2022

Antibody Therapeutic Conference (ATC)

Extended Application of Antibody

November 15th, 2022
International Convention Hall (Building C)
National Biotechnology Research Park
Nangang, Taipei, Taiwan

Organizers

TAA 社團法人台灣抗體協會 TAIWAN ANTIBODY ASSOCIATION
DDB 財團法人生物技術開發中心 Development Center for Biotechnology
BioTReC 生醫轉譯研究中心 Biomedical Translation Research Center
NBRP National Biotechnology Research Park 國家生技研究園區

Supporting Organizers

Jello
Bora Biologics 保瑞生技股份有限公司
BERKELEY LIGHTS
BECKMAN COULTER Life Sciences
cytiva
MOLECULAR DEVICES
PALL
Omics Bio 盟基生物科技
伯森生技
FirGenix
ThermoFisher SCIENTIFIC
Waters THE SCIENCE OF WHAT'S POSSIBLE.
TalMed Biologics
SARTORIUS
PharmaEssentia
酷基生醫股份有限公司 CHO PHARMA INC
均泰生物科技股份有限公司 Genetech Biotech Co., Ltd.
UNIMED 騰達行

Sponsors

Immunwork 免疫功坊股份有限公司
MYCENAX BEST PARTNER
TFBS TFBS Bioscience, Inc.
Polaris Novel Drugs For Cancer

Welcome Message

On behalf of the organizing committee, I would like to welcome you to the 9th edition of Antibody Therapeutic Conference (ATC) - 2022 Antibody Therapeutics Conference: Extended Application of Antibody, which will be held in the National Biotechnology Research Park (Taipei, Taiwan) on Nov 15th.

The application of antibody therapeutics remains a growing research area today, especially in the treatment for cancers, immune-mediated diseases and infectious diseases. Particularly, immunotherapies including antibody-mediated tumor regression, checkpoint blockade, antibody drug conjugates (ADC) and Chimeric antigen receptor T-cell therapy (CAR-T) are regarded as potential strategies to cure cancers.

To showcase a broad scope of remarkable achievements, this year the Antibody Therapeutics Conference (ATC) will focus on the extended application of antibody.

Taiwan Antibody Association(TAA), the ATC organizer, was establishment back in 2012 with the mission to facilitate the research and industrial development of antibody drugs and related technologies in Taiwan. By hosting international conference, we aim to provide a platform for the attendees to connect and communicate, along with opportunities for students, postdoctoral fellows and other participants in the field to learn new knowledge and join discussion.

Last but not least, we hope this conference is able to stimulate interactions between senior experts and young scientists working on antibody therapeutics. We sincerely hope this annual event will contribute to the advancement of antibody therapeutics and you will find it informative, insightful and inspiring.

Chung-Hsiun Herbert Wu, Ph.D.

Chairman of Taiwan Antibody Association;
President of Development Center for Biotechnology

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Extended Application of Antibody

November 15th, 2022 International Convention Hall (Building C)
National Biotechnology Research Park Nangang, Taipei, Taiwan

AGENDA

Time	Activities	Speakers
9:00 - 9:30	Registration	
9:30 - 9:40	Welcome Remarks	**Chung-Hsiun Wu, Ph.D. 吳忠勳** Chairman, Taiwan Antibody Association President, Development Center for Biotechology
9:40 - 9:50	Moderator	**Tse-Wen Chang, Ph.D. 張子文** President, Immunwork, Inc.
9:50 - 10:30	Bispecific Antibody : Sixty Years of Journey from Concept to Medicine	**Herren Wu, Ph.D. 吳和仁** President, HW Biologics Consulting, LLC Former Senior Vice President, R&D, AstraZeneca
10:30 - 10:50	Break	
10:50 - 11:30	Medicines from the central molecule of the 'central dogma' : mRNA drugs and vaccines	**Örn Almarsson, Ph.D.** Principal of AfiRx, LLC Former CTO of Lyndra Therapeutics
11:30 - 12:00	Site-specific conjugation of cytotoxic drug bundles for homogeneous ADCs with high DAR of 6, 8, or 10	**Hsing-Mao Art Chu, Ph.D 朱鑫懋** Vice President of R&D, Immunwork, Inc.
12:00 - 13:00	Lunch / Lunch Seminar	**JelloX Biotech** Next Generation Pathology in Support of Precision Drug Development **Bora Biologics** Making Success More Certain **Berkeley Lights** Accelerating Discovery and Development of Antibody Therapeutics on the Berkeley Lights Beacon Platform

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National Biotechnology Research Park Nangang, Taipei, Taiwan

Time	Activities	Speakers
13:00 - 13:10	3rd meeting of the 3rd TAA General Assembly	**Chung-hsiun Wu, Ph.D. 吳忠勳** President, DCB/Chairman, TAA **Chih-Jung Chang, Ph.D. 張志榮** COO, EirGenix Inc./Secretary General, TAA
13:10 - 13:20	Moderator	**Karen Wen, Ph.D. 溫國蘭** COO, GenomeFrontier Therapeutics Inc.
13:20 - 14:00	Adoptive T Cell Therapy of Cancer: First Principles for Lasting Responses	**Cassian Yee, M.D. 余嘉誠** Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center
14:00 - 14:30	Manufacturing CD20/CD19-targeted iCasp9 regulatable CAR-T_{SCM} cells using *qCART*, the *Quantum pBac*-based CAR-Tsystem	**Sareina Chiung-Yuan Wu, Ph.D 吳瓊媛** CEO, GenomeFrontier Therapeutics Inc.
14:30 - 14:50	Break	
14:50 - 15:00	Moderator	**Han-Chung Wu, Ph.D 吳漢忠** Director, BioTReC
15:00 - 15:40	Development of Universal Vaccine	**Chi-Huey Wong, Ph.D. 翁啟惠** Scripps Family Chair Professor, The Scripps Research Institute President Emeritus and Distinguished Research Fellow, Academia Sinica

Time	Activities	Speakers
15:40 - 17:00	Panel Discussion: Extended Application of Antibody	Moderator : **Han-Chung Wu, Ph.D 吳漢忠** Panelist : **Chung-Hsiun Wu, Ph.D. 吳忠勳** **Tse-Wen Chang, Ph.D. 張子文** **Karen Wen, Ph.D. 溫國蘭** **Lee-Cheng Liu, Ph.D. 劉理成** **Lih-jiuan Hsu, MD, Ph.D. 徐麗娟** **James Chih-Hsin Yang, MD, Ph.D. 楊志新** **Chiun Hsu, MD, Ph.D. 許 駿** **Chia-Chi (Josh) Lin, MD, Ph.D. 林家齊**
17:00 - 17:10	Closing Remarks Election Results Announcement	**Chung-Hsiun Wu, Ph.D. 吳忠勳** President, DCB/Chairman, TAA

SPEAKER

Chi-Huey Wong 翁啟惠

Scripps Family Chair Professor, The Scripps Research Institute
President Emeritus and Distinguished Research Fellow, Academia Sinica

Biosketch

Chi-Huey Wong has been a professor at The Scripps Research Institute since 1989 and is currently the Scripps Family Chair Professor of Chemistry with a joint appointment as Distinguished Fellow at Genomics Research Center, Academia Sinica. He received his BS and MS degrees from National Taiwan University, PhD in chemistry from MIT, and did his postdoctoral research at Harvard University before he joined the chemistry faculty of Texas A&M University in 1983. He is a recipient of the ACS Arthur C Cope Award, the Wolf Prize in Chemistry, the Welch Award in Chemistry, and the Tetrahedron Prize for Creativity in Organic Synthesis, and is a member of Academia Sinica, the American Academy of Arts and Sciences and the US National Academy of Sciences. He is interested in developing new methods to study biological glycosylation and to target cancer and viral infection with universal vaccines. (web:www.scripps.edu/wong)

SPEAKER

Herren Wu 吳和仁

President, HW Biologics Consulting, LLC
Former Senior Vice President, R&D,
AstraZeneca

Summary

• 29-year experience in biologic drug discovery and development.
• 50 issued US patents related to antibody/protein therapeutics and technologies.
• 117 peer reviewed publications.
• 7 FDA approved antibody therapeutics.
• Was responsible for AstraZeneca's and MedImmune's global biologic drug discovery and technology including antibody discovery, antibody/protein engineering, antibody-drug conjugates, bi-specifics/multi-specifics, therapeutic peptides, protein scaffolds, protein sciences, proteomics/metabolomics, structural biology, in vivo expressed biologics (AAV gene therapy, cell therapy and RNA/DNA therapy), and cell line generation.
• Played a key role in building AstraZeneca's and MedImmune's biologics pipeline for cancers, respiratory diseases, autoimmune diseases, inflammation, cardiovascular and metabolic diseases, infectious diseases and CNS/pain. His work has led to seven market approved biologics : (1) anti-PD-L1 antibody (Imfinzi®; durvalumab) for cancer treatment; (2) anti-IL-5α receptor antibody (Fasenra®; benralizumab) for severe eosinophilic asthma treatment; (3) anti-CD22 immunotoxin (LumoxitiTM; moxetumomab pasudotox) for hairy cell leukaemia; (4) anti-CD19 antibody (UPLIZNA™; inebilizumab-cdon) for the treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD). (5) anti-type I interferon receptor antibody (Saphnelo™, anifrolumab) for systemic lupus erythematosus; (6) Evusheld™ (tixagevimab and cilgavimab), long-acting antibody combination for both prevention and treatment of COVID-19. (7) anti-IL-13 antibody (Adbry™; tralokinumab) for atopic dermatitis. Herren is also a co-inventor for inebilizumab and anifrolumab. In addition, he has helped build hundreds of biologics in research and development with >80 programs moved into clinical development.

Education

1993-1995	Postdoctoral Fellow Department of Molecular Biology The Scripps Research Institute, La Jolla, California Dr. Carlos F. Barbas, Supervisor.
1988-1993	Ph.D., Program in Molecular and Cellular Biology University of Massachusetts, Amherst, Massachusetts Dr. Robert A. Zimmermann, Advisor.
1982-1986	B.S., Department of Chemistry National Taiwan University, Taipei, Taiwan, R. O. C.

SPEAKER

Hsing-Mao Art Chu 朱鑫懋

Vice President of R&D, Immunwork, Inc.

Biography

Hsing-Mao Chu received his Ph.D. degree from National Taiwan University in 2010. In his thesis he studied protein-protein and protein-ligand interactions at atomic resolution using X-ray crystallography. In 2011, he joined Dr. Tse-Wen Chang's laboratory in the Genomics Research Center of Academia Sinica to work on CεmX and anti-CεmX antibodies against human membrane-bound IgE, employing various antibody-engineering methodologies. Since Immunwork Inc. was founded, he was hired as the Director of R&D of the company in 2015 and was promoted to V.P. of R&D in 2019. He is responsible for managing the R&D team to develop antibody-drug conjugates, antibody-radionuclide conjugates, and fatty acid bundle-conjugated ultra-long-acting peptide drugs based on the proprietary T-E technology. He is a co-inventor in more than 60 granted patents.

Antibody drug conjugates (ADC) represent an effective approach for specifically delivering cytotoxic drugs to tumor cells, which internalize the ADC, degrade it in the lysosomes and release the cytotoxic drugs inside the cells. Production of ADCs involves the conjugation of cytotoxic drugs to antibody molecules. In earlier approaches, cytotoxic drugs are randomly conjugated to lysine or cysteine residues, which produces heterogeneous ADC molecules with varying numbers of drugs per antibody (DAR). The growing trend of ADC development is that the ADC product is homogeneous, stable, not prone to aggregate, and has a uniform and high DAR. For these goals, we have developed a proprietary "cytotoxic drug bundle" platform based on our multi-arm linker technology. These cytotoxic drug bundles include 3xlenalidomide bundle, 3xMMAE bundle, 4xMMAE bundle, 5xDM1 bundle, as well as other bundles carrying 3-5 drug molecules, etc. The combination of cytotoxic drug bundle and the molecular construct of scFv-fused IgG.Fc with a specified Cys-containing motif allows us to site-specifically conjugate two drug bundles to the thiol groups of the motif via thiol-maleimide Michael Reaction to form homogeneous ADC molecules with high DAR of 6, 8, or 10. Based on the 3xlenalidomide bundle, we have developed a homogeneous ADC candidate, TE-1146, which targets CD38 expressed by multiple myeloma cells. In several mouse models, TE-1146 displayed much stronger anti-tumor effects than approved drugs.

Cassian Yee 余嘉誠

Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center

Short BIO

Dr. Yee is a Professor in the Division of Cancer Medicine, Director of Solid Tumor Cell Therapy, Director of the Program in TCR-based Therapeutics and Co-Director of the Adoptive Cellular Therapy Platform at UT MD Anderson Cancer Center. He received his medical training in Canada, residency at Stanford and fellowship at Fred Hutchinson Cancer Research Center. He is an elected member of the American Society of Clinical Investigators, CPRIT Clinical Investigator, co-Leader of the Stand Up to Cancer- AACR/CRI Dream Team and recipient of translational scientist awards from Burroughs Wellcome Fund, Damon Runyon Cancer Research Foundation, and the Rao Potul Basic Science Award. He holds an endowed position as the Kenneth Muller Professorship of Melanoma Research. Over the last 20+ years, Dr. Yee has pioneered a form of ACT, known as Endogenous T Cell (ETC) therapy, using peripheral blood to generate a uniform population of antigen-specific memory T cells. He has conceived and executed several IND-approved first-in-human clinical studies establishing principles of T cell persistence, memory and antigen-spreading as fundamental to the success of adoptive cell therapy in a modality known as Endogenous T Cell (ETC) therapy, including the first-in-class use of tetramer-guided cell sorting to generate memory T cells and the first prospective trial using ETC in combination with immune checkpoint therapy. He is corresponding or lead author in > 80 publications, including The New England Journal of Medicine, Nature, Science, Science Immunology, Science Translational Medicine, Nature Medicine, Journal of Clinical Oncology, Journal of Experimental Medicine, Gastroenterology and Cancer Immunology Research. He holds > 15 worldwide inventions on ex vivo generation of antigen specific T cells, memory reprogramming, and antigen discovery and seeks to extend immunotherapy-based cancer treatments globally. His work converges multidisciplinary and collaborative approaches in bioengineering, metabolism, molecular immunology and cellular biology to develop effective immunotherapy strategies and adoptive cellular therapy, in particular, as a treatment modality for patients with malignant diseases.

Abstract

Adoptive T cell therapy is emerging as an increasingly important therapeutic option for patients with cancer. Greater efficacy and broader applicability of this approach can be achieved by addressing two major challenges: T cell memory and target immunogenicity. Our studies using a form of adoptive cell therapy known as Endogenous T Cell (ETC) therapy have yielded durable clinical responses and instructed the design of strategies that epigenetically render longlasting central memory T cells. A deeper understanding of the intrinsic mechanisms leading to the generation of highly persistent T cells in ETC have been instrumental in designing memory T cells for TCR-T, CAR-T and TIL therapies. To more broadly apply this principle in the clinical arena, we have expanded the portfolio of TCR targets through an antigen discovery pipeline that uses tandem mass spectrometry, propietary filtering algorithms and a platform that uses ETC technology to empirically validate candidate epitopes. To date, we have identified more than 200 novel, shared tumor-associated epitopes among both common and rare tumors, for alleles representing > 80% of Caucasian and Asian populations. We plan to extend the global reach of adoptive cellular therapy by building upon these cornerstones of immunobiology and T cell-based therapies.

SPEAKER

Sareina Chiung-Yuan Wu 吳瓊媛

CEO, GenomeFrontier Therapeutics Inc.

Manufacturing CD20/CD19-targeted iCasp9 regulatable CAR-TSCM cells using qCART, the Quantum pBac-based CAR-T system

Dr. Sareina Wu leads a team of executives in managing the operations, scientific discoveries and research development, as well as setting the overall vision for GenomeFrontier. She is a pioneer in virus-free gene therapy and has been recognized internationally for her work in the field of piggyBac transposons. In striving to reach the pinnacle in the field of gene therapy, Dr. Wu founded the innovation-driven therapeutics company GenomeFrontier in 2018. Dr. Wu applied her research findings toward the development of four crucial proprietary virus-free gene and cell engineering platforms (GTailor™, Quantum Nufect™, Quantum pBac™ and iCellar™), which GenomeFrontier has leveraged to successfully create a robust cell engineering Quantum Engine™ system. This system has the potential to cure a wide range of diseases including cancer. In fact, Dr. Wu is currently utilizing this system to demonstrate its therapeutic effectiveness in cancer treatment. She leads the company research team in the development of several pipelines of chimeric antigen receptor T (CAR-T) and T cell receptor T (TCR-T) genetic reprograming cell products for cancer treatments.

Prior to founding of GenomeFrontier, Dr. Wu founded Celgenomics, LLC in 2007 in Georgia, USA where she focused on the development of human gene therapy for the treatment of neurodegenerative diseases. She also served as Assistant Research Professor at Chang Gung University and was a Faculty member at the Medical College of Georgia. Dr. Wu received her doctoral degree from Vanderbilt University under the mentorship of Drs. Brigid Hogan and Peter Kolodziej, and carried out her postdoctoral training at UC Santa Cruz.

SPEAKER

Abstract

CD19-targeted chimeric antigen receptor therapies (CAR19) have driven a paradigm shift in the treatment of relapsed/refractory B-cell malignancies. However, >50% of CAR19-treated patients experienced progressive disease mainly due to antigen escape and low persistence. Clinical prognosis is heavily influenced by CAR-T cell function and systemic cytokine toxicities. Furthermore, it remains a challenge to efficiently, cost-effectively, and consistently manufacture clinically relevant number of virally engineered CAR-T cells. Using a highly efficient piggyBac transposon-based vector, Quantum pBac, we developed a virus-free cell engineering system, Quantum CART (qCART™), for development and production of multiplex CAR-T therapies. Here, we demonstrated in vitro and in vivo that consistent, robust, and functional CD20/CD19 dual-targeted CAR-T stem cell memory (TSCM) cells can be efficiently manufactured using the qCART™ system for clinical application. qCART™-manufactured CAR-T cells from cancer patients expanded efficiently, rapidly eradicated tumors, and can be safely controlled via an iCasp9 suicide gene-inducing drug.

SPEAKER

Örn Almarsson

Principal of AfiRx, LLC
Former CTO of Lyndra Therapeutics

BIO OF ÖRN ALMARSSON

Örn Almarsson, Ph.D., is the CTO of Lyndra Therapeutics. He joined the company in 2020. Dr. Almarsson has a record of innovation and achievement in pharmaceutical R&D dating back to the mid 1990s. He has been a catalyst of formulation design and drug development across delivery platforms as well as championing novel chemistry and engineering approaches to enable pharmaceutical products. Prior to joining Lyndra, Örn has made significant contributions in companies like Merck, Alkermes and Moderna. He is co-author on more than 70 scientific publications, some 60 patents and 3 book chapters. He serves on the scientific advisory board of a new RNA biotechnology company in the Boston area.

Dr. Almarsson holds a Ph.D. in bioorganic chemistry from the University of California, and a B.Sc. in chemistry from the University of Iceland. Aside from professional roles, he sits on the leadership council of International Institute of New England, which supports immigrants moving to the area. A former recording artist in Iceland prior to dedicating his career to research and development in pharmaceuticals, he enjoys playing the guitar and sampling fine wines in good company.

Abstract

In the past decade messenger RNA (mRNA), the central molecule of molecular biology, has gone from being a research subject and tool to a source of drug development candidates. Despite molecular complexity, fragility and intracellular delivery challenge, the interest in pursuing mRNA vaccines and therapeutics has exploded in recent years. The power of in vitro transcribed (IVT) mRNA has been put to the test in re the COVID-19 pandemic. While mRNA vaccines against Covid19 have had most of the attention, along with a few other mRNA vaccine developments, many new mRNA products are being pursued as medicines. The talk will overview the technology, the delivery challenge associated with gaining high exposures to translated proteins from mRNA dosing and provide examples from the literature. The latter include mRNA encoding for antibodies in preclinical models and in humans. The place of mRNA technology in the history and future of drug modalities will be discussed.

Panel discussion

Han-Chung Wu 吳漢忠

Director, BioTReC

Director of the Biomedical Translation Research Center (BioTReC), Academia Sinica,
Distinguished Research Fellow of the Institute of Cellular and Organismic Biology, Academia Sinica
Fellow of the National Academy of Inventors (NAI)

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 128 original articles in world-renowned journals, and 122Patents (including 84 granted patents and 38 filed patents). He has successfully licensed out 20 technologies from 68 patents to biotech companies. Seven of the licensed technologies serve as the basis for products that are currently in clinical trials or already on the market. Seven of the licensed technologies are currently in preclinical studies for the development of therapeutics. Hence, his research results not only have significant value in basic research, but also practical applications with tangible contributions to the development of the biotech industry and drug development. Dr. Wu was elected as a Fellow of the National Academy of Inventors (NAI) of the United States in 2020. This is among the highest achievable honors for an academic inventor.

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 had also served as the 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. In 2019, Dr. Wu joined National Research Biotechnology Park (NBRP), Academia Sinica, as Chief Executive Officer of BioHub Taiwan. He is currently serving as the Director of Biomedical Translation Research Center, NBRP, Academia Sinica, 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
- 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 Professor, Institute of Pathology; and Graduate Institute of Oral Biology, College of Medicine, National Taiwan University

Panel discussion

Chung-Hsiun Wu 吳忠勳

President, DCB

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

Panel discussion

Lee-Cheng Liu 劉理成

CEO, EirGenix Inc.

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.

Panel discussion

Tse-Wen Chang 張子文

President,
Immunwork, Inc.

EDUCATION AND POSITIONS HELD

- B.S. & M.S., Chemistry, National Tsing Hua University, Taiwan, 1966-1972
- Ph.D., Cell and Developmental Biology, Harvard University, 1973-1977
- Postdoctoral Fellow, Center for Cancer Research, M. I. T., 1977-1980
- Supervisor of Cellular Immunology, Ortho Pharmaceutical Corp., 1980-1981
- Director of Immunology, V. P. of Research, Centocor, Inc., 1981-1985
- Professor of Molecular Virology, Baylor College of Medicine, 1986-1991
- Cofounder 1986, and V.P. of R & D, 1986-1996, Tanox, Inc., Houston
- Professor 1996-2003; Dean 1996-1999; Tsing Hua Professor of Life Science 2003-2006; College of Life Science, National Tsing Hua University
- President, Development Center for Biotechnology, Taipei, 2000-2003
- Distinguished Professor, Genomics Research Center, Academia Sinica, 2006-2015
- Distinguished Visiting Chair, Genomics Research Center, Academia Sinica, 2016-present

RESEARCH INTERESTS

- New drug discovery and antibody engineering
- The main focus of our group is to develop humanized antibody-based and immunogen-based therapeutics, which target key molecules involved in IgE-mediated allergic pathway. We are also developing new technology platforms for improved antibody engineering. One such program is to develop humanized antibody against CεmX domain in human membrane-bound IgE, for the purpose of controlling IgE-expressing B lymphocytes. CεmX, discovered by our group, is a 52 a.a. domain with a unique sequence. Anti-CεmX, if successfully developed, may be used in combination with an anti-IgE antibody, such as omalizumab (trade name Xolair), which is also derived from Dr. Chang's invention and which is approved for allergic asthma.

Panel discussion

Karen Wen 溫國蘭

2019.3 - present
Chief Strategy Officer (CSO)Chief Strategy Officer (CSO), GenomeFrontier therapeutics,Inc

Experience

2011-2018 President of Mycenax Biotech Inc.
2001-2011 Vice President and Manager, Department of Quality Assurance of Mycenax Biotech Inc. Co-founder of Mycenx Biotech Inc. Specialized in drug development, biological development,PIC/S GMP and GDP, IVD development, ISO system, monoclonal antibody development, and business development.

1993-2000
Principal Researcher, Development Center for Biotechnology
Research Fellow of Development Center for Biotechnology, and head of research and development of ISO plant for IVD

Education
Old Dominion University/ Eastern Virginia Medical School
Doctor of Philosophy – PhD, Biomedical Science
National Taiwan University
Bachelor of Science – BS, Chemistry

Panel discussion

Lih-jiuan Hsu 徐麗娟

Deputy Executive Director,
Center for Drug Evaluation

Dr. Lih-jiuan Hsu joined Center for Drug Evaluation (CDE) in 2002, leading CDE previously as Director of Division of New Drugs, Center of Consultation, and Senior Executive Officer in Office of Executive Director, devoting herself in the development of regulatory science in Taiwan for about 20 years. Besides Deputy Executive Director of CDE, Dr. Hsu is also the Adjunct Attending Physician of Family Medicine in National Taiwan University Hospital (NTUH) and the Thesis Advisor in Department of Pharmacy and Graduate Institute of Clinical Pharmacy in National Taiwan University (NTU). Before joining CDE, Dr. Hsu was a practicing family physician. Dr. Hsu obtained her MD degree from China Medical University.

Panel discussion

James Chih-Hsin Yang 楊志新

Superintendent, NTU
Cancer Center

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.

Education

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

National Taiwan University Cancer Center	Superintendent	2020--present
Cancer Administration and Coordination Center, National Taiwan University Hospital	Director	2016--present
Graduate Institute of Oncology,College of Medicine, National Taiwan University	Director	2015--present
Graduate Institute of Oncology, College of Medicine, National Taiwan University	Professor	2009--present
The Ph.D. Program for Translational Medicine, College of Medicine, National Taiwan University	Professor	2012--present

Graduate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University	Professor	2008--present
Graduate Institute of Clinical Medicine, College of Medicine, National Taiwan University	Professor	2008--present
Department of Oncology, National Taiwan University Hospital	Adjunct Attending Physician	2020--present

Panel discussion

Chiun Hsu 許駿

Director, Department of Medical Research and Education,
NTU Cancer Center

Department of Medical Oncology Director Department of Medical Research and Education Director Gastric Cancer Attending Physician

Medical oncology, hepatobiliary cancers, cancers of the digestive system, clinical trial

EDUCATION

National Taiwan University College of Medicine, Graduate Institute of Clinical MedicinePh.D.1999-2004

National Taiwan University College of Medicine, Department of MedicineM.D.1999-2020

CURRENT POSITIONS

Department of Medical Oncology/ Department of Medical Research and Education, National Taiwan University Cancer CenterDirector2020—present

Graduate Institute of Oncology, College of Medicine, National Taiwan UniversityProfessor 2015--presen

Panel discussion

Chia-Chi (Josh) Lin 林家齊

Professor, Graduate Institute of Clinical Medicine, NTU

Department of Medical Oncology Adjunct Attending Physician
Medical treatment of lung cancer, esophageal cancer, and thyroid cancer; oncology phase I trials

EDUCATION

National Taiwan University	Graduate Institute of Clinical Medicine	Ph.D.
National Taiwan University	Department of Medicine	M.D.

Current Positions

Graduate Institute of Clinical Medicine, National Taiwan University College of Medicine	Professor
Department of Oncology, National Taiwan University Hospital	Attending Physician

COMMITTEE

Chung-Hsiun Wu 吳忠勳

President, DCB

Han-Chung Wu 吳漢忠

Director, BioTReC

Tse-Wen Chang 張子文

President,
Immunwork, Inc.

Karen Wen 溫國蘭

COO, GenomeFrontier

Wei-Kuang Chi, Ph.D. 紀威光

Consultant, Executive Director, Institute of Pharmaceutics,
Development Center for Biotechnology

Chih-Jung Chang, Ph.D. 張志榮

Secretary General, Taiwan Antibody Association (TAA)
COO, EirGenix Inc.

2022 Antibody Therapeutic Conference (ATC)
Extended Application of Antibody

November 15th, 2022 International Convention Hall (Building C)
National Biotechnology Research Park Nangang, Taipei, Taiwan

Acknowledgement

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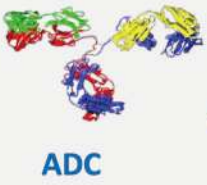

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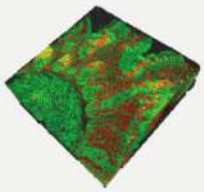

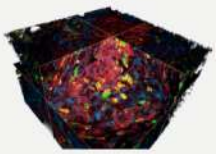

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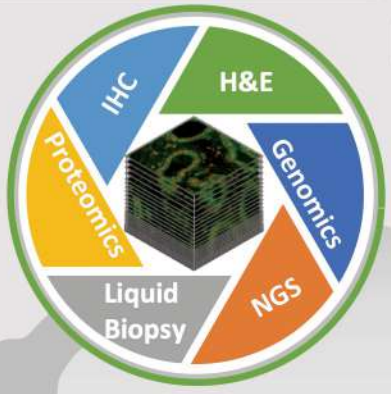
Data Integrated by 3D pathology | **Versatile tools** | **Redefine parameters**



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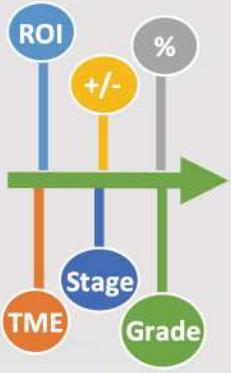

- Precision Medicine
- Immunotherapy
- Targeted Therapy
- Cell Therapy

IHC: Immunohistochemistry
NGS: Next generation sequencing

BMC Part of Springer Nature — Journal of Translational Medicine · JHC · frontiers in Oncology

ROI: Regions of interest
TME: Tumor microenvironment

Jello — MetaLite® Digital Pathology Solution

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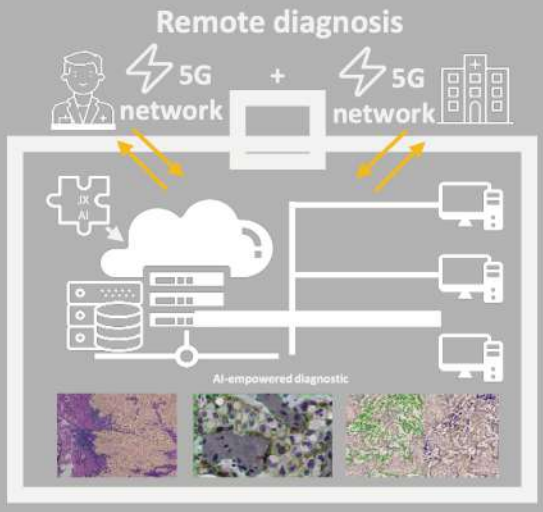

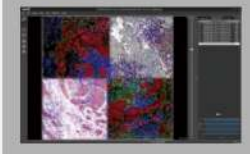

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*** Offer performance and documentation required for use in a GMP-regulated environment.**

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ÄKTA process™ is an automated liquid chromatography system built for process scale-up and large-scale biopharmaceutical manufacturing.

• Highly flexible design with a million possible configurations and a broad flow rate 1 L/h to 2000 L/h.

• Option for a third pump supports flow controlled inline dilu• tion (ILD) for automated buffer preparation.

• Suitable for GMP-regulated manufacturing with option for various automation solutions for diverse process control requirements.

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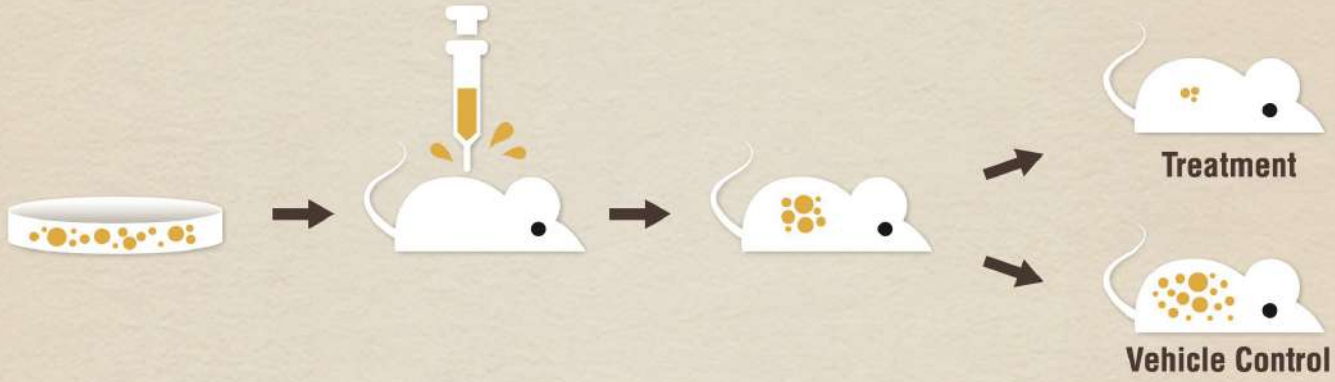

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1 分析檢測中心

- 生物樣品分析檢測
- 抗體藥物特性分析
- 危害物質檢測
- 微量分析
- 蛋白體學鑑定與分析

2 藥物研發中心

- 細胞活性研究
- 作用機轉探討
- 體外活性篩選
- 基因轉殖研究

3 臨床前試驗中心

- 疾病動物模式
- 臨床前安全性評估
- 臨床前毒理試驗
- 符合GLP標準實驗室
- 臨床前試驗規劃

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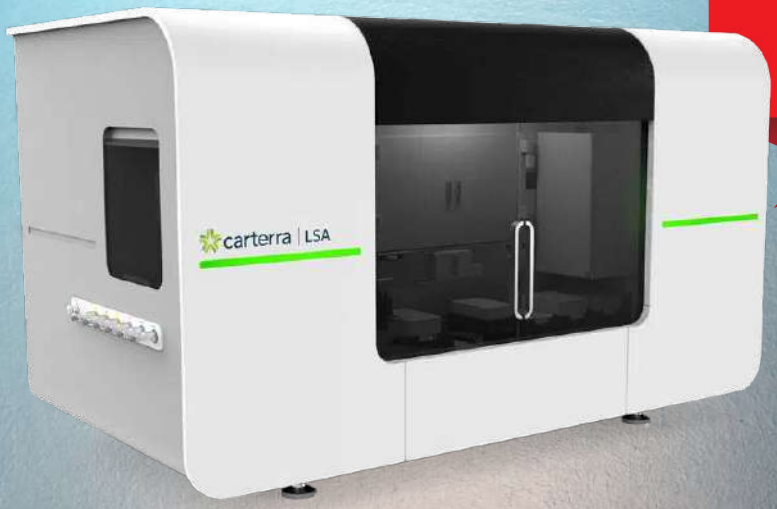


LSA 結合獨家微流體技術與表面電漿共振 (SPR) 原理，能即時平行偵測多達 384 個樣本，可大幅提升**單株抗體篩選與分辨鑑定效率**，降低潛在候選藥物被遺漏的風險，加速藥物開發流程的進行。

亮點案例

LSA 是 Eli Lilly 和 AbCelera 在發現 bamlanivimab 時使用的主要工具，這是**世界上第一個 COVID-19 治療藥物**，也是有史以來進入臨床試驗需時最短的生物製劑。

Sci Transl Med. 2021 May 12;13(593):eabf1906.

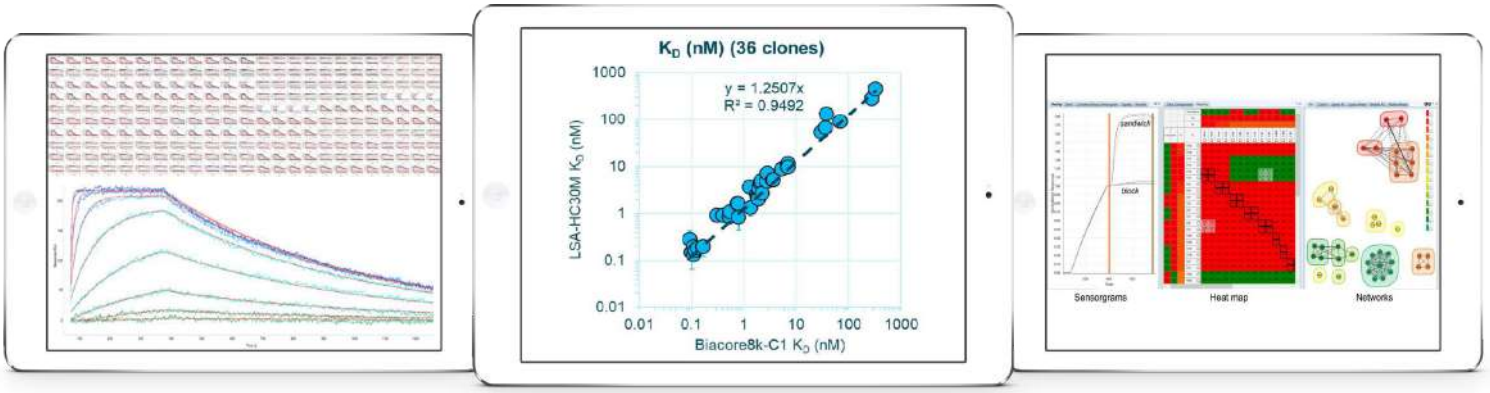
蓋茨基金會資助的全球 COVID-19 免疫治療聯盟 (CoVIC) 使用 LSA 來幫助確認來自世界各地的最有效的候選抗體藥物。

Science. 2021 Oct 22;374(6566):472-478.

LSA 整合多種單株抗體篩選與鑑定功能於一身

- **Capture-based kinetics and affinity:** Screen up to 1152 mAbs
- **Coupled kinetics:** Up to 384 immobilized ligands
- **Epitope binning:** Interrogate up to 384×384 mAb/mAb pairwise interactions
- **Epitope mapping:** Screen up to 384 mAbs against an array of up to 384 peptides

Science, Nature... 眾多文獻採用



同時進行 384 種抗體-抗原間的結合親和力、結合動力學（K_{on}, K_{off}, K_D 值）分析

僅需 1% 的樣本量，一天之內獲得 384 組高品質的動力數據

整合後端分析軟體，抗原表位的分群一目瞭然

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- Antibody and Recombinant Protein
- Antibody-Drug Conjugate
- Plasmid DNA & Viral Vector

CERTIFICATION

- **Taiwan FDA approved**
- **Japan PMDA approved**
- **US FDA inspection in 2022 Q2**
- **EU EMA inspection expected in 2022 Q4**

CELL LINE & PROCESS DEVELOPMENT

ANALYTICAL & QUALITY CONTROL

PRODUCT DEVELOPMENT

		PRE-CLINICAL	PHASE I	PHASE III	MAA/BLA
HER2 FAMILY PRODUCTS	**EG12014/EGI014** SANDOZ A Novartis Division Trastuzumab Biosimilar Signed license agreement with Novartis Sandoz	●	●	●	●
	TSY0110/EG12043 FORMOSA PHARMACEUTICALS, INC. ADC Biosimilar Co-develop with Formosa Pharmaceuticals, Inc.	●			
	EG1206A Pertuzumab Biosimilar	●	●		
	EG13074 TRZ Biosimilar (SC Formulation)	●			
	EG13084 TRZ+PRZ Biosimilar (SC Formulation)	●			
	EG62054 Biosimilar	●			
	EG74032 CRM197 Carrier protein	●			●

CAPACITY EXPANSION

MAMMALIAN GMP PRODUCTION

- Zhubei Facility: 28,000L (12 x 2,000L & 4 x 1,000L SUBs) by 2023
- Xizhi Facility: Multiple 1,000L & 200L SUBs

MICROBIAL GMP PRODUCTION

- Zhubei Facility: 1,350L (1 x 1,000L Fermentor & 1 x 350L Fermentors) by 2024
- Xizhi Facility: 1x 150L Fermentor

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簡化BioAccord LC-MS系統和Ambr® 15高通量自動生物反應器系統之間的數據傳輸流程，在10 – 15 mL微生物反應器規模下進行24組或48組平行的培養條件。Ambr® 15提供高水準的靈活性，能支援各類用途，包括：

- 細胞選殖
- 培養基與養料開發
- 早期製程最佳化
- 在模擬生物反應器的灌流培養條件下篩選

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Andrew+移液機械臂和OneLab™是實驗室裡的得力助手，有了它，很容易就能自動進行最耗費時間的液體配製工作。這個機械臂能自動處理完整的實驗室工作流程，保證能發揮一定的再現性與可追溯性：

- 安裝簡便、遠距支援
- 提供指令碼和工具組，能用於處理濃度標準化、蛋白質純化、次單位分析以及游離N-聚醣分析等作業

分析

BioAccord LC-MS系統

以BioAccord LC-MS系統直接分析生物分子和代謝產物能發揮適當的效能。這套系統包含下列經過最佳化設計的工作流程：

- 蛋白質與寡核苷酸完整質量分析
- 單株抗體(mAb)次單位分析
- 胜肽圖譜/MAM（多屬性監測方法）
- 游離N-聚醣分析
- 細胞培養基分析

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TaiMed Biologics

About TaiMed

Taimed Biologics was founded in 2007, and is located at the Biomedical Science Park in Hsinchu County in Taiwan. Our state-of-the-art multi-product cGMP manufacturing facility employs the latest single-use technology to meet stringent global regulatory requirements, where we obtained **Zero 483 observation from our recent 2022 FDA inspection.**

CDMO Services

Leveraging our extensive experience in developing commerical Trogarzo® and novel anti-HIV monoclonal antibodies in the pipeline, TaiMed offers Contract Development and Manufacturing Organization (CDMO) services for all development stages of projects, whether the need is in preclinical, clinical, or commercial manufacturing. We strive to ensure the highest standards with respect to quality, cost, and logistical requirements. **TaiMed can partner with you.**

- High-Quality and Cost-Competitive
- Flexible Manufacturing Solutions
- Full Services from Laboratory to Commercialization

TaiMed at-a-Glance

10+ years of mAb Development and Manufacturing experiences	60,000 sq.ft space in Compliance with ICH, FDA, and EMA	50L(2X), 200L(2X), 500L, 2000L(4X) bioreactor capacity	Analytical services	IND, BLA/MAA post-approval regulatory filing experiences	Highest Quality standard with FDA no 483

TaiMed Biologics Inc.
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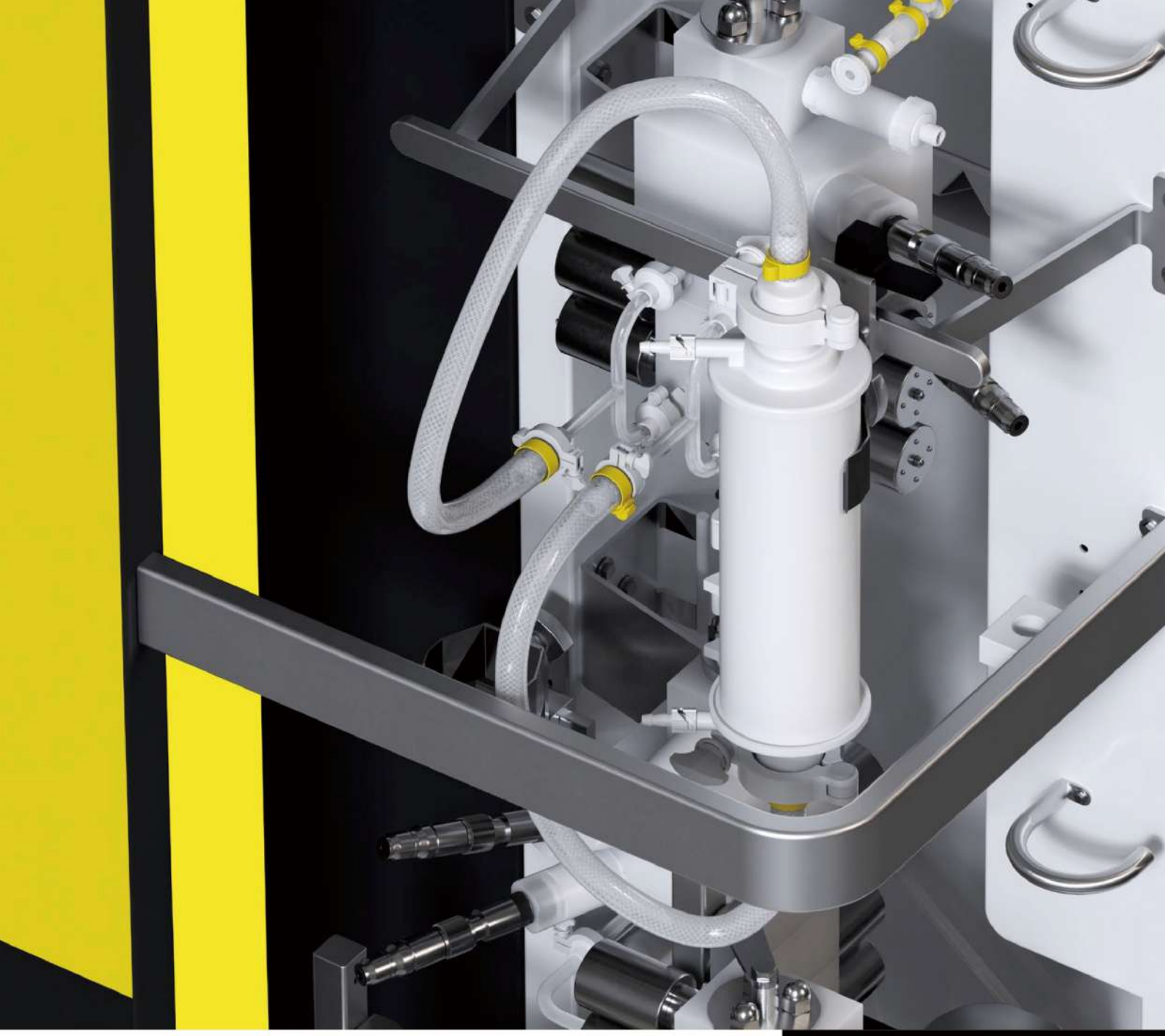
Phone: +886-3-621-2355



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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:
1. 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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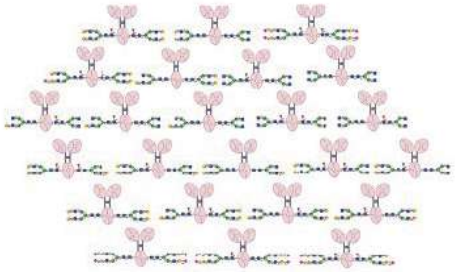
From SAR studies to GMP manufacturing

1



Lead Antibodies /

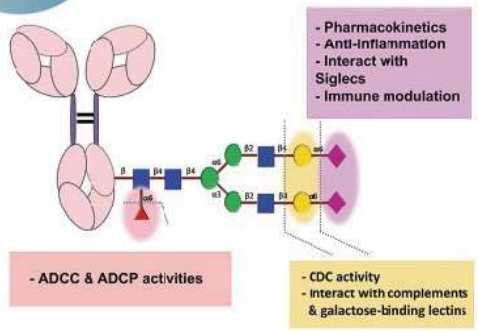
High Flexibility

- Can apply to all kinds of human IgGs and human IgG Fc-fusion proteins produced from diverse systems, such as mammalian cells, insect cells and yeast.

N-glycosylation Profile

- Highly heterogeneous

2



SAR Study /

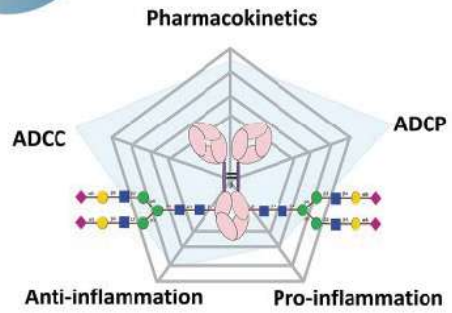
Glycan-based SAR Study

- Candidates with single, well-defined N-glycan structure can be made for functional studies.

Optimize Desired Functions or Discover New Functions

- Common structures like G0(F), G2(F), G2S2(F), or customized structures

3



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Rapid and Well Defined Process

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High Yield & Purity

- >95% single glycoform with limited loss during process.

Cost- and Time-Efficient

Drug Product /

Regulatory

- Product has been approved for Phase 1/2 trials in US and Taiwan.

Simplified CMC

- No worry for batch variation caused by glycosylation

N-glycosylation profile

- Homogeneous

V(D)JC完整定序，全面解析TCR/BCR免疫組庫資訊

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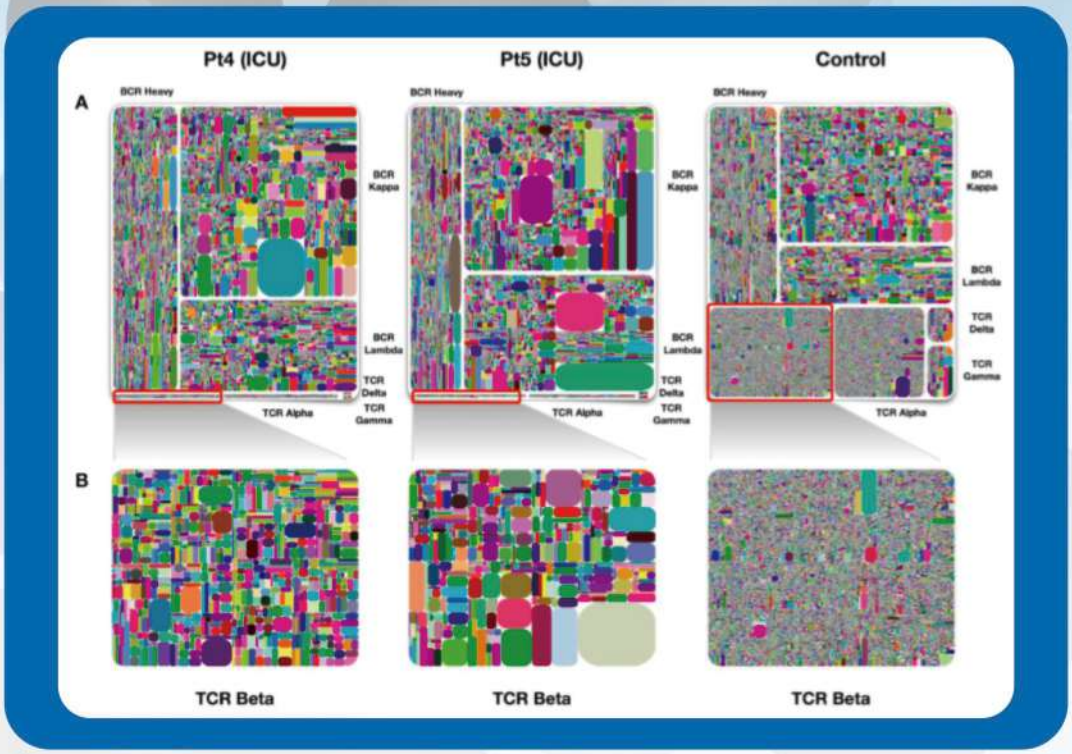
免疫組庫完全解析方案

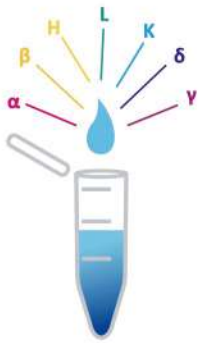


應用範圍

- 免疫細胞族群變異分析
- 個體免疫年齡評估
- 輔助疫苗開發
- 疾病狀態評估/免疫治療伴隨診斷

新一代專利dam-PCR 技術

- 一次可選擇1-7種TCR/BCR序列分析
- 卡盒式自動化建庫
- 提供詳細免疫組庫資訊



均泰生物科技股份有限公司
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Accelerating Your Research!

騰達行主要代理及經銷生命科學研究領域的產品，我們的核心價值是提供台灣生技及臨床醫學研究單位最優良的產品與最貼心的服務。騰達行近期更深耕細胞治療、大分子藥物開發與次世代定序領域，提供高品質試劑耗材與儀器，並建立整合平台，為研究人員帶來最優質的服務。

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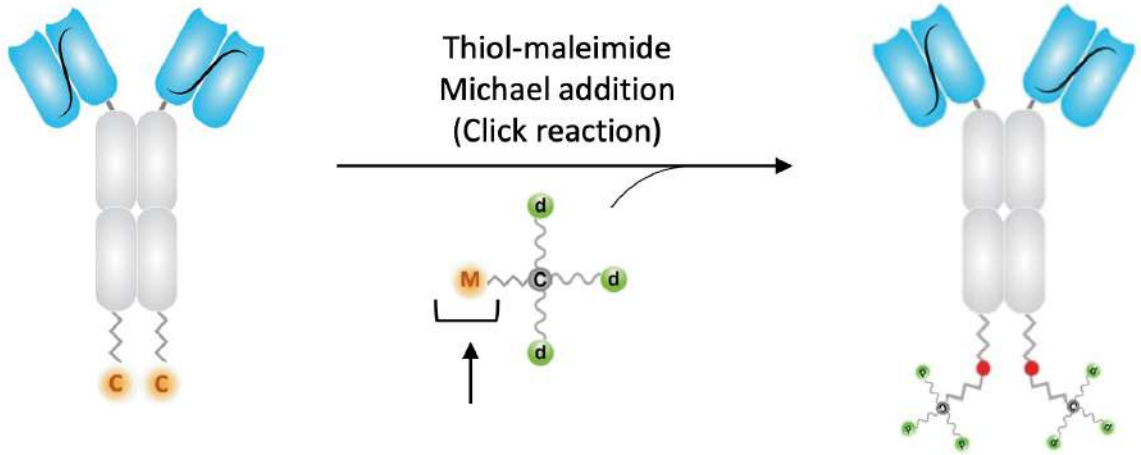
Immunwork

免疫功坊

Pioneers in T-E Pharmaceuticals

ADC/ARC with Site-Specific Conjugation



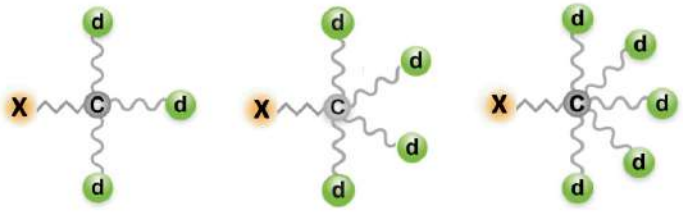
Comparison among site-specific ADC platforms

	Ambrx	Synaffix	LegoChem	Immunwork
DAR	1.9	2 or 4	2 or 4	6 or 8 or 10
Site-specific conjugation process	Engineered cell line; unnatural amino acids	Requires enzyme catalyzation	Requires enzyme catalyzation	NO unnatural amino acid and enzyme required

ADC: Antibody Drug Conjugates; ARC: Antibody Radionuclide Conjugates

X Coupling group:

- Maleimide
- BCN
- DBCO
- TCO



d Drug:

- DM1
- SN38
- Dxd
- MMAE
- Lenalidomide
- DOTA

We welcome collaborations

Model 1: License our ADC/ARC platform

Model 2: License our cytotoxic drug bundles

Phone: +886-2-2651-2268

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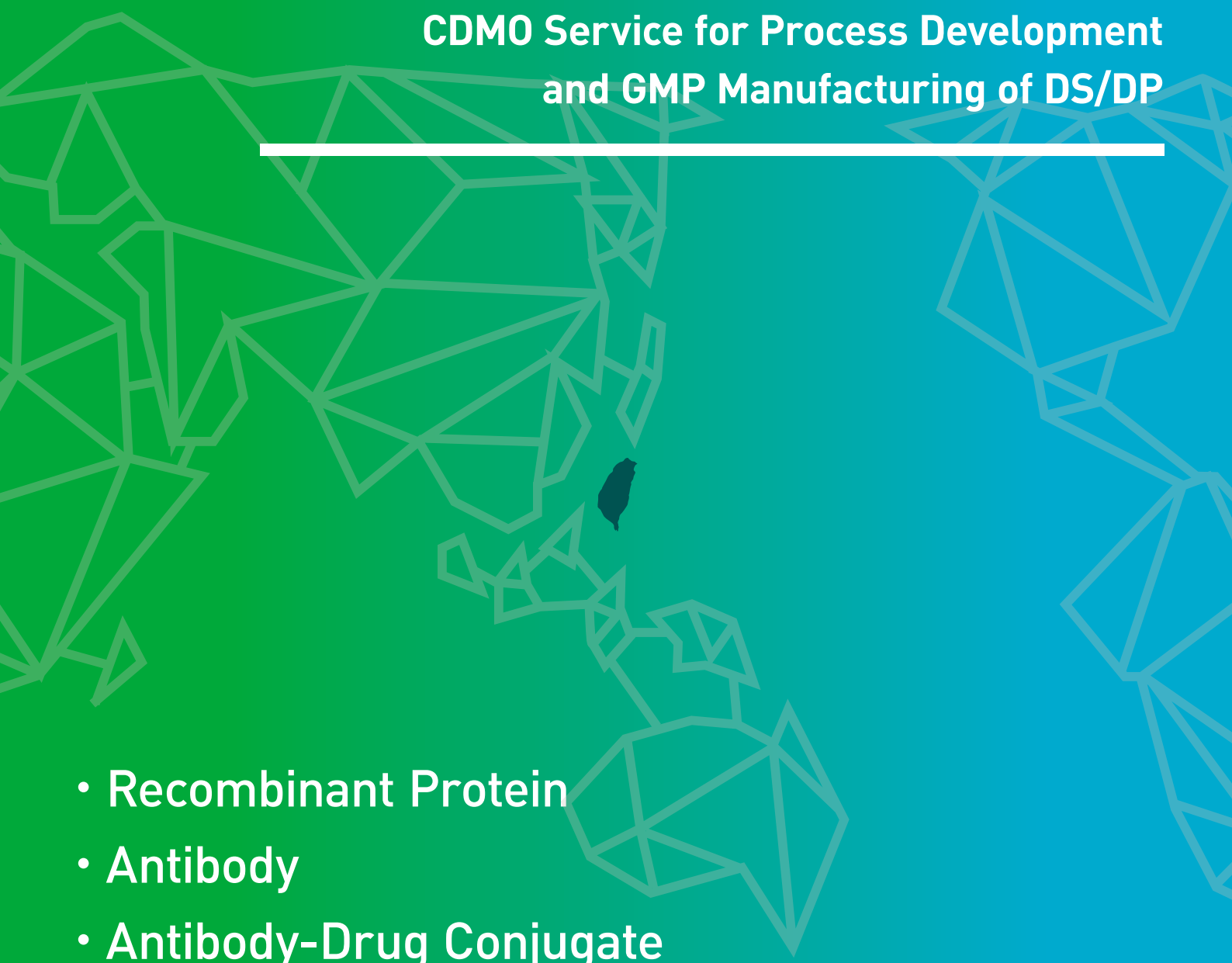
台北市研究院路一段130巷99號C棟520室

A TOTAL SOLUTION FOR BIOLOGICS

CDMO Service for Process Development and GMP Manufacturing of DS/DP



- Recombinant Protein
- Antibody
- Antibody-Drug Conjugate
- Plasmid DNA
- Cell Therapy

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TFBS Bioscience Inc.

Available Services

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Mammalian Cell Bank Characterization

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

Bacterial and Yeast Cell Bank Characterization

- Purity
- Genetic Stability
- Identity
- Viability

Virus Clearance Validation Study

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

Bulk and Lot Release Testing

- Identity and Impurity Test
- Potency Assay
- Customized Bioassay
- Testing for Vaccine / Biologics / Cellular Product

Assay Development / Optimization / Validation

- ELISA-based Assay : ELISPOT Assay / ADA Screening
- qPCR-based Assay
- Cell-based Assay : Potency assay / Neutralization Antibody Assay
- In vivo study : IBD animal model / TIL animal model / Xenograft animal model

Preclinical and Clinical Sample Analysis

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

Production of Cell Bank & Viral Vector with GMP Compliance

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

Polaris Pharmaceuticals, Inc.
www.polarispharma.com

Depleting arginine as a first-line cancer therapy

Polaris Pharmaceuticals is evaluating its lead therapeutic protein—pegargiminase, a novel targeted cancer therapy that depletes circulating arginine—in combination with standard chemotherapies and immuno-oncology drugs in various cancers, including hepatocellular carcinoma and mesothelioma.

Polaris Pharmaceuticals, Inc. (a subsidiary of Polaris Group) is a biopharmaceutical company specializing in the research and development of novel treatments for cancer. Pegargiminase (ADI-PEG 20) is a potential first-in-class targeted cancer therapy in late-stage clinical development for a wide range of cancers, including hepatocellular carcinoma (HCC) and malignant pleural mesothelioma (MPM). Pegargiminase is well tolerated, both as a monotherapy and as part of a combination therapy.

"Preclinical data revealed various biochemical mechanisms that provide compelling rationales for combining pegargiminase with other agents, and we are exploring these potential synergies in our global clinical trial program," said John Bomalaski, MD and EVP of medical affairs at Polaris.

"Evidence suggests pegargiminase induces metabolic changes that can make cancer cells more susceptible to conventional chemotherapies, and this has been borne out in clinical studies, which show combination therapy can significantly enhance the efficacy of first-line therapy. We are also exploring a potential strong synergy with cancer immunotherapy drugs."

Based in San Diego, California, USA, Polaris Pharmaceuticals collaborates with major pharmaceutical companies and more than 40 cancer centers worldwide. The multinational Polaris Group also includes high-quality in-house current good manufacturing practice (cGMP) manufacturing through wholly owned subsidiaries. Its global clinical trial program is supported by a highly experienced management team and renowned scientific advisors, including James Allison, who was awarded the 2018 Nobel Prize in Physiology or Medicine for his pioneering work on cancer immunotherapy.

Targeting arginine metabolism

Pegargiminase is a PEGylated therapeutic protein based on a microbial enzyme, arginine deiminase (ADI). It converts extracellular arginine into citrulline, thus blocking the external supply of this important nutrient to cancer cells (**Fig. 1**).

Arginine is an amino acid that is required for protein synthesis and cell survival. Cancer cells need high amounts of arginine for growth and proliferation. When the external supply of arginine is restricted, cancer cells must produce enough arginine internally via the urea cycle not only to maintain normal cellular functions, but also to support their rapid rates of growth and replication. This process requires the cancer cells to spend energy (ATP). Arginine deprivation also gives rise to a host of conditions within cancer cells, including increased autophagy, increased apoptosis, increased eukaryotic stress and altered gene expression. Healthy cells are unaffected by the depletion of circulating arginine because they are able to convert citrulline back into arginine through the urea cycle.

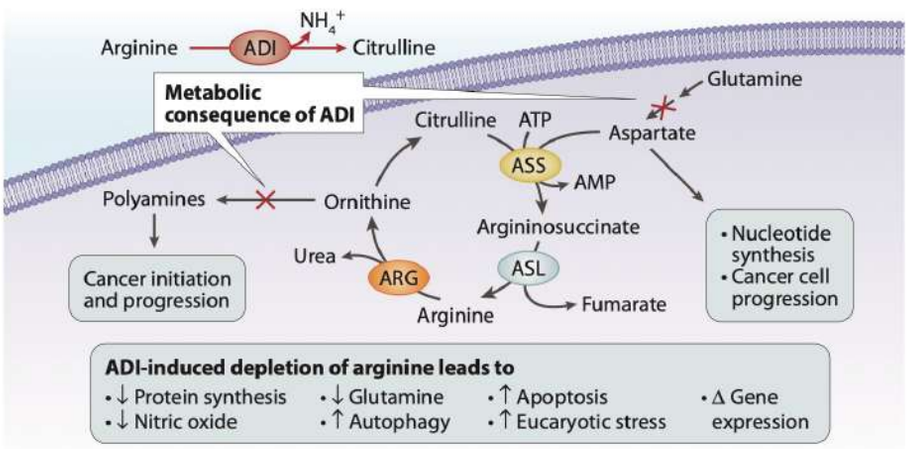

Fig. 1 | Pegargiminase converts extracellular arginine into citrulline. Cancer cells are therefore blocked from receiving this external supply of important nutrient. ADI, arginine deiminase; ARG, arginase; ASL, argininosuccinate lyase; ASS1, argininosuccinate synthetase.

There are multiple cancers with reduced expression of argininosuccinate synthetase (ASS1), the rate-limiting enzyme in internal arginine synthesis in the urea cycle. In these cancers, pegargiminase can be very effective as a monotherapy. For cancer cells with normal or even elevated levels of ASS1, pegargiminase has demonstrated strong synergy when used in combination with other systemic treatments.

Pivotal combination therapy trials

Two pivotal clinical trials are currently underway to assess the efficacy of pegargiminase in combination with standard chemotherapies, with potential marketing approvals planned for HCC and MPM by 2020.

A global phase 2 registration study (NCT02102022) designed to support accelerated approval for pegargiminase in combination with folinic acid (leucovorin), fluorouracil and oxaliplatin (FOLFOX) in HCC patients who have failed at least two lines of prior systemic treatments. Led by the Memorial Sloan Kettering Cancer Center (New York, USA), the single-arm, open-label study was expanded from a phase 1 clinical study after promising efficacy results were seen.

"Pegargiminase plus FOLFOX is showing more favorable efficacy compared to historic controls and the combination remains well tolerated," said Bomalaski. "We are committed to developing an effective treatment for the third line or later for HCC patients who have no approved treatment option."

Meanwhile, patients with MPM are taking part in ATOMIC-Meso (NCT02709512), a pivotal phase 2/3 study led by Barts Cancer Institute (London, UK). Based on data from a phase 1b study, the multicenter, randomized, double-blind trial is assessing pegargiminase in combination with pemetrexed and cisplatin, the current first-line standard-of-care chemotherapies for MPM. The study is using an adaptive biomarker-driven design with an interim analysis to be conducted at the end of phase 2.

Promising pipeline

Proof of principle for the efficacy of pegargiminase in combination with first-line therapies has also been demonstrated in other indications, including non-small-cell lung cancer, pancreatic cancer and acute myeloid leukemia. A phase 2 trial of pegargiminase in combination with gemcitabine and docetaxel for the treatment of soft tissue sarcoma is also currently underway.

Potential synergies with checkpoint inhibitors are also being explored in a phase 1 trial of pegargiminase in combination with pembrolizumab for the treatment of advanced solid tumors and in upcoming trials with dual checkpoint inhibition.

contact
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