody-drug conjugates (ADCs), and chimeric antigen receptor T-cell therapy (CAR-T), have emerged as promising new strategies for curing many types of cancers.

This year, the 2023 ATC will showcase a broad scope of remarkable achievements, focusing on extended applications of antibodies. We aim to provide a platform for participants to connect, communicate results, gain new knowledge, and engage in discussions on antibody therapeutics.

The organizing body for the ATC is the Taiwan Antibody Association (TAA), which was established in 2012 with the mission of facilitating research and industrial development of antibody drugs and related technologies in Taiwan. By hosting international conferences like this one, we intend to promote the exchange of ideas and foster collaborations between senior experts and young scientists in the field.

We hope that this conference will be informative, insightful and inspiring to all participants, thereby contributing to the advancement of antibody therapeutics. Once again, we thank you for joining us, and we wish you a successful and enjoyable experience.

Han-Chung Wu, Ph.D.

Chairman, Taiwan Antibody Association
CEO, Jung-Yaw Lin Science and Education Foundation
Director, Biomedical Translation Research Center, Academia Sinica,
Distinguished Research Fellow, Institute of Cellular and Organismic Biology, Academia Sinica
Fellow, National Academy of Inventors (NAI)

2023

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Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

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Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

AGENDA

Day 1, 5/26 (Fri)

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Time	Activities		Speakers
9:00 - 9:30		Registrat	ion
9:30 - 9:40	Welcome Remarks	吳漢忠	中研院生醫轉譯研究中心主任 台灣抗體協會理事長
9:40 - 9:45	Moderator	吳漢忠	生醫轉譯研究中心主任
9:45 - 10:15	Targeting Tumor Glycans for Cancer Therapy : Why & How	陳鈴津	中央研究院院士
10:15 - 10:45	Clinical Translation of Imaging-Based Quantitative Biomarkers to Assess Treatment Effects and Toxicity		Y Lai, MD, PhD, FACS Professor, erson Cancer Center
10:45 - 11:00		Break	
11:00 - 11:05	Moderator	王惠鈞	中央研究院院士
11:05 - 11:35	Translational Barriers for Protein Drugs : Pharmacodynamics/Pharm acokinetics Perspectives	顧曼芹	顧德諮詢有限公司總經理
11:35 - 12:05	Immune Checkpoint Enhancers (ICEs) for Immunological Diseases	周慧泉	AltruBio, Inc.總裁暨全心醫藥生技 台灣子公司董事長
12:05 - 13:20	Lunch Seminar / 4th TAA General Assembly		JelloX 捷絡生物科技(股)公司 Waters 美商沃特斯(股)公司 CYTENA BPS 生德奈生技(股)公司
13:20 - 13:25	Moderator	游正博	林口長庚紀念醫院幹細胞與 轉譯癌症研究所所長
13:25 - 13:55	Novel Antibody Drug Conjugates for the Treatment of Lung Cancer	楊志新	臺灣大學醫學院附設醫院癌醫中心分院院長
13:55 - 14:25	Antibody Therapeutics in GI Cancers	陳立宗	高醫大癌症研究中心執行長 / 國衛院癌研所特聘研究員
14:25 - 14:30	Moderator	李冬陽	臺灣永生細胞董事長
14:30 - 15:00	Challenges in Cancer Immunotherapy to Date and Potential Novel Cancer Therapy Technology - Antibody Cell Conjugation	蕭世嘉	育世博生物科技執行長
15:00 - 15:30	Writing the Future of Antibody Discovery with Synthetic DNA	王琳雅	Twist Bioscience高級資深科學家
15:30 - 15:50		Break	
		Moderat	or:吳忠勳 生技中心執行長
15:50 - 17:20	Panel Discussion	伊吳林俸曾劉賴 燧益菁珠瑾成添	醫創生物科技(股)公司總經理 醣基生醫(股)公司總經理 聯合生物製藥(股)公司總經理 研生生醫(股)公司策略長 資誠聯合會計師事務所榮譽副所長 台康生技創辦人、董事長暨總經理 台灣浩鼎生技(股)公司研發長
17:20 - 17:30	Closing Remarks	吳漢忠	中研院生醫轉譯研究中心主任 台灣抗體協會理事長





Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

AGENDA

Day 2, 5/27 (Sat)

Time	Activities		Speakers
9:00 - 9:20		Registra	tion
9:20 - 9:30	Welcome Remarks	王惠鈞 楊泮池	中央研究院院士 中央研究院院士
9:30 - 9:40	Moderator	魏耀揮 吳華林	彰化基督教醫院粒線體醫學暨自由基研究院院長 成功大學生物化學暨分子生物學研究所教授
9:40 - 10:10	The Mystery of Centriole Biogenesis	唐堂	中央研究院副院長
10:10 - 10:40	An Overtime Turned into a New Game in Structural Biology	蔡明道	中央研究院院士
10:40 - 11:10	What We Can Contribute to Cancer in Taiwan?	洪明奇	中央研究院院士
11:10 - 11:40	淺談我的學術生涯	吳妍華	中央研究院院士
11:40 - 12:10	Panel Discussion	Modera 唐 堂 蔡明道 洪明奇 吳妍華	tor:吳漢忠主任 中央研究院副院長 中央研究院院士 中央研究院院士 中央研究院院士
12:10 - 12:20	Closing Remarks	林榮耀 吳漢忠	林榮耀教授學術教育基金會董事長 中研院生醫轉譯研究中心主任



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

DAY 1 SPEAKER



陳 鈴 津 中央研究院 院士

EDUCATION AND POSITIONS HELD:

- M.D., National Taiwan University, 1968
- M.S., Yale University, 1969
- Ph.D., Microbiology/Immunology, University of Chicago, 1973
- Assistant Professor through Professor of Pediatrics, University of California, San Diego, 1977-2001
- Professor and Chief, Pediatric Hematology/Oncology, University of California, San Diego, 2001-2003
- Distinguished Professor and Deputy Director, Genomics Research Center, Academia Sinica, 2003-2013

Dr. Yu has a longstanding interest in translational research, aiming to bridge the gap between laboratory research and clinical medicine. In particular, she has been pursuing therapy targeting specific molecular alterations in cancer from small molecules to biologics. She has led several nationwide cooperative group clinical trials in the USA. As a pioneer in cancer immunotherapy targeting GD2, she has taken an anti-GD2 monoclonal antibody from IND application through phase I, II and III clinical trial which culminated in significant improvement in the outcome of high risk neuroblastoma. She is now developing therapeutic cancer vaccines targeting GD2 with anti-idiotypic antibody for neuroblastoma and melanoma, and glycans such as GloboH and Gb5 with synthetic carbohydrates for the treatment of epithelial cancers including cancers of breast, lung, ovary, pancreas, etc. She has a broad spectrum of research interest ranging from molecular signature of cancer and cancer stem cells, cell cycle regulation, in vitro and in vivo preclinical screening of novel therapeutic agents, design, development and implementation of clinical protocols for immunotherapy and other clinical investigation.

Targeting Tumor Glycans for Cancer Therapy: Why & How?

Speaker: Alice L. Yu, MD, PhD. Distinguished Chair Professor Institute of Stem Cell & Translational Cancer Research, Chang Gung Memorial Hospital at Linko.

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Abstract

Although cancer immunotherapy has been flourishing, the number of targets for the approved cancer immunotherapeutics has remained small (only 25 so far), and limited to proteins, The approval of Dinutuximab, an anti-GD2 antibody, for the treatment of high-risk neuroblastoma in 2015 marks the first new agent targeting a glycolipid molecule, largely based on the pioneer work of Dr. Yu. The benefit of immunotherapy with anti-GD2 has recently been confirmed in the long term follow up of the pivotal phase III randomized trial and a large cohort (n=1183) of non-randomized study. Strategies to improve its efficacy include combination with chemotherapy or anti-PD1, humanization of anti-GD2, and GD2-CAR cell therapy. A humanized anti-GD2 Naxitamab received FDA approval for relapsed/refractory neuroblastoma in 2020. An 9- O-acetyl derivative of GD2 (OAcGD2) was found to be highly expressed in neuroectodermal tumors but not normal neurons. Preclinical studies of anti- OAcGD2 showed significant anti-tumor efficacy without neuropathic pain associated with anti-GD2. Recently, we demonstrated OAcGD2 to be a novel marker for breast cancer stem cells. Treatment with anti-OAcGD2 may have superior anticancer efficacy by targeting cancer stem cells to reduce metastasis and recurrence of cancer.

Another glycolipid, Globo H, which is the most prevalent cancer-associated antigens, is an ideal target for cancer immunotherapy. Clinically, expression of Globo H has been reported in at least 7 types of epithelial cancers. High expression of Globo H is an independent poor prognostic factor for breast cancer, hepatoma cholangiocarcinoma and gallbladder cancer. Globo H ceramide (GHCer) is shed from tumor cells to extracellular vesicles, which is incorporated into the endothelial to promote tube formation in vitro, and angiogenesis in Matrigel plug assay in vivo. GHCer is also taken up by immune cells, causing suppression of T cell activation but promotion of expansion/function of Treg. Such dual immunosuppressive activities of GHCer are mediated by activation of adenosine A2A receptor (A2AR) / cAMP/PKA signaling pathway. Thus, GHCer is not only a tumor antigen associated with poor prognosis but also acts as an immune checkpoint and an angiogenic factor to shape the tumor microenvironment. These findings provide strong rationales for developing Globo H-targeted immunotherapy. A randomized multinational phase II trial of Globo H-KLH vaccine in metastatic breast cancer showed improved progression free survival in patients who mounted anti-Globo H immune responses, thereby providing the basis for the ongoing global phase III trial. In addition, a 2nd generation Globo H vaccine, an anti-Globo H and its ADC are undergoing early phase trials.



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DAY 1 SPEAKER



Stephen Y Lai MD Anderson Cancer Center

PRESENT TITLE AND AFFILIATION Primary Appointment

- Professor, Department of Head and Neck Surgery, Division of Surgery, The University of Texas
- MD Anderson Cancer Center, Houston, TX

Dual/Joint/Adjunct Appointment

- · Professor, Department of Radiation Oncology, Division of Radiation Oncology, The University of
- Texas MD Anderson Cancer Center, Houston, TX
- Professor, Department of Molecular and Cellular Oncology, Division of Basic Science Research,
- The University of Texas MD Anderson Cancer Center, Houston, TX

EXPERIENCE/SERVICE Academic Appointments

- Assistant Clinical Instructor, Department of Head and Neck Surgery, University of Pennsylvania,
- School of Medicine, Philadelphia, PA, 7/1999-6/2001
- Clinical Instructor, Department of Head and Neck Surgery, University of Pennsylvania, School of Medicine, Philadelphia, PA, 7/2001-6/2003
- Instructor, Department of Head and Neck Surgery, University of Pittsburgh, School of Medicine,
- Pittsburgh, PA, 7/2003-6/2005
- Assistant Professor, Department of Otolaryngology, University of Pittsburgh, School of Medicine,
- Pittsburgh, PA, 7/2005-8/2008
- Assistant Professor, Department of Head and Neck Surgery, Division of Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2008-8/2010
- Assistant Professor, Department of Molecular and Cellular Oncology, The University of Texas
- MD Anderson Cancer Center, Houston, TX, 9/2008-8/2010
- Associate Professor, Department of Head and Neck Surgery, Division of Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2010-8/2017
- Associate Professor, Department of Molecular and Cellular Oncology, Division of Basic Science
- Research, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2010-8/2017
- Professor, Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 8/2017-present

Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

- Professor, Department of Molecular and Cellular Oncology, Division of Basic Science Research
- The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2017-present
- Professor, Department of Head and Neck Surgery, Division of Surgery, The University of Texas
- MD Anderson Cancer Center, Houston, TX, 9/2017-present

EDUCATION Degree-Granting Education

- Stanford University, Stanford, CA, BA, with distinction, 1991, Economics
- Stanford University, Stanford, CA, BS, with distinction and honors, 1991, Biological Sciences
- University of California, San Francisco, CA, PhD, 1996, Biomedical Sciences
- University of California, San Francisco, CA, MD, 1998, Medical School



Clinical Translation of Imaging-Based Quantitative Biomarkers to Assess Treatment Effects and Toxicity

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Stephen Y. Lai, MD, PhD, FACS Professor, Head and Neck Surgery, Radiation Oncology, Molecular and Cellular Oncology The University of Texas MD Anderson Cancer Center Houston, TX, USA

Abstract

Head and neck squamous cell carcinoma (HNSCC) remains a leading cause of cancer deaths worldwide. Genotoxic agents, including radiation therapy (RT) and cisplatin (CDDP), are treatments that damage cellular DNA. RT and CDDP are the current standard of care in multiple solid tumors, including HNSCC. We have focused our efforts on the assessment of tumor response using minimally invasive quantitative imaging (hyperpolarized magnetic resonance imaging; HP-MRI) while patients are undergoing therapy. We showed that CDDP and other genotoxic agents trigger measurable fluctuations in tumor cell metabolism detectable through HP-MRI with [1-13C]-pyruvate in real time (confirmed by conventional biochemical assays). Genotoxic stress suppresses the apparent rate of pyruvate conversion into lactate (kPL) via lactate dehydrogenase (LDH) in a manner that correlates with anti-tumor effectiveness. Our goal is to develop this imaging-based biomarker to optimize response to therapy. Additionally, deleterious RT effects upon organs-at-risk (OARs) such as the salivary glands, deglutitive/masticatory muscles, and mandibular bone, can result in long-term sequelae such as xerostomia, dysphagia, and osteoradionecrosis (ORN), respectively. These long-term sequelae in a patient population with good clinical outcomes and extended life expectancy (human papillomavirus (HPV)-associated oropharynx cancer) are becoming increasingly relevant in the management of treatment-associated morbidity and mortality. At our institution, dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) is integrated into a multimodality clinical algorithm aimed at improving tumor diagnosis, staging, and surveillance. DCE-MRI can detect altered bone vascularity associated with bone healing, necrosis, and metastatic involvement, with excellent spatial resolution. Our objective is to validate DCE-MRI parameters as strong candidate biomarkers and to development them within the FDA Biomarker Qualification Program for eventual clinical implementation. Imaging-based quantitative biomarkers are a minimally invasive approach to optimizing treatment effectiveness against tumors, while assessing normal tissues and organs for treatment-related side effects and toxicity.



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DAY 1 SPEAKER



顧 曼 芹 顧德諮詢 總經理

- Founder and Director of Kuder Consulting Company
- Chief Executive Officer (CEO), Savior Lifetech Corporation
- Founding President and Board Member of RuenHuei Biopharmaceutical Company
- Founding President/CSO of TWi Biotech/TWi Pharma (Anchen) with 6 High Barrier ANDA filings within 18 months. Simultaneously established a pipeline of 6 new drugs including 3 biologicals
- Head of Early pharmaceutical Development in Wyeth Research USA (now Pfizer).
 Her responsibilities starts from discovery interface through clinical proof of concept.
- Oversees new drug development for over 170 new clinical leads resulting in 85 original NME IND filings.
- Developed seven (9) commercial products including Suprax, Zosyn/Tazocin, Zebeta,Isovorin, Thioplex, Sonata, Tygacil, Bosulif* and Neratinib* from preformulation through NDA and FDA PAI activities (except post merger*).
- Sherry is a graduate of National Taiwan University (B.S.) and The Ohio State University (Ph.D.) in Pharmaceutics and Pharmaceutical Chemistry.
- She currently holds over 70 patents/invention disclosures and has additional 62 Journal publications.
- She was the Vice Chair of NJ Pharmaceutical Discussion Group and is the chair elect of AAPS
 Physical Pharmacy and Biopharmaceutical section
- She sits on USP expert council and consults for sFDA, tFDA, IPEC and various Quality Councils.
 She is a licensed Pharmacist.

2023/5/16

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Translational Barriers for Protein Drugs Pharmacodynamics/Pharmacokinetics Perspectives

M. Sherry Ku, Ph.D., RPharm.

Abstract

Protein drugs have gained popularity due to its high barrier for generic entry and for their selectivity and specificity with a low risk of off-target toxicity. In particular, protein drugs breaks down to peptides and amino acids, which is of low risk in toxicity compared to the metabolites of small molecules generated via cytochrome P450 enzymes. However, protein drugs have limited oral bioavailability (typically <1–2%) and therefore have to be dosed parenterally via an invasive procedure. Luckily, proteins especially monoclonal antibodies (mAbs) have a long circulating half-life, and thus less frequent dosing. These long half-lives (11–30 days in humans) are a result of endosomal FcRn-mediated recycling. Absent or altered FC sequence can shorten the half-lives from days to hours in cases such as bispecific antibodies.

The other critical barrier for mAbs is their confined distribution in vasculature and interstitial space because of their size and polarity. Since continuous blood capillaries only allow substances with less than 1.5 kDa to reach systemic circulation, subcutaneous (SC) or intramuscular (IM) administered mAbs enter the circulation through convection forces via Fenestrated and discontinuous sinusoidal especially in the liver and spleen. Lymphatic fluid drainage also plays a role but to a small extent. The maximum plasma concentrations of mAbs are often reached around 1–8 days post dosing and bioavailability varies between 50–90% following SC dosing in humans. In spite of the variable biodistribution, SC administration is an established modality for chronic dosing given its convenience and option of self-administration.

Protein drugs have complex PKPD relationship given their limited distribution. The SC administration has a delayed peak concentration in blood but if the target is in lymph nodes, the drug may reached the target ahead of blood exposure. It is why SC administration sometimes has exhibited a higher tendency to induce anti-drug antibody compared to IV administration.

This seminar will discuss PK characteristics (ADME) of mAbs encompassing linear and non-linear elimination processes emphasizing the determinants of mAb half-life. Three case studies on IND candidate selection using PK/PD will be presented: an anti-CD4, an anti-amyloid-beta, and an anti-IL-21R mAb. Disconnection between the preclinical and clinical data and off-target elicited PK behaviors will be discussed.



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DAY 1 SPEAKER



周 慧 泉 全心醫藥生技 執行長

Dr. Judy Chou is the CEO, President and Board member of AltruBio, Inc. which is a clinical stage biotech company in San Francisco, CA, and the Chair of AltruBio Taiwan, Inc. Before taking on her current roles, she headed the global Biotech organization at Bayer Pharmaceuticals overseeing the development, manufacturing and distribution of Bayer's biotechnology product portfolio & 2000+ employees and leading the drug development and launch activities for biologics pipeline. In addition, she served as the site head for Bayer's facility in Berkeley, CA. She is well recognized by the biomedical industry for her leadership and has received the Most Influential Women in Business Award in 2018 by San Francisco Business Times.

Before Bayer, Dr. Chou held the role of Vice President of Pharmaceutical Operations at Pfizer, Inc. where she led the Development and Manufacturing organizations for both biologics and small molecule products. She was also Vice President of R&D and Manufacturing at Tanvex Biopharma and has enabled the success of the company's IPO. Throughout Dr. Chou's career, she has achieved significant milestones in biologics development and multiple filings of BLAs, NDAs, and INDs of novel products and is broadly recognized for her work at Genentech, Pfizer (Wyeth) and Abbvie (Abbott) especially in the development of breakthrough technologies and accelerated product development.

Currently, Dr. Chou also serves as the Board of Directors of Akero Therapeutics, Inc. and California Institute of Regenerative Medicines (CIRM), and advisory board members of UC, Berkeley Engineering School and Silicon Valley Women in Engineering. Before joining the industry, Dr. Chou was a research faculty member at Harvard University Medical School. Dr. Chou obtained her Ph.D. from Yale University.



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Immune Checkpoint Enhancers (ICEs) for Immunological Diseases

Judy H. Chou, Ph.D. President and CEO, AltruBio, Inc.

Abstract

AltruBio's molecules, ALTB-268 and ALTB-168 are PSGL-1 agonist antibodies serving as immune checkpoint enhancers (ICEs). The mechanism of action has been proven in four autoimmune and inflammatory diseases, including ulcerative colitis, steroid refractory acute graft-versus-host disease (SR-aGVHD), psoriatic arthritis, and psoriasis. ALTB-268 is a tetravalent version of ALTB-168 and has demonstrated higher potency via the same mechanism, making it suitable for subcutaneous administration. ALTB-268 is now being evaluated in a Phase 1 clinical trial before advancing towards clinical studies in multiple autoimmune and inflammatory disorders with the initial indiction in ulcerative colitis. The development updates will be presented.



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DAY 1 SPEAKER



楊 志 新 臺灣大學醫學院附設醫院癌醫中心分院 院長

Superintendent Office Superintendent Lung Cancer Attending Physician Department of Medical Oncology Attending Physician Basic and Clinical Oncology, Anticancer Drug Research and Development, Chemical Drug Resistance, Clinical Trials, New Anticancer Drug Development, Lung Cancer Immune Microenvironment

Research Interests

National Taiwan University Graduate Institute of Clinical Medicine, College of Medicine Ph.D National Taiwan University School of Medicine, College of Medicine M.D.

Current Positions

ouricité i obitions		
National Taiwan University Cancer Center	Superintendent	2020present
Cancer Administration and Coordination Center, National Taiwan University Hospital	Director	2016present
Graduate Institute of Oncology, College of Medicine, National Taiwan University	Director	2015present
Graduate Institute of Oncology, College of Medicine, National Taiwan University	Professor	2009present
The Ph.D. Program for Translational Medicine, College of Medicine, National Taiwan University	Professor	2012present
Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University	Professor	2008present
Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University	Professor	2008present
Department of Oncology, National Taiwan University Hospital	Adjunct Attending Physician	2020present



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DAY 1 SPEAKER



陳 立 宗 高醫大癌症研究中心執行長/國衛院癌研所特聘研究員

Education

- 1975.8 1982.7 M.D. Kaohsiung Medical College, Kaohsiung, Taiwan
- 1992.8 2001.7 Ph.D. Post-graduate School, Kaohsiung Medical University

Current Position

- 1988.08 Attending Physician, Division of Gastroenterology, Department of Medicine, Kaohsiung Medical University Hospital
- 2012.08 Adjunct Professor of Internal Medicine, Medical School, National Cheng Kung University, Tainan, Taiwan
- 2007.07 Attending Physician, Department of Internal Medicine, National Cheng-Kung University Hospital
- 2014.08 Director, National Institute of Cancer Research, National Health Research Institutes
- 2020.08 Co-affiliated, Distinguished Investigator, National Health Research Institutes
- 2020.08 Chair Professor of Internal Medicine, College of Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan
- 2020.08 Chief Executive Officer of Center for Cancer Research, Kaohsiung Medical University
- 2020.08 Chairperson, Research and Development Committee, Kaohsiung Medical University Chung-Ho Memorial Hospital

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Experience

•	1992.08 - 2005.01	Lecturer of Internal Medicine. Kaohsiung Medical University
•	1995.08 - 2009.09	Adjunct Attending Physician, Department of Oncology, National Taiwan University Hospital, Taipei
•	1995.08 - 2006.07	Adjunct Attending Physician, Department of Internal Medicine, Veteran General Hospital, Taipei
•	2002.08 - 2005.12	Associate Investigator, National Health Research Institutes
•	2005.02 - 2012.07	Associate Professor, College of Medicine, Kaohsiung Medical University
•	2006.01 - 2014.07	Investigator, National Institute of Cancer Research, National Health Research Institutes
•	2006.08 - 2007.07	Adjunct Attending Physician, Department of Internal Medicine, Tri-service General Hospital, Taipei
•	2008.03 - 2018.07	Adjunct Professor, Institute of Clinical Pharmacy and Pharmaceutical Science, National Cheng Kung University, Tainan
•	2008.03 - 2012.08	Deputy Director, National Institute of Cancer Research, National Health Research Institutes
•	2012.09 - 2018.07	(Adjunct) Professor of Internal Medicine, College of Medicine, Kaohsiung Medical University
•	2012.09 - 2013.07	Vice Superintendent and Director of Cancer Centre, Kaohsiung Medical University Hospital, Kaohsiung Medical University
•	2013.08 - 2014.07	Acting Director, National Institute of Cancer Research, National Health Research Institutes
•	2014.08 - 2020.07	Distinguished Investigator, National Health Research Institutes
•	2018.08 - 2020.07	Adjunct (Co-affiliated), Chair Professor of Internal Medicine, College of Medicine, Kaohsiung Medical University



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DAY 1 SPEAKER



蕭 世 嘉 育世博生物科技 執行長

Profile

- Over 14 years of R&D experience across biotech and academia in the areas of oncology, cell therapies, and immuno-oncology. Served for over several years in leadership roles including chief scientist and CEO. Co-founder of Acepodia, Inc.
- Track record in the discovery of cell therapy products and translation from pre-clinical candidates to FDA- approval phase, including bringing one of my own Berkeley research cell therapy drug candidate to get IND approval and to get into clinical trials in the US.
- Strong experience in advancing innovative and emerging technologies, such as NK cell therapy, gamma delta T cell therapy, antibody-cell conjugates, adoptive/CAR cell therapies (including donor-derived & cell line approaches).
- Leadership with expertise in building and leading teams across the entire spectrum of drug development, from initial discovery to IND and patent filing, safety, PK/PD, CMC, regulatory, and early-phase clinical trials. Experience in working in a fast-pace environment, including chairing high-level company committees responsible for making go or no-go decisions. Leading scientist with numerous publications and worldwide patent applications and issued patents
- Co-Founder and Chief Executive Officer at Acepodia, Inc. Awarded Dr. Y-T Lee Prize, which
 named after Nobel Laureate Dr. Lee, for the research achievement in Chemistry. Extensive
 research experiences in immune cell therapies, which lead to the discovery of ACC
 (Antibody-Cell Conjugation) technology, and to the invention of the novel cellular immunotherapy,
 ACE (Antibody-Cell Conjugation Effectors). BS in Chemistry from National Taiwan University,
 and PhD in Chemistry and Molecular Cell Biology from the University of California, Berkeley.

PROFESSIONAL EXPERIENCE

Acepodia, Inc.

Member of the Board of Directors, 2016 – Present
Founder and CEO. 2016 – Present



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- Became CEO and President of Acepodia, Inc in 2016 at the operational inception of the company to build an innovative organization to develop new therapies in immune-oncology and cell therapy medicine.
- Recruited R&D team, developed company development strategy, and executed on a capital-efficient program to bring company's lead product from lab research concept through completion of a development program comprising preclinical small animal and non-human primate studies in solid and liquid tumors.
- Helped the company built unique value by forging its path through a complex and largely unprecedented clinical, regulatory, and manufacture landscape.

Adheren, Inc.

Founder and Chief Scientific Officer, 2014 - 2015

- Chief Scientist of Adheren, Inc at the inception of the company with a focus on the interface of science and business value creation.
- Reported to the CEO and was member of both the Executive and Scientific Leadership teams with responsibility at various times for: R&D, Corporate Strategy, and Product Development.
- As a PI, I have demonstrated my ability to manage grants and the progress of experiments.
 I have managed and executed a NCI-IMAT R33 grant, and manage several collaborations with academic laboratories, including Robert Negrin and Everett Meyer labs at Stanford University, and David Schaffer lab at UC Berkeley.

University of California, Berkeley Graduate Research Associate, 2007 – 2011

Study and research of cell surface modification and protein/DNA conjugation chemistry.

Education

- 2006-2011 Ph. D., University of California, Berkeley
- 2006-2009 Graduate Student Instructor, University of California, Berkeley
- 2000-2004 B. S., National Taiwan University (Chemistry Major)



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

DAY 1 SPEAKER



王琳雅 Twist Bioscience 高級資深科學家

- Experienced in Cell biology, Immuno-Oncology, Antibody drug discovery, Assay development
- High quality publications: 15 publications, 6 scientific presentations, 2 journal/press cover graphics, and 5 patents
- · Project management and Team leading with strong organization and communication skills

RESERACH EXPERIENCE

Research Associate Academia Sinica, Molecular Biology, Taiwan	Jan. 2005 - Jan. 2012	
Postdoctoral Research Fellow, Lab Instructor Feb. 2012 - Apr. 2018 University of Southern California, Molecular Microbiology and Immunology, CA, USA		
Research Scientist AbVision Inc., Drug Discovery R&D Department, CA, USA	Jul. 2018 – May. 2020 A	
Twist Bioscience, Biopharma, CA, USA		
Staff Scientist	Jun. 2020 - Sep. 2021	
Senior Scientist	Oct. 2021 – Oct. 2022	
Senior Staff Scientist, Head of Cell Biology	Oct. 2022 – Present	

EDUCATION

Ph.D. in Microbiology	National Taiwan University	Taiwan Jul, 2011
M.S. in Microbiology and Immunology	National Cheng Kung University	Taiwan Jul, 2004
B.S. in Medical Technology/Clinical Lab Science	National Taiwan University	Taiwan Jun,2002



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Writing the Future of Antibody Discovery with Synthetic DNA

Linya Wang, Ph.D 王琳雅 Twist Bioscience 高級資深科學家

Abstract

Utilizing its proprietary DNA technology to write synthetic libraries, Twist Biopharma provides end -to-end antibody discovery libraries including both (1) highly diverse synthetic naïve antibody phage display libraries and (2) target class specific antibody phage display libraries against difficult-to-drug targets. The high throughput platform can chemically synthesize 1 million individual DNA oligos, each of them up to 300 base pairs, on a silicon chip that is roughly the same size as a smart phone. It is a game-changing throughput involves development of software, robotic, integrated ecommerce platform, and manufacture system. This silicon-based DNA synthesis platform can be applied and beneficial on various DNA products, including antibody discovery. With large collection of the libraries and high-speed production, we can obtain large variety of sequence for drug development.



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DAY 2 SPEAKER



唐 堂 中央研究院 副院長

Current Position: English / 中文

- Vice President, Academician / 副院長,院士
- Distinguished Research Fellow, / 特聘研究員
- Institute of Biomedical Sciences / 生物醫學研究所
- Academia Sinica / 中央研究院

Education / Training:

- 1974-1978 B.S. Dept. of Biology, Tunghai University, Taiwan
- 1981-1983 M.S. Dept. of Microbiology and Immunology National Yang-Ming Medical College, Taiwan
- 1984-1988 M.Ph./Ph.D. Dept. of Human Genetics, Yale University, USA

Professional and Research Experience:

- 1988-1989 Postdoctoral Fellow
 - Dept. of Medicine, Hematology Section, Yale University
- 1989-2010 Associate Research Fellow and Research Fellow Institute of Biomedical Sciences (IBMS), Academia Sinica
- 1997-1999 Deputy Director, IBMS, Academia Sinica
- 2004-2006 Deputy Executive Secretary, The Central Advisory Committee, Academia Sinica
- 2006-2007 Executive Secretary, The Central Advisory Committee, Academia Sinica
- · 2008-2009 Director, Advisory office, Ministry of Education
- 2011-2012 Advisory member, Advisory Office, Ministry of Education
- 2010- Distinguished Research Fellow, IBMS, Academia Sinica
- 2022- Academician and Vice President, Academia Sinica



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

DAY 2 SPEAKER



蔡 明 道 中央研究院 院士

- · 1978 Ph.D, Biochemistry & Medicinal Chemistry, Purdue University
- 1972 B.S., Chemistry, National Taiwan University, Taipei
- 2020 迄今 客座講座, 中研院生化所
- 2008 2020 特聘研究員, 中研院生化所
- 2012 院士, 中央研究院
- 2010 2016 副編輯, Biochemistry
- 2008 2014 所長, 中研院生化所
- 2006 2008 代所長, 中研院生化所
- 2005 2008 Director, Division of Functional Genomics, Genomics Research Center
- 2003 2008 Director, National Research Program for Genomic Medicine Core Facility Office
- 1995 2003 Director, Chemistry/Biology Interface Training Program, OSU
- 1993 2007 Director, Office of Research Campus Chemical Instrument Center, The Ohio State University
- 1992 1992 Elected Fellow, American Association for the Advancement of Science (AAAS)
- 1992 1992 Distinguished Scholar Award, Ohio State University
- 1985 1990 Camille and Henry Dreyfus Teacher-Scholar
- 1985 1985 Faculty Research Award, Ohio State Chapter of Sigma Xi
- 1983 1985 Alfred P. Sloan Fellow
- 1981 2006 Kimberly Professor of Chemistry and Professor of Biochemistry, The Ohio State University (starting as Assistant Professor)



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

DAY 2 SPEAKER



洪 明 奇 中央研究院 院士

EDUCATION

- 1983 M.A., Ph.D., in Biochemistry (Mentor: Pieter C. Winsink, Ph.D.), Brandeis University, Waltham, U.S.A.
- 1977 M.S., in Biochemistry, National Taiwan University, Taipei, Taiwan
- 1973 B.S., in Chemistry, National Taiwan University, Taipei, Taiwan

Position and selected service to advisory boards

- President, China Medical University Taichung, Taiwan 02/18/2019- present中國醫藥大學校長
- Vice President for Basic Research, The University of Texas MD Anderson Cancer Center, Houston, TX, 3/2010-02/17/19德州大學安德森癌症中心基礎科學研究副院長
- Department Chair, Department of Molecular and Cellular Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX,3/200002/17/19德州大學安德森癌症中心分子細胞 腫瘤系主任
- Director, Center for Biological Pathways, The University of Texas MD Anderson Cancer Center, Houston, TX, 9/2008-02/17/19德州大學安德森癌症中心生物信號通路中心主任
- Professor, The University of Texas M.D. Anderson Cancer Center, TX,09/94-02/17/19 德州 大學安德森癌症中心教授
- Ruth Legett Jones Distinguished Chair, The University of Texas MD Anderson Cancer Center, Houston, TX, 1/2003-02/17/19德州大學安德森癌症中心Ruth Legett Jones傑出講席教授
- President (International), Society of Chinese Bioscientists in America, 2004-2005美洲華人 牛物科學學會會長
- Member, Board of Directors, China Medical University and Hospital Health System, Taiwan, 2004-01/2019. 中國醫藥大學及附屬醫院 董事會董事
- Honorary Director, Center for Molecular Medicine, China Medical University and Hospital, Taichung, Taiwan, 9/2006-present. 中國醫藥大學及附屬醫院分子醫學中心榮譽主任
- Member, Cancer Research Advisory Board, Ministry of Health and Welfare of Taiwan, April 10, 2014 to December 31, 2017. 衛生福利部癌症研究顧問委員會委員
- Member, Scientific Advisory Board, Life Sciences Institute, Zhejiang University, Hengzhou, China, 2014- present.浙江大學生命科學學院科學顧問委員會委員

2023

ATC抗體藥物暨第18屆前瞻生醫新知研討會

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- Member, Advisory Committee, University of Macau, Macau, China, July 2015-2016澳門 大學顧問委員會委員
- Member, Selection Committee, Pezcoller Foundation-AACR Award, 2016 Pezcoller基金會 AACR獎評選委員會委員
- Member, External Advisory Board, The University of Kansas Cancer Center, 2017-堪薩斯大學癌症中心校外顧問委員會委員

As President of China Medical University (After February 2019)

- Chairman, Spring Academic Lectures, Formosan Medical Association台灣醫學會 2022.111年 春季學術演講會會長
- Member, Organizing Committee of the Cancer Symposium, Ministry of Health and Welfare.
 2022 衛生福利部癌症研討會組織委員會成員
- Member, Scientific Review on Institute of Molecular and Genomic Medicine, 2021. NHRI國家 衛生研究院分子與基因醫學研究所(分基所)學術評鑑委員
- Member, Selection Committee for the President of NHRI2021-2022. 國家衛生研究院院長遴選 委員會委員
- Member of Academic Advisory Committee (AAC), Biomedical Translation Research Center (BioTReC), National Biotechnology Research Park (NBRP), Academia Sinica, Taiwan 2021-2025 中央研究院生醫轉譯中心及國家生技研究園區學術顧問委員會成員
- Member, Advisory Committee, National Taiwan University. 2021台灣大學學術顧問委員會委員
- 16th Council Member, Taiwan Bio-Industry Organization 2020 台灣生物產業發展協會 第十六屆理事
- Member, Steering Committee, 16th&18th Outstanding Medical/Pharmaceutical Technology Award, Tien Te Lee Biomedical Foundation 2020,2022.第 16, 18屆永信李天德醫藥科技獎評審委員
- Reviewer, 24th National Chair Professor in Biology, Medicine and Agriculture, Ministry of Education. 2020-. 第24屆教育部國家講座主持人生物及醫農科學類評審委員
- Member, Academic Advisory Board (AAC), Institute of Molecular Biology, Academia Sinica, Taiwan. 2020-2025 中央研究院分子生物研究所 學術諮詢委員會
- Council Member, Green University Union of Taiwan. 2019-2021. 臺灣綠色大學聯盟第4屆理事
- Chair, Research committee of director of Institute of Molecular Biology, Academia Sinica. 2018-2020 中央研究院分子生物研究所 所長遴選委員會主席

Research Interests

洪教授的研究興趣聚焦於以下研究領域,包含1、受體酪氨酸激酶家族 Receptor Tyrosine Kinase (RTK) family 的功能及其在癌症形成與發展之作用; 2、破解癌症與微環境中相關訊息通路,以預測或解決對標靶治療的耐藥性難題; 3、開發標記引導與免疫檢查點之新療法。



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DAY 2 SPEAKER



吳 妍 華 中央研究院 院士

Current Positions

 Chair Professor, Institute of Biological Science and Technology, National Chiao Tung University (2011 -)

Education

- B.S., Department of Agronomy, National Taiwan University (1966-1967)
- B.S., Department of Agricultural Chemistry, National Taiwan University (1967-1970)
- M.S., Institute of Biochemistry, School of Medicine, National Taiwan University (1970-1972)
- Ph.D., Department of Biochemistry, University of Tennessee (1972-1976)

Professional Experience

- Post-doctoral, Department of Biochemistry, School of Medicine Georgetown University (1975-1979)
- Consultant, BRL Company, Bethesda, Maryland, USA (1978-1979)
- Associate Professor, Department and Institute of Biochemistry, National Yang-Ming Medical College (1979-1985)
- Acting Chairman, Institute of Biochemistry, National Yang-Ming Medical College (1984-1986)
- Professor, Institute of Biochemistry and Molecular Biology, National Yang-Ming University (1985-2011)
- Chairman, Institute of Biochemistry, National Yang-Ming University (1986-1991;1994-1997)
- Dean, Academic Affairs, National Yang-Ming University (1999-2001)
- Acting President, National Yang-Ming University (2000-2001, 2009.11-2010.7)
- President, National Yang-Ming University (2001-2009)
- Distinguished Chair Professor, National Yang-Ming University (2007-2011)
- Acting Chancellor, University System of Taiwan (2008-2012)
- Advisor, Yuan Science and Technology (2010-2011)
- Board Member, NHRI (2010-2012, 2013-2014, 2016-2019)
- Board Member, ITRI (2011-2016)
- Board Member, NARL (2012-2013)
- Board Member, Chung-Shan Institute of Science & Technology (2014-2017)
- Advisor, NARL, The White Paper on Science and Technology: A Preliminary Study (2014)
- President, National Chiao Tung University (2011-2015)



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PANEL DISCUSSION



吳 忠 勳 財團法人生物技術開發中心 執行長

Education

- Ph.D. in Biochemistry, University of Maryland, U.S.A.
- B.Sc. in Botanics, National Taiwan University, Taiwan

Experience

- 2018~ present, President, Development Center for Biotechnology (DCB)
- Director, Biotechnology and Pharmaceutical Industries Promotion Office, MOEA
- Chairman, Taiwan Bio Industry Organization
- Chairman, Taiwan Antibody Association
- Vice President, Precision Medicine & Molecular Diagnostics Industry Association of Taiwan
- Director, Institute for Biotechnology and Medicine Industry(IBMI)
- Director, Taipei Biotechnology Service and Business Trade Association
- Director, Chinese Association for Industrial Technology Advancement
- Director, Taiwan Pharmaceutical Manufacture and Development Association
- Supervisor, Monte Jade Science and Technology Association of Taiwan
- 2017~ 2018, Acting President, Development Center for Biotechnology (DCB)
- 2017~ 2018, Vice President, Development Center for Biotechnology (DCB)
- 2014~2017, Executive Director, Institute of Biologics, Development Center for Biotechnology(DCB)
- 2013~2014, Director/Senior Research Fellow, Department of Protein Engineering, Development Center for Biotechnology (DCB)
- 2008~2009, Founder/Chairman/CEO, Geniusway Biotech.
- 2006~2008, Founder/Chairman/CEO, Geniusway Technology
- 2000~2004, Cofounder/Chief Scientific Officer/Vice President of Business Development, AbGenomics Inc.
- 1996~2000, Associate Professor, Institute of Molecular Medicine, College of Medicine, National Taiwan University
- 1995~1996, Lecturer, Institute of Molecular Medicine, College of Medicine, National Taiwan University
- 1992~1995, Jane-Coffin-Childs Memorial Fund Fellow, Department of Embryology, Carnegie Institution of Washington, Baltimore, Maryland, USA

Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

PANEL DISCUSSION



伊慶燧 醫創生物科技(股)公司 總經理

Education

- Univ. of Georgia, USA Ph.D in Pharmaceutical Chem. 藥學博士
- Taipei Medical Univ. 台址醫學大學 B.S in Pharmacy 藥學士

Experience

- 醫創生物科技 Creaticon Biotech, 新竹 總經理 President
- 寶齡富錦生技股份有限公司, 台北, 檢驗試劑部副總, Vice President
- 凌越生醫. 台北. 顧問/技術指導Consultant/Technical Director
- Innovacon/Alere Corporation, CA, USA 副總VP/品質與法規
- Apollo Medical Corporation, CA, USA 創始人Founder
- Meridian Bioscience, OH, USA 副總 Vice President/研發與法規
- Cambridge Bioscience, MA, USA 主任 Director/產品發展部
- BioClinical System, MO, USA 合夥人 Partner/研究員
- Terumo Medical Corporation, MD, USA 經理Manager/檢驗試劑部門
- Leeco Diagnostics, MI, USA 資深研究員 Senior Scientist

Accomplishment

- Non-extraction Testosterone RIA (1980)
- T3, T4, and TSH EIAs, microwell format (1984)
- Apolipoprotein A RIA (1985)
- Home pregnancy EIA (1985)
- Avian Infectious Diseases 4 products (1985)
 COVID-19 Antigen Rapid Test (2020)
- Lyme disease EIA; for Canine (1986)
- Adenovirus & Enteric Adeno 40/41 EIAs (1987)
- HIV Latex Test (1987)
- Recombinant HIV EIA (1988)
- Clostridium difficile EIA (1990)
- E coli Toxin EIA (1995)

- Non-column glycohemoglobin A1C Test (1979)
 Helicobacter pylori Stool Antigen EIA (1998)
 - Helicobacter pylori Stool Antigen Rapid Test (2001)
 - Enterovirus EIA/Rapid Test prototype (2005/2011)

 - Effectiveness of Cancer Treatment癌症個人 化療效 (Precision Medicine)......



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PANEL DISCUSSION



吳 宗 益 醣基生醫(股)公司 總經理

Dr. Chung-Yi Wu obtained his Ph.D. degree from the Department of Applied Chemistry at National Chiao Tung University. He joined Academician Chi-Huey Wong's lab for his postdoctoral research.

In 2006, Dr. Wu accepted a position as an assistant research fellow at the Genomic Research Center in Academia Sinica to continue his research in glycoscience and obtained his position as research fellow in 2016. During this period, Dr. Wu published more than 100 academic papers and was granted for more than 40 patents. His achievements garnered him prestigious awards such as the 2014 American Chemical Society David Y. Gin New Investigator Award, Taiwan Bio-Development Foundation Lecturer Scholar Award, and National Chiao Tung University Applied Chemistry Department Distinguished Alumnus Award. Moreover, Dr. Wu is the main contributor of the more than 20 patents in the field of homogenous antibody, glycoprotein, glycovaccine, and glycoarray technologies that were transferred from Academia Sinica to our company.



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

PANEL DISCUSSION



林 淑 菁 聯合生物製藥(股)公司 總經理

Dr. Shugene Lynn is the Chief Executive Officer and a member of the Board of Directors of United BioPharma (UBP). She also serves as a board member of several companies within the UBI group. Prior to joining UBP in January 2019, she was the executive vice president of corporate development at UBI Asia, responsible for corporate strategic planning and financing

She has been with the UBI group since 1999, beginning as a bench scientist with increasing responsibility from project to program management, to corporate development, and has been associated with every step along the path of UBI growth in Asia. She was the first scientist in the UBI group to be engaged in the antibody humanization platform, and has since led a team to build the therapeutic monoclonal antibody process development platform, and brought the HIV drug candidate UB-421 from cell line development to clinical phase I and II stages. During her tenure at UBI Asia, the company was awarded 11 government research grants, and sponsored three monoclonal antibody drug candidates into clinical trials.

Dr. Lynn received her B.S. in plant pathology and Ph.D. in life sciences from the Institute of Zoology both from National Taiwan University. She completed her postdoctoral training at Academia Sinica and received the Outstanding Postdoctoral Fellow Award in 1998 for her eight first author publications in international journals.



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PANEL DISCUSSION



俸 清 珠 研生生醫(股)公司 策略長

BIOGRAPHY

I have worked over 20 years in the biomedical industry serving both operational and consu ting roles. With in-depth knowledge in CMC and project management, I had brought the first biological medicinal product from preclinical to commercial in Taiwan. On business development, I involved in team-building for CDMO business and have successfully concluded CDMO contracts worth more than 1.6 B NTD. I also have helped a company to achieve the investment up to the triple of original goal in its fund-raising. I would welcome the opportunity to work with you to the company's next level!.

PROFESSIONAL EXPERIENCE

PF Consulting Ltd.— Taiwan (2023.01 — Present) Funder/ Chief Consultant

- Provide consulting services for the drug development and business development
- Engage proper talents for customers' temporary need

AcadeMab Biomedical Inc. –Taiwan (2021.10 – Present) Chief Strategy Officer

- Facilitate the company/ project positioning to maximize their value
- Assist fund-raising
- Establish strategic plans for new drug development and technical platforms development
- Manage business development activities for out-licensing and research servicesed

United Biopharma Inc. – Taiwan (2019.11 – 2021.09) Vice President, Business Development Center

- Established and trained teams for business development on CDMO services and out-licensing
- Trained and led multiple functional groups to establish necessary organization, document and work flow for business development



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Mycenax Biotech Inc. – Taiwan (2001.09 - 2019.07) Vice President Business Development (2018-2019)

- Set the strategic marketing plan to explore business opportunities
- · Managed global business development activities for both CDMO services and pipeline out-licensing
- · Collaborated with technical teams to implement the services in line with global trend
- · Led contract negotiation with global customers and worked with legal counsel as required

Regulatory Affair (2007-2019)

- Led and maintain registration strategy and prepare submission dossier for in house pipelines
- Worked closely with BD and technical team to provide strategic regulatory guidance and review
- Prepared and/or attended the scientific advisory meetings with TFDA, FDA, EMA and PMDA

Project Management (2003-2019)

- Led the project management team for the development of biological products for both CDMO projects and in house pipeline from pre-clinical, clinical to the commercial
- Led the multidisciplinary task force in the evaluation of the new biologic entities, as the candidate of licensing-in

Department of Quality Control (2001-2015)

- Managed QC team and continuously improve its work efficiency
- · Kept the quality control in compliance with global standards
- Helped to establish Quality Assurance system
- Co-host customer GMP audits and authority inspections



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PANEL DISCUSSION



曾 惠 瑾 資誠聯合會計師事務所 榮譽副所長

Current Positions

- Advisory Committee, Bio Taiwan Committee (BTC)
- Vice Chairman, Taiwan Bio-industry Organization
- Vice Chairman, Precision Medicine Industry Association of Taiwan.
- Independent Director, Delta Electronics, Inc
- Independent Director, Asustek Computer Incorporation
- Advisor, Biomedical Translation Research Center, Academia Sinica

Experience

- Deputy Chairman/ Assurance Leader/ Markets Leader/ Industry Development Leader, PwC Taiwan
- Synergies Leader, PwC CaTSH(Greater China)

Education

- Master of Business Administration, Executive MBA, National Taiwan University and Fudan University
- Master of Commerce, Department of Accounting, National Chengchi University

Expertise

Audrey has rich experiences as a partner and leaders in PwC and sophisticated experience in assisting the development of biotech/med-tech industry/digital health industries. She is familiar with stakeholders in the biotech ecosystem and their demands in every stage including,

Project selection/ Business models / Deal structures / Exit strategies (cross border merger and acquisition and IPO). She successfully assists many biotech and med-tech companies to become publicly listed in Taiwan, the United States, and Hong Kong exchanges.



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PANEL DISCUSSION



劉 理 成 台康生技(股)公司 創辦人、董事長暨總經理

Dr. Liu has 30 years of product, process development and manufacturing experience in biotech, pharmaceutical and specialty chemical industries. Prior to returning to Taiwan to start up EirGenix, Dr. Liu was the President and COO of AnGes Inc., a biotech enterprise in its late developmental stage.

He joined AnGes in 2002 as a Vice President of Product Management. He also served as a Vice Chairman in the Supervisory Board of Avontec GmbH, a Munich based joint venture with AnGes, from 2004 to 2010.

Before his tenure with AnGes, he had served various management and professional positions to lead product/process development at GenVec, Novartis, W.R.Grace & Co. and Halcon SD.

Dr Liu holds a doctoral degree in Chemical Engineering & Applied Chemistry from Columbia University, and a BS degree in Chemical Engineering from National Taiwan University.



Antibody Therapeutic Conference & 18th Frontiers in Biomedical Sciences Conference

PANEL DISCUSSION



賴明添 台灣浩鼎生技(股)公司研發長

Education

- B.S. Tunghai University (1981)
- M.S. National Taiwan Normal University (1983)
- Ph.D. University of Minnesota (1987–1992)
- Post-doctoral study. Massachusetts Institute of Technology (1992–1995)

Experience

OBI Pharma浩鼎生技 (2019 - present)

Chief Scientific Officer

Lead R&D teams to develop novel clinical candidates of monclonal antibodies, antibody drug conjugates (ADC), and CAR T cell therapies. He also leads the teams to further advance current clinical trials.

Merck Sharp & Dohme默沙東 (1995-2019)

Director of Biology Discovery

During his more than 23 years tenure at Merck, he led several teams in optimizing lead candidates and identified 14 pre-clinical candidates for further development in clinical to treat HIV patients. One of the clincal candidates showed positive outcomes in Ph 3 pivotal trials and was approved by FDA in 2018.





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Acknowledgement

Thanks for your supporting

Board Committees

吳漢忠、張子文、張大慈、李東陽、温國蘭、張志榮

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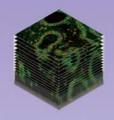


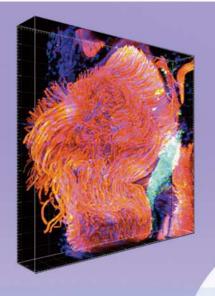




3D Digital Pathology Imaging

Precision Medicine
Immunotherapy
Targeted Therapy
Cell Therapy





2022-2023 Publication

Lung cancer
3D PD-L1 profiling

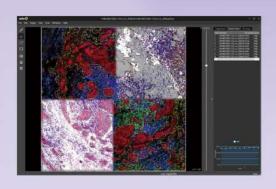
Prostate cancer
3D Gleason scoring

Lupus nephritis 3D interstitial inflammation

Oral cancer domain-KEY deep learning algorithm

Breast cancer histopathology deep learning algorithm

Sofeware & AI Models







MetaLite®

- Edge device available
- CPU-based
- Stand-alone
- Sever-plug application
- Easy-scalable
- Multi WSI format support

(1) Tumor Recognition



Recognition accuracy 99%

(2) Invasion Detection



Diagnostic speed enhancement >20%

(3) Immune Scoring



Diagnostic precision enhancement >30%

Value-Added Features

- 1. Matching right patients to right drugs
- 2. Matching right drugs to right indications
- 3. Finding amenable patients for biopharma







Harmonizing workflows across development, manufacturing & QC

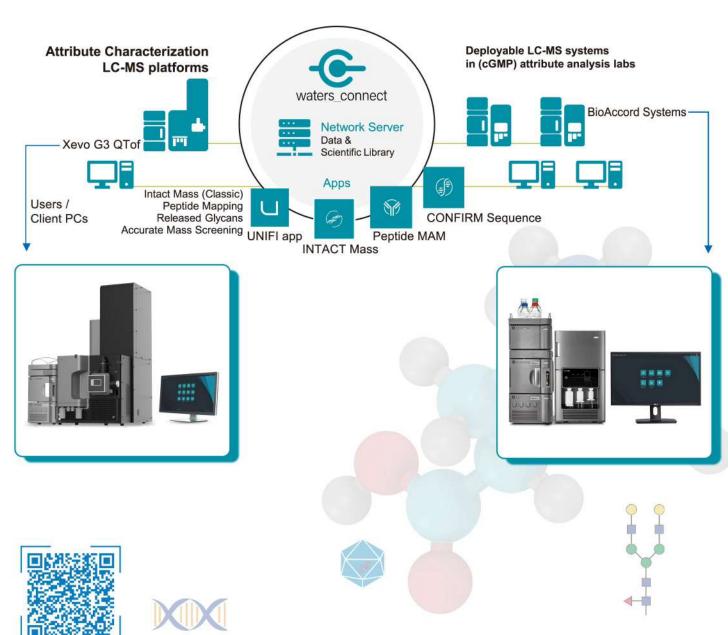


ENSURING DATA INTEGRITY, OPERATIONAL EFFICIENCY AND SCALABILITY

Characterization

Attribute Monitoring

Routine/QC Release





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3 Cell Line Development

4 Formulation Development

Preclinical Process Optimization & Analytical Development

6 Clinical Trial Material



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Mission

Redefine treatment approaches for patients with rare blood cancers and other diseases to achieve better health and quality of life.

Research & Development

Research with creative thinking and innovation to discover, develop, and bring to market efficacious, safe and cost-effective therapies.

Core Technology

Redesign the protein drug by utilizing a novel pegylation platform, which combines protein engineering and PEG-polymer chemistry to preserve biological activity, resulting in our lead product, Ropeginterferon alfa-2b.

Manufacturing

Our world-class cGMP biologics facility in Taichung has been certified by Taiwan Food and Drug Administration (TFDA), European Medicines Agency (EMA) and U.S. FDA, and is expecting to be certified by more national regulatory authorities.

TREAT THE SOURCE OF PV

Introducing Ropeginterferon alfa-2b

FDA-approved disease-modifying agent for Polycythemia Vera (PV) that selectively targets and depletes *JAK2* mutated hematopoietic stem cells (HSCs) in the bone marrow^{1,2}

References:

- Gisslinger H, Klade C, Georgiev P, et al. Ropeginterferon alfa-2b versus standard therapy for polycythaemia vera (PROUD-PV and CONTINUATION-PV): a randomised, non-inferiority, phase 3 trial and its extension study. Lancet Haematol. 2020;7(3):e196-e208. doi:10.1016/S2352-3026(19)30236-4
- 2. 百斯瑞明仿單. PharmaEssentia Corporation.



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Applikon AppliFlex ST

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- ≥ 2 L 20 L
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Cell line Development

Total Solution

Benchtop to Manufacture

Applikon Bio >2 L-20 L

₱ 500 mL, 3 L, 15 L







Xcellerex XDR-50

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- Single-Use Bag



Bioreactor Scaler

Switching Process Parameter





Lucullus PIMS





Biomass assessment

Factory







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info@thco.com.tw







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ACROBiosystems Group, founded in 2010 and listed in 2021, is a biotechnology company aimed at being a cornerstone of the global biopharmaceutical and health industries by providing products and business models innovation. The company spans across the globe and maintains offices, R&D centers, and production bases in 12 different cities within the United States, Switzerland, England and Germany. ACROBiosystems Group has established numerous long-term and stable partnerships with the world's top pharmaceutical enterprises, including Pfizer, Novartis, and Johnson & Johnson, and numerous well-known academic institutes. The company comprises of several subsidiaries such as ACROBiosystems, bioSeedin, Condense Capital, and ACRODiagnostics.

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CD19

CD22

ВСМА

CD47

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EGF R

CTLA-4

c-MET

PD-1

PD-L1

HER2

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FMC63

Her2 Siglet-2 CD19

Siglet-3

Mesothelin

Glypican 3

BCMA

EpCAM

FAP Cytokine

IL-2 and IL-2 Receptor

IL-4 and IL-4 R alpha

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VEGF165

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LIV-1

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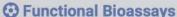
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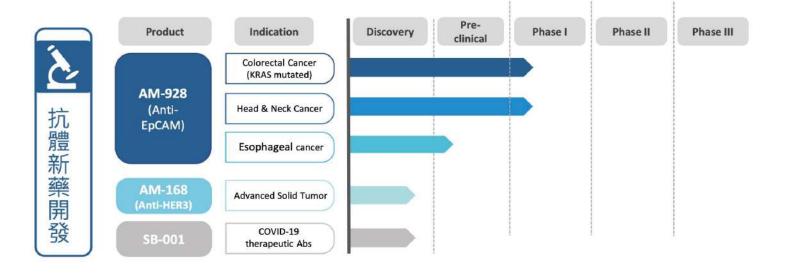


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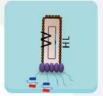
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Single B cell human antibody







Human antibody mouse



EIRGENIX WE MAKE BIOLOGICS



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- · Total Capacity: 29,400 L
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Microbial Production

- Total Capacity: 180 L (1,530 L by 2024)
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 (1 x 350 L, 1 x 1,000 L Fermentors by 2024)



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PRODUCT DEVELOPMENT

BIOSIMILAR CO-DEVELOPMENT AND LICENSING OPPORTUNITIES AVAILABLE

PR	TOUCT		PRE-CLINICAL	PHASE I/II	PHASE III	MAA/BLA
STS	EG12014/EGI014 Trastuzumab Biosimilar	SANDOZ A Rowartia Division SIGNED LICENSE AGREEMENT WITH NOVARTIS'S SANDOZ	•	•	•	•
Y PRODUCT	TSY0110/EG12043 ADC Biosimilar	CO-DEVELOP WITH FORMOSA PHARMACEUTICALS, INC.	•			
ER2 FAMIL	EG1206A Pertuzumab Biosimilar		•	•		
뿦	EG13074 TRZ Biosimilar (SC Formulation)		•			
	EG13084 TRZ+PRZ Biosimilar (SC Formulation)					
	EG62054 Biosimilar		•			
	EG74032 CRM197 Carrier protein I for conjugate V	accines	•			•



DispenCell™ Single-Cell Dispenser

Immediate and traceable proof of clonality

Empowers scientists to isolate single cells more efficiently and reliably.





Benefits

An enhanced user experience for faster and better results



Easy to use

Intuitive with a simple interface and easy to set up. No cleaning or calibration required.



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Its unique design ensures gentle dispensing for better viability and cloning efficiency.



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產品優勢



2% DMSO 濃度



批次穩定性高







什麼是細胞治療?

細胞治療是透過將自己的細胞-自體(autologous)細胞,或別人 的細胞-同種異體 (allogeneic) 細胞, 經過體外培養和加工程序後 ,再將這些處理過的細胞重新輸入進患者體內,以達到治療或預防 疾病之目的。

BioLegend 推出一系列專門用於細胞治療GMP等級的重組蛋白、 功能性抗體和細胞培養試劑等,適用於細胞治療各個階段細胞培 養使用!

Cell-Vive™ CD Cell Separation Buffer, GMP (貨號: 420512)

無血清 (serum-free)

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無防腐劑 (azide-free)

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Cell-Vive™ T-NK Xeno-Free Serum Substitute

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快速分離淋巴細胞與周邊單核細胞(PBMC's)最佳工具。 可以直接用全血分離,15分鐘即可完成。







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579L 729L

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1-24支 樣本數

829L



MagPurix® 24 EVO

959L

Ultra Low Energy ULT Freezer

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- · 均溫±3℃。



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Lonza

Lonza Nucleofector 4D generation II

有別於一般電穿孔電擊法,專利技術 Nucleofector 是以電穿孔為基礎,配合配套試劑,高效率地將核酸直接 送達細胞。經實驗證實,細胞在接受電擊後兩小時,即能觀察到基因表現,不僅加速實驗分析,其高效的轉殖 率,對於轉殖不易的 Primary cells, Neuron cells 及 Stem cells 來說, 更是一大福音。

Core unit

4D-Nucleofector®系統的指 揮中心,操作所有功能模組

X unit

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更多細胞數需求







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Unmatched scalability from 1×10^4 up to 1 x 109 cells





Nucleofector
and the Art of the
應用領域

	Department	Disease	Relevant Cells, e.g.
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	Neurobiology	Alzheimer's Parkinson's	Cortical neurons Dorsal root ganglia
	Stem Cell Research iPS Generation	Disease pathogenesis	Mesenchymal stem cells Embryonic stem cells Human fibroblasts Human CD34+ cells Human monocytes
	Cancer/Oncology/Tumor Biology	Breast Prostate	Mammary epithelial cells Prostate epithelial cells
	Cardiology or Respiratory Research	Heart disease Stroke	Cardiomyocytes HUVEC, HMVEC, SMC Bronchial epithelial cells
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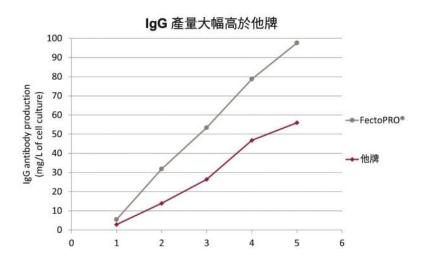




蛋白、抗體生產細胞適用(如 CHO、HEK293 系列)

- 將 Plasmid DNA 送至細胞以生產蛋白或抗體
- 在懸浮細胞中可達更高的蛋白及抗體產量
- 適用 HEK293 與 CHO 細胞及其衍生株 HEK293S, HEK293F, Expi293, CHO-S, CHO-K1 與 ExpiCHO™-S
- 試劑、Plasmid 用量低,有效降低成本
- 另有 FectoCHO CD Medium 可搭配使用,適用於優化各種 CHO 細胞株的培養與生產





可兼容多種 medium 系統

FectoPRO® is compatible with various serum free media (examples below)

CHO cell system	HEK-293F cell system
FreeStyle [™] CHO (Gibco)	Expi293 [™] (Gibco)
ProCHO [™] 4 (Lonza [®])	FreeStyle [™] 293 (Gibco)
FreeStyle [™] F17 (Gibco)	FreeStyle [™] F17 (Gibco)
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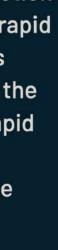
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Mammalian Cell Bank Characterization

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- · Adventitious Agent Testing
- Genetic Stability Microbiology
- Tumorigenicity and Oncogenicity

Bacterial and Yeast Cell Bank Characterization

- Genetic Stability
 Identity
- Viability



Virus Clearance Validation Study

- DNA / Protein Impurity Clearance
- Virus Clearance Validation
- Phage Clearance Validation



Bulk and Lot Release Testing

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- Potency Assay
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- qPCR-based Assay
- · Cell-based Assay: Potency assay / Neutralization Antibody Assay
- In vivo study: IBD animal model / TIL animal model / Xenograft animal model



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- · Pharmacokinetic (PK) and Toxicokinetic (TK)
- Immunogenicity
- Neutralization Assay
- · Cytokine Profile and Immuno-bioassay



Production of Cell Bank & Viral Vector with GMP Compliance

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- AAV / LV / RV / Customized Viral Vector Production
- . Full Panel of QC Test for Viral Vector & CAR-T Product



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永笙(StemCyte)成立於1997年,經營據點橫跨臺灣和美國。永笙已建立近4萬筆臍帶血公捐細胞庫,提供穩定安全的細胞治療原料,協助超過2300例移植治療。永笙持續開發臍帶血細胞治療適應症,正在進行:長新冠二期、脊髓損傷二期、急性中風一期等人體臨床試驗。

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細胞原料供應

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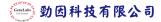






























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