2020

Antibody Therapeutics Conference

Antibody Drug Development in the Post-COVID-19 Era and the Strategy of New Generation Antibody Drug Development

October 29th ,2020
International Convention Hall (Building C)
National Biotechnology Research Park
Nangang, Taipei, Taiwan.

TAA 社團法人台灣抗體協會 TAIWAN ANTIBODY ASSOCIATION

DOB 財團法人生物技術開發中心 Development Center for Biotechnology

BCC 生醫商品化中心 BioMed Commercialization Center

Organizers

TAA 社團法人台灣抗體協會 TAIWAN ANTIBODY ASSOCIATION

DCB 財團法人生物技術開發中心 Development Center for Biotechnology

BCC 生醫商品化中心 BioMed Commercialization Center

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Welcome Message

2020 Antibody Therapeutics Conference
Antibody Drug Development in the Post-COVID-19 Era and the Strategy of New Generation Antibody Drug Development

Dear Conference Participants and Colleagues,

On behalf of the Organizing Committee, I would like to welcome you to the ninth edition of Antibody Therapeutic Conference (ATC) - 2020 Antibody Therapeutics Conference: Antibody Drug Development in the post-COVID-19 Era and the Strategy of New Generation Antibody Drug Development will be held in the National Biotechnology Research Park (Taipei, Taiwan) on Oct 29th, 2020.

The applications of antibody therapeutics remain a growing field today, especially in the treatment of cancers, immune-mediated diseases and infectious diseases, which all highlighting the critical pharmaceutical importance of antibody therapeutics. Particularly, immunotherapy including antibody-mediated tumor regression, checkpoint blockade, antibody drug conjugates (ADC) and adoptive cell therapy (ACT) acts as potential strategies to cure cancers.

The COVID-19 outbreak in the last quarter of 2019 has posed a major impact on the global economy and society. The industry, government, academia and research institutes worldwide have all invested resources to actively develop diagnostic tests, therapeutic drugs and vaccines for COVID-19. To leverage the achievements so far, this year's ATC focuses on sharing current development status and drug design concepts of antibody drugs for the treatment of COVID-19 hoping to inspire more ideas for the development of antibody drugs in the post-COVID-19 era.

ATC is an international forum for the field of antibody discovery, antibody engineering, antibody therapeutics development and commercialization with the aim to provide opportunities for the attendants to have good connections and to assist the training and advancement of students, postdoctoral fellows and other new members in the field, in part through sponsorship of international scientific meetings.

Last but not least, we hope the meeting stimulated cross talks between senior experts and young scientists working on antibody therapeutics. This meeting not only provides a forum for sharing your insightful research but also a great opportunity to network with your fellow professionals. We hope this meeting will contribute to the advancement of the field of the antibody therapeutics and you will find this meeting an informative, constructive and inspiring experience.

Chung-Hsiun Herbert Wu, Ph.D

Chairman of Taiwan Antibody Association;
CEO, Development Center for Biotechnology

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2020 Antibody Therapeutics Conference
Antibody Drug Development in the Post-COVID-19 Era and the Strategy of New Generation Antibody Drug Development

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Committee

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Chairman of Taiwan Antibody Association;
CEO, Development Center for Biotechnology

Wei-Kuang Chi, Ph.D. 紀威光 博士

Vice President, Executive Director, Institute of Pharmaceutics,
Development Center for Biotechnology

Shih-Chong Tsai, Ph.D. 蔡士昌 博士

Executive Director, Institute of Biologics,
Development Center for Biotechnology

Chih-Jung Chang, Ph.D. 張志榮 博士

Vice President, Chief Operating Officer (COO), EirGenix Inc.

Program

2020 Antibody Therapeutics Conference
Antibody Drug Development in the Post-COVID-19 Era and the Strategy of New Generation Antibody Drug Development

Time	Activities	Speaker
10:00 - 10:30	Registration	
10:30 - 10:35	Welcome Remarks	Chung-hsiun Wu, Ph.D. (吳忠勳理事長) Chairman of Taiwan Antibody Association
10:35 - 10:40	Moderator	Chung-hsiun Wu, Ph.D. (吳忠勳理事長) Chairman of Taiwan Antibody Association
10:40 - 11:10	Potent Neutralizing Monoclonal Antibodies Directed to Multiple Epitopes on the SARS-CoV-2 Spike	David D. Ho, M.D. (何大一院士) Director, Aaron Diamond AIDS Research Center, Columbia University
11:10 - 11:40	Therapeutic Prospects for SARS-CoV-2 Infection with Cytokine Storm	Chang-Youh Tsai, M.D., Ph.D. (蔡長祐主任) Director, Division of Allergy, Immunology and Rheumatology, Taipei Veterans General Hospital
11:40 - 12:10	Potential of human B cell-derived monoclonal antibodies against SARS-CoV-2 spike	Kuan-Ying Arthur Huang, MD, DPhil. (黃冠穎醫師) Attending Physician, Department of Paediatrics, Chang Gung Children's Hospital
12:10 - 12:15	Group photo	
12:15 - 13:20	Lunch 2nd meeting of the 3rd TAA Board of Directors	
13:20 - 13:30	2nd meeting of the 3rd TAA General Assembly	
13:30 - 13:35	Moderator	Wei-Kuang Chi, Ph.D. (紀威光副執行長) Vice President, R&D, Development Center for Biotechnology
13:35 - 14:05	Anti-SARS-CoV-2 Monoclonal Antibodies for Diagnosis and Therapy of COVID-19	Han-Chung Wu, Ph.D. (吳漢忠主任) Director, Biomedical Translation Research Center (BioTReC), Academia Sinica, Taiwan
14:05 - 14:35	The Impact of COVID-19 Pandemic on Biomanufacturing Operations	Lee-Cheng Liu, Ph.D. (劉理成總經理) President & CEO, EirGenix Inc.
14:35 - 14:55	Break	
14:55 - 15:00	Moderator	Shih-Chong Tsai, Ph.D. (蔡士昌所長) Executive Director, Institute of Biologics, Development Center for Biotechnology
15:00 - 15:30	Current Trend in Antibody-Drug Conjugates and Site-specific Trimannosyl Conjugation platform	Shih-Hsien Chuang, Ph.D. (莊士賢副所長) Deputy Director, Medicinal Chemistry Department, Institute of Pharmaceutics, Development Center for Biotechnology
15:30 - 16:00	Proteomic profiling of antibody-drug conjugate biomarker panel for rational drug design	Sheeno Thyparambil, Ph.D. Senior Director R&D, mProbe Inc.
16:00 - 16:05	Closing Remarks	Chung-hsiun Wu, Ph.D. (吳忠勳理事長) Chairman of Taiwan Antibody Association

※ The length of a keynote speech is 25 minutes presentation + 5 minutes Q&A.
※ The organizer reserves the right to make changes to the event program.

Moderator

吳忠勳　博士

Chung-Hsiun Herbert Wu, Ph.D.

Chairman of Taiwan Antibody Association
CEO, Development Center for Biotechnology
Chairman of Taiwan Bio Industry Organization

Education

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

Experience

- Director of Institute of Biologics, Development Center of Biotechnology
- Principal, KingConcept Biotechnology
- Co-founder, Chief Innovation Officer, and Sales Vice President, AbGenomics Corp.
- Associate Professor, Institute of Molecular Medicine, NTU College of Medicine
- Carnegie Institution of Washington Department of Embryology
- Jane-Coffin-Childs Memorial Fund Fellow

Moderator

紀威光　副執行長

Wei-Kuang Chi, Ph.D.

Vice President, R&D,
Development Center for Biotechnology

Education

- Ph.D., University of Pennsylvania, USA

Experience

- Adjunct Associate Professor, Graduate Institute of Biotechnology, Chinese Culture University
- Biologics-related regulations editor, Drug Inspection Bureau/Drug Administration Department, Ministry of Health
- Adjunct Researcher, Plasma Derivatives Consultation Committee/Preventive Medicine Institute, Ministry of Health
- Adjunct Associate Professor, Institute of Biomedical Science and Technology, Taipei Medical College

Moderator

蔡士昌 所長

Shih-Chong Tsai, Ph.D.

Executive Director, Institute of Biologics,
Development Center for Biotechnology

Education

Ph.D. Department of Cell Biology and Physiology
Indiana University School of Medicine, Indianapolis, Indiana, USA

M.S. Graduate Institute of Biochemistry, College of Medicine,
National Taiwan University, Taipei, Taiwan.

B.S. Department of Food Sciences
Fu Jen Catholic University, Taipei, Taiwan.

Experience

Acting Executive Director and Senior Scientist
Institute of Biologics, Development Center for Biotechnology

Deputy Executive Director and Senior Scientist, Institute of Biologics
Development Center for Biotechnology

Director and Senior Scientist
New drug development, Institute of Biologics, Development Center for Biotechnology

Research Scientist
New drug development, Institute of Biologics, Development Center for Biotechnology

Research Scientist
Department of Microbiology, Development Center for Biotechnology,

Postdoctoral Research fellow
Institute of Biomedical Sciences, Academia Sinica

Postdoctoral Research fellow
Program of Cardiomyocyte development ,Department of Pediatrics,
Indiana University School of Medicine

Keynote Speaker

何大一　院士

David D. Ho, M.D.

Director, Aaron Diamond AIDS Research Center,
Columbia University

Potent Neutralizing Monoclonal Antibodies Directed to Multiple Epitopes on the SARS-CoV-2 Spike

David D. Ho is the Founding Scientific Director of the Aaron Diamond AIDS Research Center and the Clyde and Helen Wu Professor of Medicine at Columbia University Irving Medical Center. He received his degrees from California Institute of Technology and Harvard Medical School.

Dr. Ho has been at the forefront of AIDS research for 39 years, publishing over 400 papers. His elegant studies unraveled the dynamic nature of HIV replication in vivo and revolutionized our basic understanding of this horrific disease. This knowledge led him to champion combination antiretroviral therapy that resulted in unprecedented control of HIV in patients. An automatic death sentence has been transformed into a manageable disease, and over 25 million worldwide are currently on such therapy. Dr. Ho's research team is now devoting considerable efforts on vaccine and antibody research in order to halt or slow the spread of the AIDS epidemic. He worked on SARS and is now devoted time to develop drugs and antibodies against the new coronavirus.

Dr. Ho has received fourteen honorary doctorates. He was named Time Magazine's Man of the Year in 1996 and the recipient of a Presidential Medal from Bill Clinton in 2001. He was also inducted into the California Hall of Fame. Dr. Ho was also recognized by the Kingdom of Thailand with the Prince Mahidol Award in Medicine, and given the Distinguished Alumni Award by Caltech. He is a member of the US National Academy of Medicine as well as the Chinese Academy of Engineering.

Abstract

The SARS-CoV-2 pandemic rages on with devasting consequences on human lives and the global economy. The discovery and development of virus-neutralizing monoclonal antibodies could be one approach to treat or prevent infection by this novel coronavirus. Here we report the isolation of 61 SARS-CoV-2-neutralizing monoclonal antibodies from 5 infected patients hospitalized with severe disease. Among these are 19 antibodies that potently neutralized the authentic SARS-CoV-2 in vitro, 9 of which exhibited exquisite potency, with 50% virus-inhibitory concentrations of 0.7 to 9 ng/mL. Epitope mapping showed this collection of 19 antibodies to be about equally divided between those directed to the receptor-binding domain (RBD) and those to the N-terminal domain (NTD), indicating that both of these regions at the top of the viral spike are quite immunogenic. In addition, two other powerful neutralizing antibodies recognized quaternary epitopes that are overlapping with the domains at the top of the spike. Cyro-electron microscopy structures of one antibody targeting RBD, a second targeting NTD, and a third bridging two RBDs revealed recognition of the closed, "all RBD-down" conformation of the spike. Several of these monoclonal antibodies are promising candidates for clinical development as potential therapeutic and/or prophylactic agents against SARS-CoV-2.

Keynote Speaker

蔡長祐　主任

Chang-Youh Tsai, M.D., Ph.D.

Director, Division of Allergy, Immunology and Rheumatology,
Taipei Veterans General Hospital

Therapeutic Prospects for SARS-CoV-2 Infection with Cytokine Storm

Education :

1976 – 1983	National Taiwan University School of Medicine
1989 – 1992	Institute of Clinical Medicine (PhD program) National Yang-Ming University

Experience :

2015 – present	Director Division of Allergy, Immunology & Rheumatology aipei Veterans General Hospital
2000 – present	Professor of Medicine Faculty of Medicine School of Medicine, National Yang-Ming University
1993 – 2000	Associate Professor Faculty of Medicine School of Medicine, National Yang-Ming University
1996 – 1997	Research Fellow W.M. Keck Autoimmune Disease Center The Scripps Research Institute, La Jolla, CA, USA
1988 – 1989	Attending Physician Division of Medicine Department of Emergency Medicine Taipei Veterans General Hospital
1989 – present	Attending Physician Division of Allergy, Immunology, & Rheumatology Department of Medicine Taipei Veterans General Hospital
1987 – 1988	Chief Resident Physician Department of Medicine Taipei Veterans General Hospital
1986 – 1987	Senior Resident Physician Division of Allergy, Immunology, & Rheumatology Department of Medicine Taipei Veterans General Hospital

Keynote Speaker

1983 – 1987	Junior Resident Physician Department of Medicine Taipei Veterans General Hospital
1982 – 1983	Intern National Taiwan University Hospital
1982 – 1983	Intern National Taiwan University Hospital

Licensure and Certification :

1983	Licensed to Practice Medicine, R.O.C. Certificate No: 011765
1983	Educational Council for Foreign Medical Graduate (ECFMG)
1983	Visa Qualifying Examination (VQE)
1983	Nation's Higher Civil Service Examination for Public Health Physician

Professional Organizations :

1986 – present	Taiwan Society of Immunology
1987 – present	Taiwan Society of Internal Medicine
1986 – present	Taiwan Society of Family Medicine
1986 – present	Taiwan Society of Rheumatology
1993 – present	Chinese Medical Association-Taipei
1998 – present	New York Academy of Sciences

Academic Assignment

2011 – present	Member of the Editorial Board, Rheumatology, UK
2012 – present	Chief Executive Officer, Arthritis Foundation, Taiwan

Honors and Awards :

1992 – 1994	Research Award, National Science Council, Taiwan
1994	Chinese Medical Association Award, Taiwan
1996	Chinese Medical Association Award, Taiwan
2000	Taiwan Society of Rheumatology Award for Outstanding Investigator
2000	International Who's Who of Professionals
2000	Federation of Immunology Societies in Asia (FIMSA) Award for Young Investigator
2001	Taiwan Society of Immunology Award in Memory of Mr. Sheng-Sheu Tei
2003	Taiwan Society of Immunology Award for Investigation on Systemic Lupus Erythematosus
2004	Taiwan Society of Immunology Award in Memory of Mr. Sheng-Sheu Tei

Abstract

A 48 year-old lady with an underlying diseases of hypertension, diabetes mellitus and breast cancer came back from China late in March 2020, presenting with fever and devastating dyspnea as well as cardiac embarrassment. After confirming to be infected by SARS-CoV-2 she was immediately admitted to the quarantine intensive care unit of a Cardinal hospital in the suburban area of Taipei City. The condition deteriorated rapidly despite therapies with levofloxacin and oseltamivir. Thus, she was intubated and transferred to Taipei Veterans General Hospital for further care. Because of severe acute respiratory distress syndrome with profound hypoxemia, she was soon put on the extracorporeal membrane oxygenation (ECMO) support. Tubal hydroxychloroquine 400 mg twice a day, intravenous teicoplanin as well as tazocin were also given. Because of a deterioration of the bilateral consolidation in lungs and continuous need for oxygen support (with FiO2 100%), we suspected a presence of cytokine storm in the lungs and decided to give her intravenous tocilizumab with a dose of 320 mg and 240 mg intravenously 12 hours apart. After the second dose of tocilizumab, the condition dramatically improved with swift clearing of bilateral pulmonary infiltration and normalization of acute phase reactants (CRP & ESR) as well as the general condition. The patient was finally discharged from the hospital with no conceivable sequelae of pulmonary fibrosis. She is still followed up in Chest Department in Taipei Veterans General Hospital.

In this mini-review, the viral infection (such as COVID-19) associated with ARDS and the possibilities of therapeutic modalities for it will be briefly discussed.

Keynote Speaker

黃冠穎 醫師

Kuan-Ying Arthur Huang, MD, DPhil.

Attending Physician, Department of Paediatrics,
Chang Gung Children's Hospital

Potential of human B cell-derived monoclonal antibodies against SARS-CoV-2 spike

Current Posts :

2016 -	Associate Professor	Chang Gung Memorial Hospital
2007 -	Attending Physician	Chang Gung Memorial Hospital

Educational Qualifications :

2002	National Taiwan University, M.D.
2011	Nuffield Department of Clinical Medicine, Oxford University, Ph.D.

Fellowships & Awards

2019	Distinguished Research Award	Infectious Diseases Society of Taiwan
2017	Distinguished Research Award	Chiung-Lin Chen Pediatric Research Foundation
2014	Best Research Award	Pediatric Academic Societies and Asian Society for Pediatric Research

Membership :

European Society of Clinical Microbiology and Infectious Diseases, Infectious Diseases Society of Taiwan, Taiwan Pediatric Association

Membership :

European Society of Clinical Microbiology and Infectious Diseases, Infectious Diseases Society of Taiwan, Taiwan Pediatric Association

Selected Recent publications :

1) Huang et al, Emergence of genotype C1 Enterovirus A71 and its link with antigenic variation of virus in Taiwan. PLoS Pathog. 2020
2) Zhou et al, Structural basis for the neutralization of SARS-CoV-2 by an antibody from a convalescent patient. Nat Struct Mol Biol. 2020
3) Rijal et al, Broadly inhibiting anti-neuraminidase monoclonal antibodies induced by trivalent influenza vaccine and H7N9 infection in humans. J Virol. 2020.
4) Huang et al, Structure-function analysis of neutralizing antibodies to H7N9 influenza from naturally infected humans. Nat Microbiol. 2019.
5) Huang et al, Epitope-associated and specificity-focused features of EV71-neutralizing antibody repertoires from plasmablasts of infected children. Nat Commun. 2017.
6) Huang et al, A Potent Virus-Specific Antibody-Secreting Cell Response to Acute Enterovirus 71 Infection in Children. J Infect Dis. 2015.
7) Huang et al, A Focused antibody response to influenza linked to antigenic drift. J Clin Invest. 2015.

Abstract

SARS-CoV-2 emerged in December 2019 and resulted in a global pandemic with an estimated 3% overall fatality rate. No specific drugs or vaccines are yet available for COVID-19, and prompt diagnosis and management are crucial for containing or mitigating the outbreak. Evidence indicates an elicitation of SARS-CoV-2-specific antibody response upon natural infection or immunization of in animals and humans. Human B cell-derived monoclonal antibodies are produced from COVID-19-convalescent individuals and are shown to bind spike glycoprotein of SARS-CoV-2. Anti-spike human antibodies neutralize wild-type virus. The anti-RBD human monoclonal antibodies form cross-inhibiting clusters represented and the neutralizing activity of anti-RBD antibodies is linked with ACE2 receptor blockade. Potent neutralizing monoclonal antibodies offer potential formulations for the development of prophylactic and therapeutic agents against SARS-CoV-2.

Keynote Speaker

吳漢忠　主任

Han-Chung Wu, Ph.D.

Director, Biomedical Translation Research Center (BioTReC),
Academia Sinica, Taiwan

Anti-SARS-CoV-2 Monoclonal Antibodies for Diagnosis and Therapy of COVID-19

Dr. Han-Chung Wu is currently a Distinguished Research Fellow of the Institute of Cellular and Organismic Biology, Academia Sinica, Taiwan. He is also a Professor at the College of Medicine of the National Taiwan University. His research primarily focuses on two fields, cancer research and infectious diseases, and includes components of both basic research and applied science. Dr. Wu's research interest focuses on the identification of novel tumor antigens, development of targeting drug delivery systems for cancer therapy and molecular imaging. He has developed phage display technologies for the generation of fully human monoclonal antibodies and the identification of peptides for a variety of target molecules. As of today, Dr. Wu has published over 110 original articles in world-renowned journals, and 92 Patents (including 64 granted patents and 28 filed patents). He has successfully licensed out 16 technologies from 48 patents to biotech companies. Three of the technology transfers have completed clinical trials and the products are on the market, two of the technology transfers are currently in clinical trials, and seven of the licensed technologies are currently in preclinical studies for the development of therapeutics.

Aside from conducting research, Dr. Wu has also been responsible for coordinating academic activities and overseeing administration at the Institute of Cellular and Organismic Biology as the Vice Director and Acting Director. He has also served as Director of the Department of Intellectual Property and Technology Transfer, Academia Sinica to promote the protection of intellectual property and the technology transfer, and use the industrialization of intellectual property rights to enhance social welfare. May 2019, Dr. Wu joined National Research Biotechnology Park (NBRP) as Acting Chief Executive Officer of BioHub Taiwan, then Acting Director of Biomedical Translation Research Center (BioTReC), Academia Sinica. On Sept 1, 2020, Dr. Wu served as the Director of BioTReC, with the mission of promoting the biotechnology industry development in Taiwan.

Professional Experience

- Director, Biomedical Translation Research Center, Academia Sinica, Taiwan
- Distinguished Research Fellow, Institute of Cellular and Organismic Biology, Academia Sinica
- Acting Director, Biomedical Translation Research Center, Academia Sinica, Taiwan
- Acting Chief Executive Officer, National Biotechnology Research Park/BioHub Taiwan
- Director, Department of Intellectual Property and Technology Transfer, Academia Sinica
- Acting Director, Institute of Cellular and Organismic Biology, Academia Sinica
- Vice Director, Institute of Cellular and Organismic Biology, Academia Sinica
- Research Fellow, Institute of Cellular and Organismic Biology, Academia Sinica
- Joint Appointment Research Fellow, Genomics Research Center, Academia Sinica
- Joint Appointment Professor, Institute of Pathology; and Graduate Institute of Oral Biology, College of Medicine, National Taiwan University

Keynote Speaker

Honors & Awards

- 2008 Academia Sinica Young Investigator Award
- 2010 Yung-Shing Young Investigator Award
- 2011-2014, NSC Outstanding Research Award, National Science Council, Taiwan
- 2015 Chair, Taiwan Bio-development Foundation (TBF) Award
- 2015 Ho Jen-Dui Distinguished Honor Award
- 2015-2018, MOST Outstanding Research Award, Ministry of Science and Technology, Taiwan
- 2018-2020, Special Research Fellow Award, Ministry of Science and Technology, Taiwan
- 2018 International Inventor Prize and Lifetime Achievement Academic Award
- 2018 The Executive Yuan Award for Outstanding Science and Technology Contribution
- 2019 Award for Excellent Contributions in Technology Transfer, Ministry of Science and Technology, Taiwan
- 2019 Taiwan Reputed University Startups to Taiwan Unicorns, (TRUS-U Program, 50 million NTD/year), Ministry of Science and Technology, Taiwan
- 2020-2023, Special Research Fellow Award, Ministry of Science and Technology, Taiwan

Abstract

The virus responsible for the coronavirus disease 2019 (COVID-19) pandemic, SARS-CoV-2, has necessitated major adjustments in our daily lives and caused great uncertainty worldwide. One promising approach to fight the virus is the use of neutralizing antibodies that reduce the viral load to protect from disease progression and speed patient recovery. We generated 152 novel mAbs with high reactivity and specificity against SARS-CoV-2: 38 against RBD, 20 against S1, 52 against S2, and 42 against NP. Among the anti-RBD mAbs, 17 showed high neutralizing activity. We successfully developed 12 chimeric antibodies (chAbs) using genetic engineering, six of which exhibit highly potent neutralization activities with PRNT50 values between 6.71 and 35.51 ng/ml. We then used site-directed mutagenesis to replace ACE2-binding residues within the RBD and found that the key residues, Y453, F486, and N501, were respectively recognized by neutralizing chAbs, RBD-chAb-28, -45/-51, and -25. Molecular docking studies predicted that these antibodies target three different sites in the receptor binding motif (RBM) within the RBD of SARS-CoV-2 S protein. We developed several chAbs with high neutralizing potency. These novel therapeutic antibodies have high potential for the prevention and treatment of COVID-19. A cocktail of therapeutic chAbs that target three separate epitopes on the RBM of SARS-CoV-2 spike protein may increase therapeutic efficacy and decrease the potential for virus escape mutants, serving to benefit a wide range of COVID-19 patients.

Keynote Speaker

劉理成　總經理

Lee-Cheng Liu, Ph.D.

President & CEO, EirGenix Inc.

The Impact of COVID-19 Pandemic on Biomanufacturing Operations

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.

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.

Keynote Speaker

莊士賢　副所長

Shih-Hsien Chuang, Ph.D.

Deputy Director, Medicinal Chemistry Department,
Institute of Pharmaceutics, Development Center for Biotechnology

Current Trend in Antibody-Drug Conjugates and Site-specific Trimannosyl Conjugation platform

Dr. Chuang received his PhD degree in Medicinal Chemistry from National Tsing Hua University in 2005. He joined DCB and started his career in drug discovery since 2006. As a principal investigator in institute of pharmaceutics, Dr. Chuang led several drug discovery projects especially on oncology field. For example, the Nek2/Hec1 inhibitor against advanced refractory solid tumors collaborated with Taivex Therapeutics was in Phase I clinical trial. Besides, Dr. Chuang also focused on developing novel technology platforms such as next generation antibody-drug conjugates (ADC) and proteolysis targeting chimera (PROTAC). Dr. Chuang had over 20 papers published in peer-reviewed journals.

Abstract

Antibody–drug conjugates (ADC) are one of the fastest growing drug class in the next generation antibody development. Up to date, there are nine ADCs in the market against both solid tumor and hematological malignancy. With these approved drugs, the global ADC market is expected to grow from $2.6 billion (2019) to $24.6 billion (2026) at a 7-year compound annual growth rate (CAGR) of 37.8%. Therefore, lots of new technologies in this field have been developed including novel targets, site-specific conjugation methods, hydrophilic linkers, and novel payloads. We will discuss about the trend for the next generation ADC and introduce our unique site-specific trimannosyl conjugation platform and ADC products in DCB.

Keynote Speaker

Sheeno Thyparambil, Ph.D.

Senior Director R&D, mProbe Inc.

Proteomic profiling of antibody-drug conjugate biomarker panel for rational drug design

Profile : Award winner, innovative and accomplished leader with extensive background in personalized medicine and molecular diagnostics. Dedicated to proteomic biomarker discovery and validation in clinical setting as evidenced by 28 US issued patents. Developed and implemented high complexity proteomic assays in a clinical lab environment. Experience with regulated environments including GLP, CAP and CLIA. Comprehensive experience authoring, editing, and proofreading scientific research documents and presentation materials. Strong interpersonal and communication skills for bridging between scientific and business concepts, negotiating timelines and facilitating collaboration.

Expertise includes :

- 15+ years of Mass spectrometry experience
- Clinical Validation of biomarkers
- Molecular Oncology
- Molecular Oncology
- Strategic Planning
- Patent

PROFESSIONAL EXPERIENCE

mProbe, Inc, Rockville, MD — 2019 – Present
Senior Director (R&D)

Scientific and Strategic leader for organization wide oncology R&D efforts
Lead the business efforts of Oncology diagnostics Product Line
Responsible for integration of proteomics and metabolomics efforts at mProbe.

NantOmics LLC, Rockville MD (formerly OncoPlex Diagnostics, Rockville) — 2009 – 2019
Principal Scientist, Product Development — 2015 – 2019
Senior Scientist, Mass Spectrometry — 2010 – 2015
Scientist, Mass Spectrometry — 2009 – 2010

Founding mass spectrometrist and co-inventor on multiple patents. Key contributor to company buildout on strategy, hiring and logistics. Responsible for providing analytical leadership during the development of proteomic assays. Responsible for pioneer clinical validation study. Support regulatory submissions as a subject matter expert. Collaborative, cross-functional team player including members from proteomic/genomic sciences, pathology and medical affairs. Identify and establish relationships with industry and academic partners.

- Founding mass spectrometrist at OncoplexDx/NantOmics.
- Reduced an innovative technology to clinical practice. Developed the first tissue proteomic clinical assay from FFPE tissue.
- 29 US issued patents.
- Awarded inaugural (2017) NantHealth Presidential Award for Scientific achievement
- Developed and implemented high complexity proteomic assays in a clinical lab environment. Analytically validated three hundred (300+) new assays over 9 years of work.
- Responsible for implementing 30 biomarkers on the clinical report.
- Managed the release of the next 40 biomarkers on the clinical report by interfacing with Molecular Oncology, Mass Spectrometry, Operations and Medical Director.
- Published (joint first author) the first clinical validation paper on mass spec based approach to identify durable responders to trastuzumab from FFPE tissue
- Manage the business development collaboration with external pharma partners
- Authored the mass spectrometry portions of key clinical documents including, clinical study protocols and clinical study reports.
- Support regulatory submissions as a subject matter expert and contribute scientific and technical sections of key regulatory documents including premarket approval (PMA) of Class III medical devices documents.
- Communicated research findings through preparation and publication of eight (8) original manuscripts.
- Established multiple collaborations with KOLs across Europe and US.
- Worked within a cross functional team to provide internal and external medical affairs support.
- Involved in key hiring decisions for ~90% of the scientific team across Mass Spectrometry and Bioinformatics.

Myeloma Institute of Research and Therapy, Univ. of Arkansas for Medical Sciences (UAMS) 2008 to 2009
Post-doctoral Fellow

- Biomarker discovery from serum or bone marrow samples of multiple myeloma patients treated with VTD (Velcade, Thalidomide, Dexamethsone) regimen.
- Post-translation modifications (PTM) research of treated patients using mass spectrometry based approaches (Orbitrap).
- ntegration of proteomic data with genomic information to elucidate pathways that are key in resistance to VTD therapy.

Food and Drug Administration (FDA)/National Center for Toxicology Research (NCTR)
Degree Granting Institute : UAMS 2008 to 2009

Pre-doctoral Fellow

- Joint program by UAMS (didactic) and NCTR/FDA (research)
- Research conducted in the Division of Systems Toxicology
- Oakridge Institute for Science and Education (ORISE) fellowship
- Co-authored one of the earliest works on systems biology integrating proteomic, genomic and metabonomic approaches to elucidate the impact of valproic acid in hepatotoxicity
- Biomarker discovery and validation of hepatocellular carcinoma biomarkers from human liver samples (tissue and serum)
- Authored a book chapter on primary liver carcinogenesis

RELEVANT EDUCATION

Ph.D. (Biochemistry and Molecular Biology), University of Arkansas for Medical Sciences

PROFESSIONAL AFFILIATIONS

American Society of Clinical Oncology (ASCO)
American Association for Cancer Research (AACR)
American Society for Mass spectrometry (ASMS)

Abstract

With the advancement of linker technology and new payloads, antibody drug conjugates (ADC) approvals have improved in the recent years. Most ADC approvals have occurred in hematological malignancies. For solid tumors, several ADCs have failed clinical trials due to futility or toxicity. While a great deal of attention has been focused on measuring the receptor protein levels mostly by IHC, the payload targets remain generally ignored. Due to the unique mechanism of ADCs, quantitative protein measurement of both the antibody target and markers of sensitivity or resistance to the payload can help in the design of rational drug combinations. We have developed a method to solubilize formalin fixed paraffin embedded (FFPE) tissue and measure the protein concentrations of both receptor and payload targets using quantitative mass spectrometry. We quantitate simultaneously 72 protein biomarkers that are important to oncology. These include multiple antibody target proteins necessary for ADC response, such as receptor tyrosine kinases (EGFR, HER2, HER3, AXL), transporters (FRalpha, NaPi2b), and tumor antigens (Trop2,Mesothelin, DLL3, CD30, GPNMB,CD56, Nectin-4, CD19, CECAM5, PSMA etc.) that are currently approved or in clinical trials. Besides the antibody target, we also measure the payload biomarkers of sensitivity (TOPO1) or resistance (TUBB3).

On exploration of our large quantitative biomarker data from FFPE clinical tissue, we determined that in colorectal cancer, expression of EGFR(83%), HER2(52%), HER3(21.5%), Axl(3.7%), Mesothelin(26.5%), FRalpha(3.7%), and Trop2(60%) showed a wide a dynamic range. These needs to be paired with appropriate payloads (anti-tubulins or anti-TOPO1). Previously we identified that HER2 expression >750amol/µg correlated with HER2 overexpression. Accordingly, 1.4% of CRC patients overexpressed HER2, of which 40% had TOPO1 expression >1350amol/µg (75th percentile) suggesting that these patients may receive benefit from a HER2/TOPO1 ADC. However, the newer generation of ADCs work at low levels of Her2 which expands the potential responders to 52%. If the cut-off of 1350 amol/µg of TOPO1 (75th percentile) is considered, then 27% of CRC is likely to respond to a HER2-TOPO1 ADC (e.g. DS-8201). Similarly, 60% of CRC has Trop2 expression and applying similar cut-off for TOPO1 results in 20% potential responders to HER2-TOPO1 ADC (e.g. Sacituzumab govitecan or DS-1062). Similarly analysis of our glioblastoma dataset revealed that majority of glioblastoma expresses EGFR(84%) which suggested likely response to anti-EGFR ADC, however, concurrent expression of TUBB3(97%) may indicate resistance to several known payloads, such as taxanes and MMAE. Conjugation with another payload that targets sensitivity marker TOPO1 (68% expression) is a likely option. Proteomic analysis also revealed detectable levels of multiple RTKs (AXL(20%), IGF1R(10%), MET (5%), and HER2 (9%), indicating potential response to RTK inhibitors.

The ability to quantitate protein biomarkers of receptors and payloads using multiplexed mass spectrometry from just two sections of FFPE tissue enable rational drug design based on actual targets of the ADC. Additionally, proteomics enabled patient stratification may result in proper matching of patients for clinical trials.