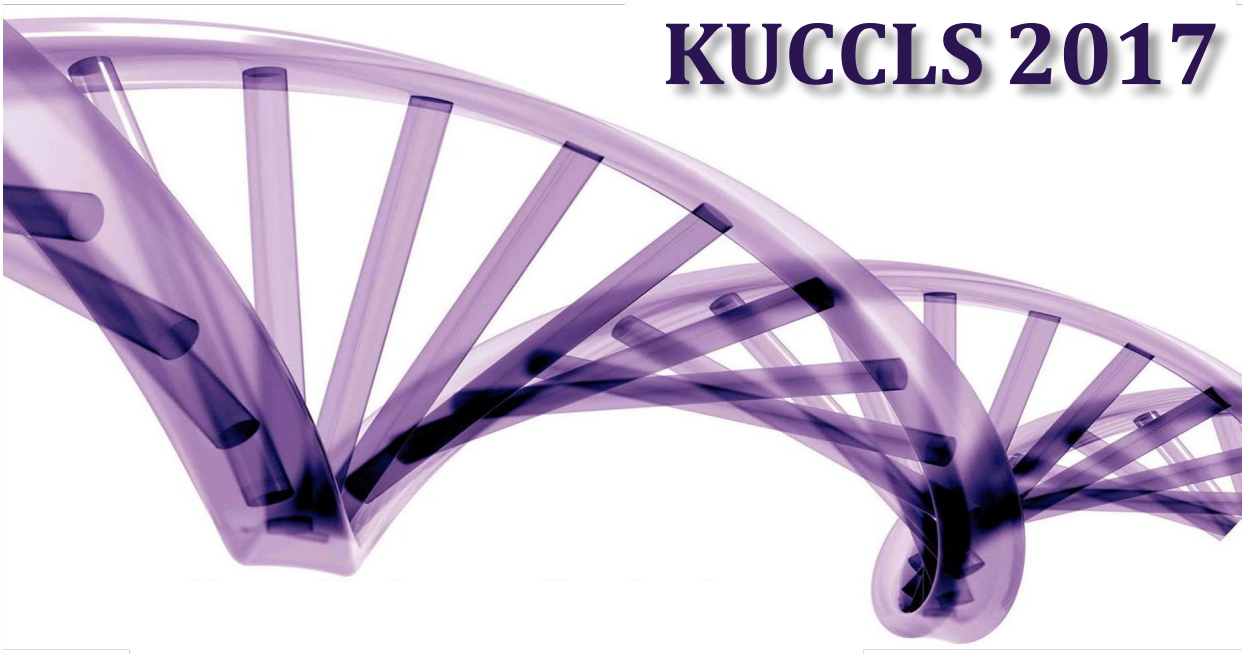
Korea-US Cooperative Conference for Life Science 2017

November 2 - 4, 2017

Institute for Bioscience and Biotechnology Research (IBBR), Rockville, MD, USA



Collaboration and Innovation in the Healthcare Industry

Organized by

KAPAL
Korean-American Professional Association in Life Sciences

Hosted by

Osong High-Tech Medical Cluster

About Us

- The only bio R&D cluster in the world located inside Osong Life Science Complex where industry, academia, R&D, medicine and government are gathered together
- Total Cluster Size 1,131,000㎡, Estate Size 768,000㎡, Developing Site 34,000㎡

Core Research Support Facilites

New Drug Development Center

Medical Device Development Center

Laboratory Animal Center

Clinical Drug Manufacturing Center

Incentives

For Global Workforce
- 5 Year Increase in Allowed Period of Work for Resident Professional
- Capacity of Foreign Medical Professional to Practice Medicine in Korea

For Clinical Tests
- Incentives for Clinical Test Applicants
- Within the Cluster, Legal Assessment is Limited to Institutional Review Board

For Production and Export
- Approval for Production and Export of Foreign Pharmaceutical Components
- Approval for Production and Export of Foreign Medical Device

For Commercialization
- Order Priority for MIC-Based Patents over Other Patents
- Establishment of Production Facility for Resident Research Organization

CHUNGCHEONGBUK-DO KBIOHEALTH

Invitation Letter

Dear Participants,

On behalf of the organizing committee, it is my great pleasure to welcome you to Korea – US Cooperative Conference for Life Science (KUCCLS) 2017. This is the third annual KUCCLS, which has been a platform for building a collaborative bridge between Korea and US life sciences and to promote innovation and advancement in biosciences. As an old proverb that says: if you want to go quickly, go alone; if you want to go far, go together, it has become clear that a good collaboration is a key to a continuous growth in life sciences. I believe that establishing successful partnerships between the Korean and US life science will be a main engine to the advancement and innovation in this important field and hope that all participants maximize the networking, learning, and initiating a collaboration during the conference.

KUCCLSI 2017 will provide a unique opportunity for all participants to expand their networks and to start a dialogue for potential collaborations. As a home of FDA, NIH, JHU, University of Maryland and other leading universities, Maryland offer exceptional benefits and scientific resources as a strategic hub for the growth of biosciences and the health industry. This year, KUCCLS2017 is aligned with the NIH-KSA organized Annual Bioscience and Engineering Symposium (ABES) which will be held on November 4, 2017. These two back-to-back events will provide a platform for a synergy between early discovery and biopharmaceutical R&D, and bring bioscience experts from both academia and industries together.

KUCCLS2017 would not have been possible without the generous sponsorships from many companies and institutes. We also recognize the important contributions from multiple organizations including Chuncheongbuk-do, Embassy of the Republic of Korea, Korea health industry development institute, and Ministry of health and welfare. Lastly, we thank all speakers, organizing members, and participants and look forward to having a successful KUCCLSI 2017.

Luke Yun Suk Oh, Ph.D.

President of Korean-American Professional Association in Life Sciences (KAPAL)

KUCCLS+ABES 2017 Program

Thursday, November 2

4:30 - 6:00 pm *Registration & Networking*

6:00 - 6:30 pm **Opening Remarks**

Luke Oh, PhD, President (Korean-American Professional Association in Life Sciences)

Min-Soo Park, Minister-Counselor for Health & Welfare (Embassy of the Republic of Korea)

Benjamin Wu, Deputy Secretary, Maryland Department of Commerce (Maryland)

In Sung Chung, Director General of Bureau of Bio Technology and Environment (Chungcheongbuk-do)

Byoung Joon Song, PhD, President (NIH-Korean Scientist Association)

6:30 - 7:30 pm *Dinner*

7:30 – 8:15 pm **Keynote presentation 1**

Adoptive Cell Therapy "Immune cell-LC" for liver and brain tumor
Duckjoo Lee, MD, PhD (CEO, GreenCrossCell)

8:15 – 9:00 pm **Hosting sponsor presentation**

Introduction of Osong Medical Innovation Foundation
Gusun Park, Director General, (Osong Medical Innovation Foundation Department of Strategy Planning, Chungcheongbuk-do)

Global Strategy of Korea Bio-Medical Industry
Jung Hoon Wu, Director General, (Korea Health Industry Development Institute (KHIDI))

9:00 – 10:30 pm *Networking*

Friday, November 3

7:30 – 8:30 am *Breakfast*

8:30 – 10:00 am **Session I: Korea Life Science presentation**

Kyu Sang Lee, Clinomics

Seon-Joo Yoon, Abion

Jong Moon Kim, Toolgen

Dong Seok Kim, Peptron

Do Soo Jang, Huons

Chulhee Choi, Cellex Life Sciences

10:00 - 10: 15 am *Coffee Break*

10:15 – 12:00 pm **Session II: Regulatory pathway and updates**

FDA, can we talk, Agency open for discussion
Hyun Joo Son, PharmD (Senior Program Management Officer, CDER, FDA)

FDA's Expedited Programs to Accelerate Drug Development and Marketing Approval
Bruce Babbitt, PhD (Vice President – Technical, PAREXEL Consulting)

Special considerations on biotechnology product comparability
Linan Ha, PhD (Principal Consultant, PAREXEL Consulting)

12:00 – 1:00 pm *Lunch*

1:00 – 1:45 pm **Keynote presentation 2**

Strategy for Entering Global Market: Korean Pharma Perspective
Yong Hae Han, PhD (Daewoong Pharmaceutical Co., Ltd.)

1:45 – 2:40 pm

Session III: US Life Science presentation

Resources for Growing your U.S. Business
Judy Costello (Managing Director, BioHealth Innovation)

Gene and Cell Therapy: Strategies for Treating HIV, Cancer, and Inherited Genetic Diseases
Jeffrey Galvin (CEO and Co-founder, American Gene Technologies)

2:40 – 3:00 pm

Late Breaking presentation

Where Science and People can flourish
Hyun Jung Helen Lee, MD (CSO & CMO, Samyang Biopharm)

3:00 – 3:15 pm *Coffee Break*

3:15 – 5:00 pm

Session IV: Legal challenges

Strategic patent considerations in the Biosimilars Space
Joo Mee Kim (Rothewell, Figg, Ernst & Manbeck, P.C.)

IP Portfolio Life Cycle Management Aligned with Drug R&BD
Sunhee Lee (Sughrue Mion, PLLC)

Generic Pharmaceutical Litigation in the US
Shailendra Maheshwari (Dentons US LLP)

5:00 – 5:45 pm

Keynote presentation 3

Biosimilar Development and CMC Considerations
Min Kyoung Jeon, PhD (Team leader, Celltrion)

5:45 – 7:00 pm *Dinner*

7:00 – 8:30 pm

Career Development	Focus Group Discussion
Moderator: **Jeong Kuen Song, PhD**	**Strategy/challenge to initiate the US-based life science company**

Saturday, November 4

8:00 -9:00 am **Annual Bioscience and Engineering Symposium (ABES)**

Registration and Breakfast

9:00 - 9:10 am **Opening Remarks and Logistics**

Byoung-Joon Song, PhD (NIH-KSA President)

9:10 - 9:40 am **Keynote Lecture I**

Therapeutic strategies aimed at achieving sustained virologic remission in HIV infection
Tae-Wook Chun, PhD (NIAID)

9:40 - 10:40 am **Session 1**

Chair: Juhyung Lee, PhD (NIDDK)
4 presentations (12 min + 3 min Q&A)

10:40 - 10:50 am *Coffee Break*

10:50 - 11:20 am **Keynote Lecture II**

Advanced glycation end-products produced by activated macrophages: a common contributor to inflammation and degenerative diseases
Bonghee Lee, PHD (Gachon Univ.)

11:20 - 12:05 pm **Session 2**

Chair: Youngchan Kim, PhD (NIAAA**)**
3 presentations (12 min + 3 min Q&A)

12:05 - 1:10 pm *Lunch (Samyang Biopharm hiring presentation)*

1:10 - 1:20 pm **Special Member Recognition**

Johng S. Rhim, PhD for outstanding contribution

1:20 - 1:50 pm **Keynote Lecture III**

Novel fluorescent dyes for real-time, intraoperative, organ-specific visualization in vivo
Je-Pyung Cha, PhD (George Washington Univ.)

1:50 - 2:35 pm **Session 3**

Chair: Jung Eun Park, PhD (NINDS)
3 presentations (12 min + 3 min Q&A)

2:35-2:45 pm *Coffee Break*

2:45 - 3:15 pm **Keynote Lecture IV**

RARRES1 Links CCP2-Mediated Tubulin Deglutamylation to VDAC Regulation, Metabolic Reprogramming and Cell Survival
Mi-Hye Lee, PhD (Georgetown Univ.)

3:15- 4:15 pm **Session 4**

Chair: Ga-Yeon Son, PhD (NIDCR)
4 presentations (12 min + 3 min Q&A)

4:15 - 4:30 pm *Break and voting for the best talk*

4:30 - 5:00 pm **Special Presentation**

NIH Funding Opportunities for Career Development Awards and Other Research Grants
Minkyung Song, PhD (NCI)

5:00 - 5:15 pm **Closing Remarks and Award Ceremony**

5:30 – 7:00 pm *Dinner*

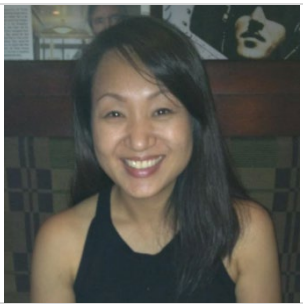
SPEAKERS

Keynote presentation 1: " *Adoptive Cell Therapy 'Immune cell-LC' for liver and brain tumor* "

Duck-Joo Lee, MD, MMSc, MPH, PhD
CEO, Green Cross Cell

Dr. Lee is CEO of Green Cross Cell. Dr. Lee was a professor in the Department of Family Practice, and the Director of Foreign affairs and Collaboration at Ajou University Medical Center.

He has extensive experiences in both academia and industry. Dr. Lee was a professor in the Department of Family Practice, and the Center Head in Aging and Wellbeing Center at Ajou University. Dr. Lee was also a professor and Superintendent of Daewoo General Hospital. In addition, Dr. Lee was the president & CEO of MyGene.
Dr. Lee is serving as a chairman of Korean Academy of Functional Medicine, and as a Senior Advisor in Korean Society of Integrative oncology, Korean Society of Osteoporosis and Korean Academy of Anti aging Medicine.
Dr. Lee earned his PhD from Korea University School of Medicine, earned MPH from University of Minnesota, and earned MS from Yonsei University Postgraduate School of Medicine.



Session II: "*FDA, can we talk, Agency open for discussion"*

Hyun Joo Son, PharmD
U.S. Food and Drug Administration

CDR Hyun Joo Son graduated from the UMCP with a BS in Chemistry. Soon after, she attended Howard University, College of Pharmacy and received her Pharm.D.

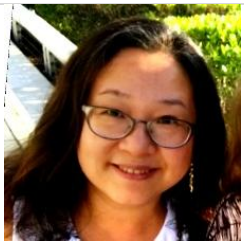
Right after graduation, she worked as the pharmacy manager for a competitive retail pharmacy company for several years, until joining the FDA in 2005. She was the Regulatory Project Manager in the Division of Transplant and Ophthalmology Products from 2005 to 2008. During this time, she managed all TB products within the division. In 2008, she became the Safety Regulatory Project Manager for the division. In this role, she was responsible for all post-market safety issues as well as working with companies regarding risk evaluation and mitigation strategies (REMS). In January 2013, she was given the opportunity to join the CDER Drug Shortage Staff (DSS). In this role, she works to address potential and actual shortages of drugs that have a significant impact on public health. Through communication, facilitation and negotiation, the DSS works with pharmaceutical manufacturers, review divisions, compliance and other components of FDA to manage product shortages.

Session II: "*FDA's Expedited Programs to Accelerate Drug Development and Marketing Approval* "

Bruce P. Babbitt, PhD
Vice President - Technical, PAREXEL Consulting

Dr. Babbitt's primary expertise is in early-stage development of New Chemical and Biological Entities with major focus on Oncology and Rheumatology related indications.

He has an extensive experience with FDA's Expedited Programs (Fast Track, Breakthrough, Accelerated Approval, Priority Review) and Orphan Drug programs. Dr. Babbitt is responsible for regulatory strategic planning and preparation of briefing documents in support of formal meetings with regulators (CBER, CDER, ex-US regulatory agencies) as well as preparation/review of INDs/CTAs, NDAs/BLAs/MAAs. Majority of Dr. Babbitt's clients have been small to medium sized companies typically integrating PAREXEL Subject Matter Experts onto internal drug development/project management teams.
Dr. Babbitt previously headed R&D at both LipoGen, Inc. and Cellcor, Inc. He has a PhD in Biochemistry (Univ. of Tennessee) and conducted post doc work in cellular immunology at Harvard and Washington University Medical Schools.



Session II: " *Special considerations on biotechnology product comparability* "

Linan Ha, PhD
Principal Consultant, PAREXEL Consulting

Dr. Ha has over 13 years of experience in drug development, regulatory science, and research. Dr. Ha's area of expertise includes monoclonal antibodies, antibody-drug conjugates (ADCs), biosimilars, Fc-fusion proteins, and therapeutic proteins.

Dr. Ha possesses an in-depth understanding of the current regulation and relevant guidance documents and has extensive experience in handling highly complex and difficult CMC issues for biological products at different stages of development, which include, but are not limited to, comparability, QbD study design, cell substrate, reference standard qualification and requalification, analytical method validation, process development, characterization, and validation, and immunogenicity assay validation.
At PAREXEL, Linan is experienced in providing strategic guidance to clients for development programs in a stage appropriate manner. She possesses extensive expertise in developing adequate comparability exercise to fulfill the regulatory requirement for establishing comparability at different stage of development, particularly, for late stage manufacturing change, site transfer, and establishing comparability for biosimilar products during their life cycles. Linan possesses extensive knowledge in the preparation and reviewing Module 3 submissions for INDs and BLAs.
Prior to joining PAREXEL, Linan worked as a Chemistry, Manufacturing, and Controls (CMC) team leader for a regulatory team in the Office of Biotechnology Products (OBP) at the FDA. In this role, Linan functioned as Application Technical Lead (ATL) for numerous BLA submissions and provided technical leadership to a quality assessment team. She performed secondary reviews on all CMC reviews generated by the assigned staff, including NME, biosimilar, fusion proteins, and multiple ADC products at different development stages.

Keynote presentation 2: "*Strategy for Entering Global Market: Korean Pharma Perspective*"

Yong Hae Han, PhD
VP, Daewoong Pharmaceutical Co., Ltd.

Dr. Yong-Hae Han is the vice president and head of the Life Science Research Institute Daewoong Pharmaceutical.

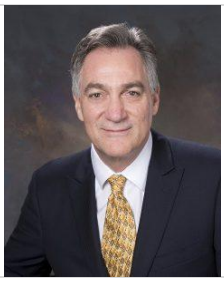
He received his B.S. degree in pharmacy, M.S. degree in Pharmaceutics, and Ph.D. in Pharmaceutics from the College of Pharmacy, Seoul National University, Korea. He completed a postdoctoral fellowship training in biopharmaceutics at the University of Tokyo, Japan. He continued his research career as a visiting fellow at NIH/NIEHS, USA, and research assistant professor at the University of North Carolina, USA.
Dr. Han started his professional career in the pharmaceutical industry at Bristol-Myers Squibb (BMS), New Jersey, USA in 2002. During his 12 years of tenure at BMS, Dr. Han made significant contributions to the development and successful commercialization of new drugs such as Eliquis®, Daklinza®, Sunvepra®, Farxiga®, and Ongliza®, etc.
Returning to Korea in 2014, he served as an executive consultant at KHIDI (2014-2014) and led a global new drug development program at Enzychem Lifesciences as President and CTO (2014-2016). He joined Daewoong Pharmaceutical in January 2017.
Dr. Han has authored more than 100 scientific publications, book chapters, abstracts, and patents.

Session III: "*Resources for Growing your U.S. Business*"

Judy Costello
Managing Director, BioHealth Innovation

Judy Costello is the Managing Director of Economic Development for BioHealth Innovation, Inc. (BHI). A longtime supporter of the region's entrepreneur and start-up communities, Judy Costello joined BioHealth Innovation in August 2017.

Prior to joining the Business Alliance, Costello held positions in economic development, financial services marketing, and university public relations. She is a graduate of Georgetown University, and holds a MBA from Loyola University in Maryland. She previously served as Director of the Maryland Department of Commerce's Office of BioHealth and Life Sciences and Deputy Director of the department's BioMaryland Center. She previously worked for fifteen years for the Business Alliance organizing venture pitch forums, entrepreneur bootcamps, tech transfer showcases, educational seminars, and other programs connecting entrepreneurs, faculty innovators, students, and industry leaders in Maryland, DC and Virginia with each other and with those providing funding and other resources to young companies.



Session III: "*Gene Therapy-The New Frontier*"

Jeffrey A. Galvin
CEO and Co-founder, American Gene Technologies

Jeffrey A. Galvin is the CEO and Co-founder of American Gene Technologies™ (AGT). He earned his BA degree in Economics from Harvard in 1981.

He has more than 30 years of business and entrepreneurial experience including founder or executive positions at a variety of Silicon Valley startups. Several of his companies were taken public and/or sold to public companies, including one in the medical-technology arena that was sold to Varian, the leading maker of linear accelerators used in cancer therapy. Following his startup experience, he retired to become an Angel Investor in real estate and high tech. He came out of retirement to found and fund AGT after meeting Roscoe Brady at NIH.

Late Breaking presentation: "*Where Science and People can flourish*"

Hyun Jung Helen Lee, MD, MHCM
CSO & CMO, Samyang Biopharm

Dr. Lee is in charge of establishing strategies of corporate and R&D as Chief Strategy Officer and leading clinical development as Chief Medical Officer at Samyang Biopharm.

Hyun Jung Helen Lee MD, MHCM is a board-certified gynecologist and an experienced pharmaceutical professional with 14 years' experience in pharmaceutical industry.
She has experienced in oncology drug development in Global, US and Asia region working in early and late stages from phase I to III and has the first hand regulatory experience as a medical lead for the submission to the FDA/EMA and other regulatory agencies like PMDA in Japan.
Prior to joining Samyang Biopharm, she served as the Global Head of Solid Tumor Clinical Development at Shire in the US. She has held various executive positions at Baxalta / Baxter and Eli Lilly in the US and had worked as a product physician at Pfizer Korea.
After graduating from Yonsei University College of Medicine in Seoul, Korea, she completed her residency training at Severance Hospital, and later, earned her master's degree in Health Care Management at Harvard School of Public Health.

Session IV: " ***Strategic patent considerations in the Biosimilars Space*** **"**

Joo Mee Kim
Member, Rothewell, Figg, Ernst & Manbeck, P.C.

Ms. Kim has been practicing across the full spectrum of intellectual property law for over 20 years. Ms. Kim's practice focuses on litigating patent cases and counseling clients for obtaining, licensing and enforcing patents in various technology areas including pharmaceutical, biotechnology, chemical, electronics and mechanical areas.

Ms. Kim has a broad range of experience in patent matters both in the United States and Korea. Ms. Kim has extensive experience in patent litigation including Hatch-Waxman litigation and patent troll litigation, both in district courts and the Court of Appeals for the Federal Circuit. Ms. Kim litigated on behalf of LG Electronics, Mylan Pharmaceuticals, Rexall, Inc., Nature's Bounty and LG Electronics. Ms. Kim has also handled a number of alternative dispute resolution cases including arbitration cases before the American Arbitration Association (AAA).
Ms. Kim has considerable expertise and experience in handling the post-grant proceedings created by the America Invents Act especially in IPR proceeding representing both petitioners and patent owner. Ms. Kim's practice also includes counseling clients for maximizing licensing revenue from patented and patentable technologies. She also counsels various clients in pharmaceutical, biotechnology, chemical, biomedical and electronic areas for strategic exploitation of their patents and for development of effective defenses against infringement allegations. Ms. Kim has represented clients in a broad range of due diligence associated with merger and acquisition and has provided written opinions to evaluate freedom-to-operate, invalidity and/or infringement issues in the technical field of pharmaceuticals, genetic engineering, molecular biology, monoclonal antibodies, cancer treatments, and protein production in plants.

Session IV: " ***IP Portfolio Life Cycle Management Aligned with Drug R&BD*** **"**

Sunhee (Sunny) Lee
Partner, Sughrue Mion, PLLC

Ms. Lee is a member of the firms Biotechnology/Pharmaceutical Group. She has extensive experience in prosecuting patent applications and writing opinions regarding patentability, infringement and freedom-to-operate.

Ms. Lee's work focuses on biotechnology area including nucleic acid and polypeptide sequences, antibodies, pharmaceuticals, and regenerative drug areas. Her work also covers drug delivery systems. She was a member of the firm's litigation team for the recent AZ v. Hanmi in the District Court of New Jersey, which was the Korean drug companies' first US Hatch-Waxman litigation.
She is named in the 2015 Rising Stars within the Washington DC metropolitan area by the Washington DC Super Lawyers Magazine. She speaks fluent Korean and is a registered Korean Patent Attorney.
Ms. Lee serves as a co-chair of the Asia Pacific Committee of the AIPLA AIPPI US division, a co-chair of the International Cooperation Committee of the Korea Patent Attorney Association (KPAA), and a Korea Innovation Center (KIC) Washington DC leadership mentor. She also served as a president of the KAIPBA.

Session IV: "*Generic Pharmaceutical Litigation in the US*"

Shailendra (Shalu) K. Maheshwari
Partner, Dentons US LLP.

Shailendra (Shalu) Maheshwari is a partner in Dentons' Intellectual Property and Technology practice. He is also one of the key members of the Firm's Section 337 International Trade Commission (ITC) practice. He is resident in the Firm's Washington, DC office.

Shalu focuses his practice on patent litigation and counseling, but has significant experience with other areas of IP as well, including hatch waxman litigation, trademarks and trade secrets. In addition to the ITC, he has litigated patent infringement cases in district courts throughout the country, including in California, Delaware, Wisconsin, New Jersey and the Eastern District of Texas. He has represented clients in in a wide range of products and industries, including life sciences, medical and dental device, chemical films, automotive parts, biometric authentication, cloud synchronization, non-volatile memory, wireless technologies, networking, data compression and transmission, microprocessors, semiconductor manufacturing and packaging equipment, light emitting diodes (LEDs) and optics, databases and software, as well as Internet and business method patents. He has also drafted patent opinions for pharmaceutical, electronics and biotechnology companies, performed patent portfolio analyses for biotechnology acquisition deals and drafted patent licenses for a variety of technologies.
Shalu is a member of the New York, New Jersey and District of Columbia Bars. Shalu also has an extensive hard science background that includes several years of research at the US National Institutes of Health, as well as experience running clinical trials at Johns Hopkins Bayview Hospital.

Keynote presentation 3: "*Biosimilar and Regulatory Pathways – Remsima / Infectra Case Study "*

Min Kyoung Jeon, PhD
Team leader, Celltrion, Inc.

Dr. Jeon is the team leader and manager in Corporate Regulartory Affairs 1 at Celltrion, Inc.

Dr. Jeon has over 6-year experience as a regulatory specialist dedicated to the CMC area. Dr. Jeon has worked across submissions, variations and strategy for CMC approach. Dr. Jeon contributed to successful marketing approval for Remsima (infliximab biosimilar), and she also involved in post marketing life cycle management for Remsima.
Dr. Jeon earned her PhD in Biological Sciences / Biomedical Science & Engineering Program from KAIST in 2011. Dr. Jeon is the named inventor of several Korean patents regarding transformed cell line and a method for stimulating antigen specific cytotoxic T lymphocyte using dendritic cells.

Korea life Science presentation

	Note(English)	Note(Korean)
Clinomics	Low cost, high accuracy liquid biopsy and genomic analysis platform for cancer screening	암의 조기 진단을 위한 고민감도의 저렴한 액체 생검 및 유전체 분석 플랫폼
ABion	Development of CDx-based innovative targeted cancer therapeutics.	동반진단 공동 개발을 통한 암 표적 치료
Toolgen	ToolGen, Inc. is a publicly traded biotechnology company focused on the development and applications of genome editing technology that can be used as essential tools for editing the genetic information in microbial, plant, animal, and human cells. In biomedical fields, genome editing will enable genome-editing therapy for many rare hereditary diseases. It can also be used to establish and improve safe and efficient cell therapies for various diseases. As an innovative molecular breeding tool, it can be used to develop crops, plants and animals with improved nutrition and growth characteristics. With intellectual properties covering foundational genome editing tools and technologies, our mission is to translate the potential of our innovative platform technology into transformative products for biomedicine and agricultures.	툴젠은 미생물, 식물, 동물 및 인간 세포의 유전 정보를 편집하는 데 필수적인 도구로 사용할 수 있는 유전체교정 (CRISPR) 전문회사입니다. 생물 의학 분야에서 CRISPR 기술은 많은 희귀 유전 질환에 대한 게놈 편집 치료를 가능하게 하며, 다양한 질병에 대한 안전하고 효율적인 세포 치료법을 확립하고 향상시키는 데에도 사용될 수 있습니다. 또한 혁신적인 분자 육종 도구로서 향상된 영양 및 성장 특성을 지닌 작물, 식물 및 동물을 개발하는 데 사용할 수 있습니다. 툴젠은 CRISPR IP를 바탕으로 혁신적인 플랫폼 기술의 잠재력을 생물 의약 및 농업을 위한 변형 제품으로 개발하고 있습니다.
Peptron	Drug repositioning: A new treatment strategy for the treatment of Parkinson's disease through GLP-1 agonists.	신약재창출: GLP-1 agonists를 이용한 파킨슨병 치료제 개발
Huons	Huons Global : Total Health Care Solution Provider - Introduction of Huons and related company Introduction of Biologics Pipeline - HU014/HU024 (Botox Biosimilar, Ophthalmic Drug)	휴온스 글로벌 및 자회사 소개 현재 개발중인 바이오제품 소개 - HU014 (휴톡스) - HU024 점안제
Cellex	Exosome engineering for delivery of therapeutic proteins: Principles and applications	Exosome을 이용한 therapeutic proteins의 delivery 원리와 응용

Conference Organizers and Hosts

KAPAL

Luke Oh, Ph.D. (President)
Hong-Woon Yang, Ph.D. (Vice President)
Helena Ahn, Ph.D. (Financial Director)
Suntae Kim, Ph.D. (Science Director)
Byung Ha Lee, Ph.D. (General Director)
Bumrae Cho, J.D. (Program Director)
Sang Tae Park, Ph.D. (Senior Director)
Jeong Kuen Song, Ph.D. (Senior Director)
Heemin Rhee, Ph.D. (Senior Director)

Chungcheungbuk-do

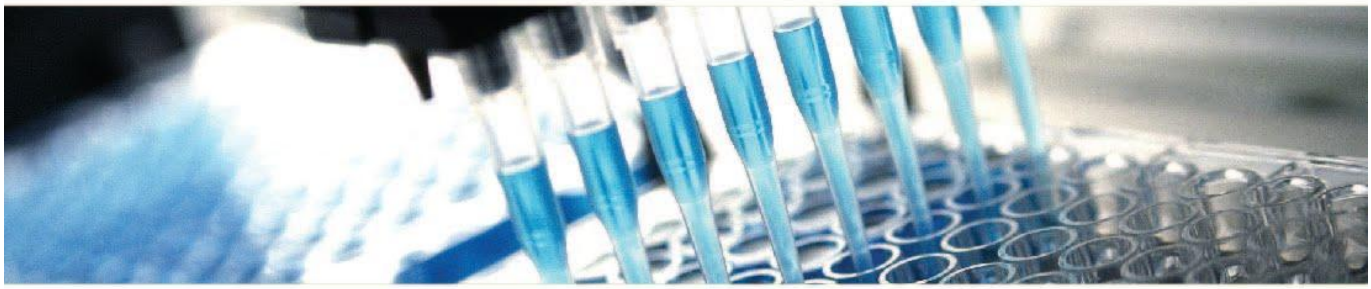
Sung Soo Jun (Assistant Director)

KHIDI USA

Jung-Hoon Woo (Director General)

ROTHWELL FIGG
IP Professionals

Rothwell Figg is a quality-focused intellectual property firm. From our office in Washington, DC, our lawyers and IP professionals handle all aspects of IP law on a worldwide basis, including: patent, trademark, and copyright law; trade secrets; trade names; character protection; unfair competition; litigation; licensing; counseling; contracts; First Amendment and defamation issues; and obtaining patent, trademark, and copyright registrations.



Biosimilars and Biologics Practice

Rothwell Figg has the experience and technical knowledge required to develop a successful IP strategy for the most sophisticated biologic and biosimilar matters, including issues related to regulatory approval, securing patent rights, counseling and opinions, post-grant challenges, and asserting or defending against patents in litigation. We understand the manufacturing, regulatory, and legal requirements for biologics and biosimilars, and we put our IP experience to work for our clients. We have extensive experience litigating in life sciences, and we have extensive experience with post-grant proceedings, counseling and opinions, and patent prosecution, including international involvement. Additionally, the majority of our lawyers have first-hand industry experience, and many have advanced degrees in areas such as microbiology, genetics, biochemistry, bioinformatics, chemistry, biotechnology, pharmacy, biology, zoology, and other scientific fields.

The firm recently launched BiosimilarsIP.com - a blog tracking regulatory issues and events, providing analysis of legal decisions from federal courts and the PTAB, and offering updates on current news related to biologics and biosimilars. Please visit BiosimilarsIP.com and sign up to receive updates.

Hatch-Waxman Practice

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Company & Business Area

1. Company : Green Cross Cell Corp. (www.greencrosscell.com)

- **Main business : Anti-cancer immune cell therapy research and production, KGMP Service etc.**
- **Establishment : September, 1992**
- **Capital : 5,300,000$ (5.83 Billion won)**
- **Stock Listed : KOSDAQ(031390)**
- **Employees : 130 Persons**

2. Business Area

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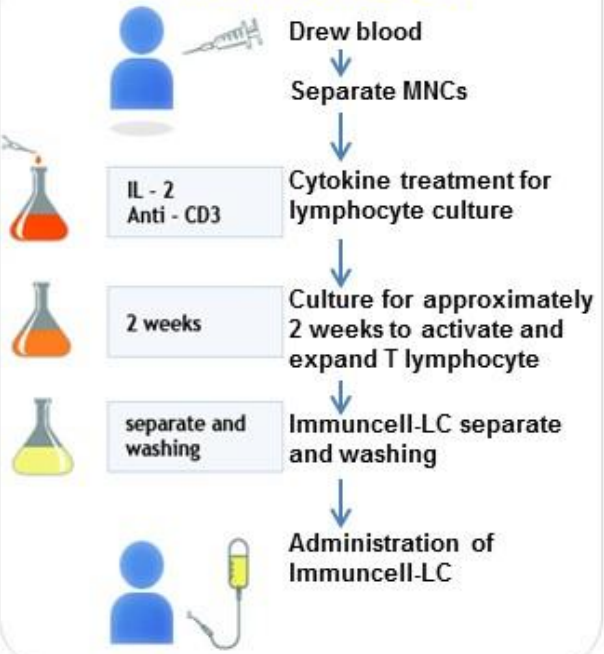


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Image: Fraser River Delta as it enters the ocean

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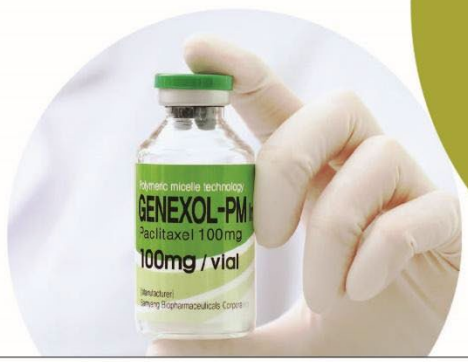

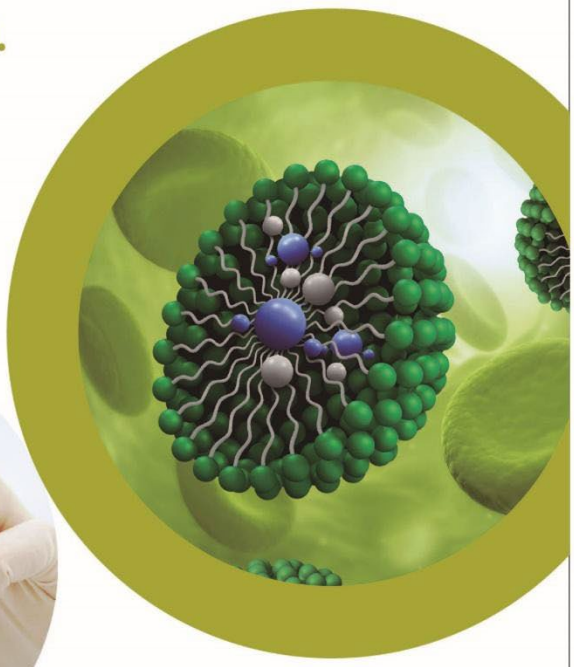


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Placebo
86
52
86
47
88
56
81
56
6M
12M
18M
24M
[OMERACT1-OARSI2 RESPONSE RATE (%)]
Source: US Phase II Clinical Trial (TGC09201)
1 OMERACT: Outcome Measures in Rheumatology
2 OARSI: Osteoarthritis Research Society International

2017 Annual Bioscience and Engineering Symposium (ABES) Program

Dear Participants of the 2017 ABES,

On behalf of the Organizing Committee and President of the NIH Korean Scientists Association (NIH-KSA), I would like to welcome all of you to the 2017 Annual Bioscience and Engineering Symposium (ABES). ABES is an annual flagship event organized by the NIH-KSA to promote scientific exchange and networking interactions among Korean and Korean-American Scientists and Engineers in the Washington D.C. Metropolitan area and vicinities.

I am pleased that ABES2017 will be held in a joint session with KAPAL. This year, we are especially grateful to have three tenure-track investigators and a distinguished scientist as Keynote Speakers: Dr. Tae-Wook Chun (Earl Stadtman Investigator at NIAID), Dr. Bonghee Lee (Professor and Director at Gachon University Medical School), Dr. Jaepyeong Cha (Assistant Professor at George Washington University Medical School) and Dr. Mi-Hye Lee (Assistant Professor at Georgetown University Medical School).

In addition to showcasing the excellent research conducted by NIH-KSA members and others, we have invited fourteen active Korean-American scientists and engineers to discuss their research results. Finally, we also have a special session where Dr. Minkyung H. Song at the NCI will discuss NIH funding opportunities for career development awards, including the NIH K-series awards for junior scientists to become independent investigators.

Finally, I would like to thank the following sponsors who have provided generous supports for the 2017 ABES and NIH-KSA monthly seminar series: Macrogen Corp, KSEA, KUSCO, KASBP, KAPAL Members, BioLegend, and other private sponsors.

I hope that you will find the program informative and that the symposium will provide you with valuable opportunities for scientific exchange, networking, and collaborating with other fellow scientists and engineers.

Sincerely yours,

Byoung-Joon Song, PhD

ABES 2017 Organizing Committee

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2017	**Dr. Byoung-Joon Song**

2017 ABES Program Schedule

8:00 Registration and Breakfast

9:00 Opening Remarks and Logistics (Dr. Byoung-Joon Song, NIH-KSA President)

9:10 **Keynote Lecture I: Dr. Tae-Wook Chun**, NIAID "Therapeutic Strategies Aimed at Achieving Sustained Virologic Remission in HIV Infection"

9:40 Session 1, Chair: Dr. Juhyung Lee, NIDDK (4 speakers; each 12 min + 3 min Q&A)

10:40 Coffee Break

10:50 **Keynote Lecture II: Dr. Bonghee Lee**, Gachon University "Advanced Glycation End-Products Made by Activated Macrophages: a Common Contributor to Inflammation and Degenerative Diseases"

11:20 Session 2, Chair: Dr. Youngchan Kim, NIAAA (3 speakers; each 12 min + 3 min Q&A)

12:05 Lunch (Samyang Biopharm hiring presentation)

01:10 Special Member Recognition (Dr. Johng S. Rhim for outstanding contribution)

01:20 **Keynote Lecture III: Dr. Jaepyeong Cha**, George Washington University "Novel Fluorescent Dyes for Real-Time, Intraoperative, Organ-Specific Visualization In Vivo"

01:50 Session 3, Chair: Dr. Jung Eun Park, NINDS (3 speakers; each 12 min + 3 min Q&A)

02:35 Coffee Break

02:45 **Keynote Lecture IV: Dr. Mi-Hye Lee**, Georgetown University "RARRES1 Links CCP2-Mediated Tubulin Deglutamylation to VDAC Regulation, Metabolic Reprogramming and Cell Survival"

03:15 Session 4, Chair: Dr. Ga-Yeon Son, NIDCR (4 speakers; each 12 min + 3 min Q&A)

04:15 Break and voting for the best talk (15 min)

04:30 **Special Session: Dr. Minkyung Song**, NCI "NIH Funding Opportunities for Career Development Awards and Other Research Grants"

05:00 Closing Remarks and Award Ceremony

05:15 Dinner

Keynote Speaker's Career Brief:

Tae-Wook Chun, PhD
Chief, HIV Immunovirology Unit, Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health
The Johns Hopkins University School of Medicine; PhD
California State University, San Bernardino; BS

Bonghee Lee, DVM, PhD
Directors and Professor, Center for Regenerative Medicine, Center for Genomics and Proteomics, Gachon University Medical School
Children's Hospital of University of Pennsylvania; Postdoc
College of Veterinary Medicine, Seoul National University; PhD
College of Veterinary Medicine, Seoul National University; MS
College of Veterinary Medicine, Seoul National University; DVM

Jaepyeong Cha, PhD
Assistant Professor, Sheikh Zayed Institute for Pediatric Surgical Innovation, Children's National Health System, Department of Pediatrics, George Washington University School of Medicine and Health Sciences
The Johns Hopkins University; PhD
Seoul National University; MS
Seoul National University; BS

Mi-Hye Lee, PhD
Assistant Professor, Lombardi Comprehensive Cancer Center/ Georgetown University
Department of Biochemistry, School of Dentistry, Kyungpook National University; PhD
Department of Biochemistry, College of Natural Sciences, Kyungpook National; MS
Department of Biochemistry, College of Natural Sciences, Kyungpook National; BS

Special Session Speaker's Career Brief:

Minkyung Song, PhD
Program Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health Extramural Research Program
Food and Drug Administration; Interdisciplinary Regulatory Review Scientist
National Institutes of Health; Postdoc and Senior Staff Fellow
Biochemistry and Molecular Biology, University of Minnesota Medical School; PhD
Biochemistry, Yonsei University; BS

The List and Abstracts of Short Talks for 2017 ABES

Session 1. ***Chair: Juhyung Lee, PhD, NIDDK***

1. ***Byung Hyun Kang, PhD*** (National Institute of Allergy and Infectious Diseases)
   "Functional and spatial heterogeneity of colon macrophages"
2. ***Caeul Lim, PhD*** (National Institute of Allergy and Infectious Diseases)
   "Plasmodium vivax transmission and vector immune evasion: the role of Pvs47"
3. ***Jinha Yu, PhD*** (National Institute of Diabetes and Digestive and Kidney Diseases)
   "Discovery of potent and selective A3 adenosine receptor agonists; N6-Substituted 5'-N-methylcarbamoyl-4'-selenoadenosines"
4. ***Kwang H. Choi, PhD*** (Uniformed Services University of the Health Sciences)
   "Effects of intravenous ketamine infusion on fear memory and brain glucose utilization (18F-FDG PET) in Sprague-Dawley rats"

Session 2. ***Chair: Youngchan Kim, PhD, NIAAA***

5. ***Keewan Kim, PhD*** (National Institute of Child Health and Human Development)
   "Dairy food intake and reproductive function among premenopausal women: BioCycle Study"
6. ***Young-Eun Cho, PhD*** (National Institute on Alcohol Abuse and Alcoholism)
   "Molecular mechanisms of gut leakiness and inflammatory liver injury caused by binge alcohol or fructose drinking"
7. ***Sang-Min Jang, PhD*** (National Cancer Institute)
   "The Replication-initiation determinant protein (RepID) modulates replication by recruiting CUL4 ubiquitin E3 ligase to chromatin"

Session 3. ***Chair: Jung Eun Park, DVM, PhD, NINDS***

8. ***Youngchan Kim, PhD*** (National Institute on Alcohol Abuse and Alcoholism)
   "Anomalous ultra-fast energy transfer suggests coherent energy transfer between fluorescent proteins"
9. ***Seung-Kwon Ha, DVM, PhD*** (National Institute of Neurological Disorders and Stroke)
   "Human and nonhuman primate meninges harbor lymphatic vessels that can be visualized noninvasively by MRI"
10. ***Joon Ha, PhD*** (National Institute of Diabetes and Digestive and Kidney Diseases)
    "A mathematical model predicts future diabetes"

Session 4. ***Chair: Ga-Yeon Son, PhD, NIDCR***

11. ***Hye Kyung Lee, PhD*** (National Institute of Diabetes and Digestive and Kidney Diseases)
    "Assessment of cytokine-sensing mammary super-enhancers within a complex locus using CRISPR/Cas9 genome editing and 'base editing' in mice"
12. ***In Gyu Kim, PhD*** (Georgetown University)
    "GTF2I mutation lead to thymic epithelial tumor through induction of oncogenes and cell transformation"
13. ***Young-Kwon Park, PhD*** (National Institute of Diabetes and Digestive and Kidney Diseases)
    "GR, KLF4 and Krox20 are dispensable for adipogenesis"
14. ***Younghoon Jang, PhD*** (National Institute of Diabetes and Digestive and Kidney Diseases)
    "Inhibiting enzymatic activities or deleting SET domains destabilizes MLL3/MLL4 proteins and prevents enhancer activation in cell differentiation"

*Based on the result of voting for the best talk (4:15-4:30 PM), Johng S. Rhim Young Investigator Awards will be given to top two speakers, NIH-KSA President Award for the third and fourth, and Excellent Research Award for all other participated speakers.

Abstracts

Session 1

[Keynote Speaker]

Therapeutic strategies aimed at achieving sustained virologic remission in HIV infection

Tae-Wook Chun, PhD, NIAID

Antiretroviral therapy (ART) suppresses plasma viremia to below the limit of detection in the vast majority of human immunodeficiency virus (HIV)-infected individuals. Consequently, the clinical outcome for HIV-infected individuals on ART is significantly improved. However, it has not been possible to eradicate HIV by ART alone, likely due in part to the persistence of various viral reservoirs in lymphoid tissues. In this regard, the existence of latently infected, resting CD4+ T cells carrying replication-competent HIV has posed one of the major challenges to the long-term control or eradication of HIV in infected individuals on ART. In addition, recent data have suggested that ongoing/residual HIV replication may persist in aviremic infected individuals receiving ART. In the past few years, major research efforts have been dedicated to a better understanding of the pathogenesis of persistent HIV infection and to the development of therapeutic strategies aimed at eradicating virus in infected individuals receiving. Historic and recent data from our laboratory on potential mechanisms of HIV persistence and prospects for eradication and new therapeutic approaches in HIV-infected individuals receiving effective ART will be discussed.

[Short Talk Speakers]

Functional and Spatial Heterogeneity of Colon Macrophages

Byung Hyun Kang, PhD, NIAID

Intestinal macrophages are essential to maintain immune homeostasis in the gut. Intestinal macrophages have a relatively high turnover rate, and are constantly replenished by blood-born Ly6hi monocytes whereas other tissue resident macrophages in steady-state are known to be derived from embryonic precursors. Previous reports form our lab and others indicate that intestinal macrophages are heterogeneous populations, however the extent of this heterogeneity has not been defined, in particular with regard to the functions and localization of these cells in the intestinal tissue. Furthermore, how these heterogeneous cell populations may communicate with each other or with other cells to maintain the

tissue homeostasis have not been addressed. Here, we performed droplet-based single cell mRNA sequencing (Drop-seq) on CD45+lineage(TCRgd/TCRab/CD19)-MHCIIhi cells isolated by flow cytometry from the colons of wild-type mice in the steady-state, which includes known macrophage and dendritic cells. Analysis of single cell transcriptomics identified multiple discrete colon macrophage populations, with predicted functional specialization, and revealed potential developmental relationships between these cell populations. Furthermore, by combining these data with in situ immunofluorescence staining of tissue sections for surface markers associated with particular macrophages populations, we are evaluating the relationship between differential localization and functionality of these heterogeneous populations.

Plasmodium vivax transmission and vector immune evasion: the role of Pvs47

Caeul Lim, PhD, NIAID

Understanding how the malaria parasite Plasmodium circumvents the immune system of Anopheles vector is essential to reduce disease transmission. The surface protein Ps47 mediates Plasmodium falciparum evasion of the Anopheles gambiae complement-like immune system. This allows the parasite to be successfully transmitted to humans. Previous studies in our group has demonstrated the potential of Pfs47 as a vaccine candidate, as antibodies against the protein shows strong and reproducible transmission blocking activity.

In this current study, we aim to extend these finding to another major human malaria parasite, Plasmodium vivax. Previous data from field studies shows a correlation between specific anopheles species and Pvs47 sequences. Unlike P. falciparum, however, studies with P. vivax are limited due to the lack of a robust in vitro system. To circumvent this issue, we use the existing tools of P. falciparum to directly test the role of Pvs47 in evading the mosquitoes' immune system. We also explore the use of Plasmodium knowlesi as a potential model system for P. vivax. P. knowlesi is primarily a primate malaria species and has historically been used to as a model for P. vivax due to their relative close phylogenetic relationship. We take advantage of the recent advances made in transmission studies using P. knowlesi here at the NIH, and we are currently trying to improve upon it to establish a reliably gametocyte-producing line.

Discovery of potent and selective A3 adenosine receptor agonists; N6-Substituted 5′-N-methylcarbamoyl-4′-selenoadenosines

Jinha Yu, PhD, NIDDK

G-protein coupled receptor (GPCR), which also known as 7 transmembrane helical (7TM) receptors, is the largest family of cell surface receptor, over 800 members encoded by the human genes. Drug

discovery in GPCR-family have been fruitful; between one-third and one-half of the marked drugs are GPCR-related drugs.

Adenosine receptors (ARs), consisting of four subtypes (A1, A2A, A2B, and A3), are a class of GPCR-family. Among these subtypes, A3 adenosine receptor (=A3 AR) is a promising target for inflammatory disease and cancer. Numerous A3 AR agonists and antagonists have been developed as novel therapeutics for many diseases; 2-chloro-N6-(3-iodobenzyl)-5′-N-methylcarbamoyladenosine (Cl-IB-MECA, Ki = 1.4 nM for human A3 AR) is in phase II clinical trial for hepatocellular carcinoma and is projected to enter a clinical trial for nonalcoholic steatohepatitis.

Based on the potent A3 AR agonist Cl-IB-MECA, novel N6-substituted 5′-N-methylcarbamoyl-4′-selenoadenosines, comprising selenium at C-4' were designed, synthesized, and evaluated for adenosine receptors binding affinities. Among the compounds tested, N6-3-iodobenzyl analogue showed the most potency (Ki = 0.57 nM) and high selectivity for A3 AR (≥800- and 1900-fold selective for A1 AR and A2A AR, respectively). This analogue inhibited chemoattractant-induced migration of microglia/monocytes without inducing cell death at ≤50 μM. These results demonstrate that the potential for the development of 4′-selenonucleoside A3 AR agonists as novel antistroke agents as well as inflammatory disease.

Effects of intravenous ketamine infusion on fear memory and brain glucose utilization (18F-FDG PET) in Sprague-Dawley rats

Kwang H. Choi, PhD, Uniformed Services University of the Health Sciences

Rationale: First responders and clinicians administer intravenous ketamine, a multimodal dissociative anesthetic, in the aftermath of traumatic injury to provide sedation and analgesia for trauma victims. However, the impacts of post-trauma administration of ketamine on brain function and stressful memory are controversial.

Objective: We investigated the effects of sub-anesthetic intravenous ketamine infusion (2 hr) on fear memory and in vivo brain glucose metabolism (BGluM) in rats.

Methods: Male Sprague-Dawley rats received a single ketamine infusion either immediately after auditory fear conditioning (0, 1, 5, and 10 mg/kg/h) or 1 day after fear conditioning (0, 5 mg/kg/h). Fear memory retrieval, extinction, and recall were measured at post-ketamine day 2, 3, and 4. Effects of intravenous ketamine infusion (0, 5 mg/kg/h) on BGluM were measured using 18F-fluoro-deoxyglucose positron emission tomography (FDG-PET) and computed tomography (CT).

Results: Ketamine infusion given immediately after fear conditioning dose dependently enhanced fear memory retrieval, delayed fear extinction, and enhanced fear recall in rats. The medium dose given 1 day after fear conditioning had the same effects on fear retrieval, extinction, and recall. Ketamine infusion also increased BGluM in the hippocampus, amygdala, and hypothalamus as compared to those of the saline infusion group.

Conclusions: These results suggest that intravenous ketamine infusion following stressful event may enhance aversive memory consolidation and delay fear extinction via activation of the fear memory circuits such as the amygdala, hippocampus, and hypothalamus.

Session 2

[Keynote Speaker]

Advanced glycation end-products made by activated macrophages: a common contributor to inflammation and degenerative diseases

Bonghee Lee, DVM, PhD, Gachon University Medical School, Korea

Advanced glycation end-products (AGEs) and their receptor (RAGE) have been implicated in the progression of many intractable diseases, such as diabetes and atherosclerosis. They are also critical for pathologic changes in chronic degenerative diseases, such as Alzheimer's disease, Parkinson's disease, and alcoholic brain damage. Recently activated macrophages were found to be a source of AGEs and the most abundant form of AGEs, AGE-albumin produced by macrophages, has been implicated in many chronic diseases and believed to act through common pathways. Inhibition of AGEs has been shown to prevent the pathogenesis of AGE-associated diseases in humans and experimental models, and therapeutic advances have resulted in the discovery of several agents that prevent the adverse effects of AGEs and disease states. A few anti-inflammatory molecules that inhibit AGE synthesis or secretion have been shown to be good candidates for ameliorating diabetic complications as well as degenerative diseases. I will briefly talk about the current understanding of AGE production by activated macrophages, its pathological role in different disease states, and therapeutic and/or diagnostic strategy related to the inhibition of the receptor to AGEs and various models of human diseases.

[Short Talk Speakers]

Dairy food intake and reproductive function among premenopausal women: BioCycle Study

Keewan Kim, PhD, NICHD

Background: Dairy food intake has been associated with infertility; however, little is known regarding associations with reproductive hormones or anovulation.

Objective: We investigated whether dairy foods and nutrients were associated with reproductive hormones across the menstrual cycle and anovulation.

Methods: We measured serum reproductive hormones 8 times per cycle for 2 cycles from 259 regularly menstruating women. Dairy food intake was assessed 4 times per cycle via 24-hour dietary recall, including categories of 1) total, low- and high-fat dairy products, 2) dairy nutrients (fat, lactose, calcium, phosphorus), and 3) dairy foods (milk, cheese, butter, cream, yogurt, ice cream). Weighted linear mixed models were used to evaluate associations between dairy food intakes and hormone levels, and modified Poisson regression models to evaluate anovulation. Models adjusted for age, BMI, race, physical activity, Mediterranean diet score, total energy, protein, fiber, caffeine, and other hormones.

Results: Every serving increase in total, low- and high-fat dairy foods and in amount of all dairy nutrients tested was associated with an approximate 5% reduction in estradiol, but not associated with anovulation. Total and high-fat dairy foods were positively associated with luteinizing hormone. Yogurt (risk ratio [RR]: 2.1; 95% confidence interval [CI]: 1.2, 3.7) and cream (RR: 1.8; 95% CI: 1.0, 3.2) intakes >0 servings were associated with a higher risk of anovulation.

Conclusions: Our study demonstrated associations between dairy food intakes and lower estradiol, and between cream and yogurt intakes and anovulation. These results highlight the potential role of dairy in reproductive function in healthy women.

Molecular mechanisms of gut leakiness and inflammatory liver injury caused by binge alcohol or fructose drinking

Young-Eun Cho, PhD, NIAAA

Background: Increased endotoxemia through leaky gut is a leading cause of multiple organ failure (sepsis) and death in rodents and humans. However, the underlying mechanisms of gut leakiness and organ damage caused by binge alcohol or many other substances including fructose (contained in many soft drinks) and high fat diets are poorly understood. We hypothesized that ethanol-inducible cytochrome P450-2E1 (CYP2E1) plays an important role in alcohol-mediated gut leakiness, endotoxemia and inflammatory tissue injury through increased oxidative/nitrative (nitroxidative) stress. We also hypothesized that decreased tight junction (TJ) proteins and increased apoptosis of enterocytes contribute to elevated gut leakiness, endotoxemia and liver damage. Therefore, this study was aimed at investigating the role of CYP2E1 and alterations of gut junctional complex proteins in promoting alcohol or fructose-induced gut leakiness, systemic endotoxemia and liver damage. **Methods**: The levels of ileum junctional

complex proteins, oxidative stress markers and apoptosis-related proteins in rodents, T84 colonic cells and autopsied human ileums who died from heavy alcohol intoxication and their respective controls were determined by immunoblot, immunoprecipitation, immunofluorescence, and mass-spectral analyses. **Results**: Binge alcohol or fructose exposure caused apoptosis of gut enterocytes with elevated serum endotoxin and liver inflammation or fibrosis. The levels of intestinal CYP2E1, iNOS, nitrated proteins and apoptosis-related marker proteins were significantly elevated in binge alcohol- or fructose-exposed rodents compared to controls. Differential mass-spectral analyses of the TJ-enriched fractions of intestinal epithelial layers revealed that several TJ, adherent junction (AJ) and desmosome proteins were markedly decreased in binge alcohol-exposed rats. Consistently, the levels of TJ proteins (claudin-1, claudin-4, occludin and ZO-1), AJ proteins (β-catenin and E-cadherin) and desmosome plakoglobin were very low in binge alcohol or fructose-exposed rats, wild-type mice, and autopsied alcoholic human ileums but not in Cyp2e1-null mice. Additionally, pretreatment with specific inhibitors of CYP2E1 and iNOS prevented disorganization and/or degradation of TJ proteins in alcohol-exposed T84 colon cells. Furthermore, immunoprecipitation followed by immunoblot confirmed that intestinal TJ and AJ proteins were nitrated and degraded via ubiquitin-dependent proteolysis, resulting in their decreased levels. **Conclusion**: These mechanistic results for the first time demonstrate the critical role of CYP2E1 and nitration of intestinal junctional complex proteins in binge alcohol or fructose-induced gut leakiness and endotoxemia, contributing to hepatic inflammation and/or fibrosis. Furthermore, these results can explain the underlying mechanisms of numerous reports of gut leakiness with decreased TJ proteins in the past.

The Replication-initiation determinant protein (RepID) modulates replication by recruiting CUL4 ubiquitin E3 ligase to chromatin

Sang-Min Jang, PhD, NCI

The DDB1-CUL4-RBX1 (CRL4) E3 ubiquitin ligase complex targets a wide range of key substrates involved in various cellular pathways, including cell-cycle progression, signal transduction, DNA repair and maintenance of genomic integrity and tumour suppression. CRL4 complexes bind numerous DDB1 and CUL4-associated factors (DCAFs) that have been identified as substrate receptors for the ubiquitin ligase activity. We studied the role of a DCAF, RepID (DCAF14/PH interacting protein [PHIP]), which was previously shown to bind a group of DNA replication origins, in chromatin assembly of the CRL4 complex. We found that RepID was crucial for recruiting CUL4A/B to chromatin through an interaction is mediated by RepID's WD40 domain. Depletion of RepID prevented CUL4A/B association with chromatin, causing CRL4 substrates to accumulate and facilitating G2/M arrest, reduced G1/S transition and induction of re-replication. These changes reduced the sensitivity of the cells to the neddylation inhibitor MLN4924 (pevonedistat). The effects of RepID depletion were partially alleviated by an alternative ubiquiting complex called SKP1-CUL1-F-box (SCF), which utilizes the F-box protein SKP2 as a substrate receptor, compensated for the absence of CRL4 on late replication origins in RepID-deficient cells and allowed completion of the cell cycle. SKP2 associated with a group of replication

origin that was distinct from the origins associated with RepID. In accordance, RepID-deficient cells were markedly more sensitive to SKP2 inhibitors. Together, our results imply that two ubiquitin ligase complexes (CRL4 and SCF) differentially bind to two distinct groups of replication origins to modulate the progression of DNA replication.

Session 3

[Keynote Speaker]

Novel fluorescent dyes for real-time, intraoperative, organ-specific visualization in vivo

Jaepyeong Cha, PhD, George Washington University

Accurate, real-time visualization is critical for efficient, effective and safe surgery. Although optical imaging using near-infrared (NIR) fluorescence has been used for visualization of anatomic structures and physiologic functions in open and minimally invasive surgeries, its efficacy and adoption remain suboptimal due to the lack of specificity and sensitivity. Herein, we report a novel class of compounds, which are exclusively metabolized in liver or kidney, rapidly excreted into to biliary or urinary systems, and emitted NIR fluorescence spectrums. These new compounds have significantly higher quantum yields and higher specificity to visualize kidney and/or liver than any currently available reagents.

[Short Talk Speakers]

Anomalous ultra-fast energy transfer suggests coherent energy transfer between fluorescent proteins

Youngchan Kim, PhD, NIAAA

Fluorescent proteins (FPs) have revolutionized biomedical research by enabling genetic protein tagging and the visualization of cellular interactions in living cells. Two typical assumptions for these experiments using FPs are that FPs act independently (i.e. very weak coupling) and that they behave like classical organic fluorophores. When conventional fluorophores are in close-proximity (< 1 nm) and/or are cooled to temperatures approaching absolute zero, stronger coupling is possible. Under these conditions coherent energy transfer (CET) may enable multiple fluorophores to behave as a single quantum entity. CET is thought to play a key role in photosynthesis, and vis-à-vis technology, may enable quantum computing. CET manifests as ultra-fast long-distance energy transfer within fluorophore assemblies. Antibunching, a uniquely quantum mechanical behavior, is consistent with CET. Physiological temperatures extinguish CET by promoting rapid collisional dephasing of fluorophore vibrational modes. Moreover, because FP

fluorophores are encased in a ß-barrel structure, proximities closer than 2 nm are not possible. Thus, CET between FPs at physiological temperatures is thought to be impossible. Nonetheless, using two-photon excitation and time-correlated single photon counting we have observed both anomalous ultra-fast energy transfer and strong antibunching behaviors in FP assemblies composed of mVenus, mClover, or mNeonGreen. Our experiments suggest stronger than expected coupling between FPs. Thus, we speculate that CET between FPs at physiological temperature may be possible.

Human and nonhuman primate meninges harbor lymphatic vessels that can be visualized noninvasively by MRI

Seung-Kwon Ha, DVM, PhD, NINDS

Here, we report the existence of meningeal lymphatic vessels in human and nonhuman primates (common marmoset monkeys) and the feasibility of noninvasively imaging and mapping them in vivo with high-resolution, clinical MRI. On T2-FLAIR and T1-weighted black-blood imaging, lymphatic vessels enhance with gadobutrol, a gadolinium-based contrast agent with high propensity to extravasate across a permeable capillary endothelial barrier, but not with gadofosveset, a blood-pool contrast agent. The topography of these vessels, running alongside dural venous sinuses, recapitulates the meningeal lymphatic system of rodents. In primates, meningeal lymphatics display a typical panel of lymphatic endothelial markers by immunohistochemistry. This discovery holds promise for better understanding the normal physiology of lymphatic drainage from the central nervous system and potential aberrations in neurological diseases.

A mathematical model predicts future diabetes

Joon Ha, PhD, NIDDK

We have developed a new algorithm to fit our previously published mathematical model (Ha. et al., Endocrinology, 2016) to Oral Glucose Tolerance Test data. The mathematical model was originally designed for understanding underlying mechanisms of progression to diabetes. The current fitting algorithm has been developed to estimate major metabolic parameters, peripheral and hepatic insulin sensitivity and beta-cell function. Insulin sensitivity estimated by the fitting model has shown a good correlation with insulin sensitivity measured by insulin clamp and MINMOD, R2=0.5. The model can be used to fit two longitudinal OGTT data to predict a future glycemic status.

Session 4

[Keynote Speaker]

RARRES1 Links CCP2-Mediated Tubulin Deglutamylation to VDAC Regulation, Metabolic Reprogramming and Cell Survival

Mi-Hye Lee, PhD, Georgetown University

RARRES1, a retinoic acid regulated carboxypeptidase inhibitor associated with stem cell differentiation and tumorigenesis is among the most commonly methylated loci in multiple cancers but has no known function. Here we show that RARRES1 interaction with cytoplasmic carboxypeptidase 2 (CCP2) inhibits tubulin deglutamylation, which in turn inhibits the mitochondrial voltage dependent anion channel (VDAC) to regulate expression of stem cell markers, anoikis, anchorage independent growth and sensitivity to multiple apoptotic stimuli. Depletion of RARRES1 alters mitochondrial membrane potential, AMPK activation, energy balance, and metabolically reprograms cells to a more energetic and anabolic phenotype in which both glycolytic and mitochondrial capacities are increased. RARRES1 localizes to sites of neural and hematopoietic stem cell differentiation and manipulation of zebrafish RARRES1 or CCP2 results in reciprocal changes in the expression of glycolysis genes. We conclude that RARRES1 modulation of tubulin/mitochondria interactions is a fundamental regulator of cancer and stem cell metabolism and survival.

[Short Talk Speakers]

Assessment of cytokine-sensing mammary super-enhancers within a complex locus using CRISPR/Cas9 genome editing and ‘base editing’ in mice

Hye Kyung Lee, PhD, NIDDK

Super-enhancers have been suggested to control lineage-specific genetic programs. There is little known about whether super-enhancers within complex loci can communicate with each other. We addressed this question in a 400kb locus that is composed of six mammary-specific genes highly activated by the cytokine prolactin, two silent genes, and one broadly expressed gene. Within this region we have identified 22 putative enhancers that are characterized by the binding of the cytokine-sensing transcription factor STAT5 and the presence of activating (H3K27ac) histone marks. We have also identified a putatively primordial super-enhancer spanning four constituent enhancers within the locus. We have deleted these enhancers individually and in various combinations in the mouse genome. Initial analyses demonstrated that this super-enhancer controls expression of the entire locus. We have addressed the significance of the super-enhancer on the regulation of this locus. Deletion of individual enhancers from the super-enhancer had debilitating consequences on three out of the nine genes within the locus.

Specifically, one enhancer within the super-enhancer was responsible for activating a subset of the 22 enhancers in the locus. This is the first study to demonstrate that a super-enhancer communicates with, and activates, specific cytokine-sensing enhancers.

GTF2I mutation lead to thymic epithelial tumor through induction of oncogenes and cell transformation

In Gyu Kim, PhD, Georgetown University

TF2I is a multifunctional protein associated with the transcriptional regulation of several genes that control cell proliferation, cell cycle, angiogenesis, cellular stress response, and development through sequence-specific DNA binding. Despite the many functions of TF2I, alterations of GTF2I in tumors have not been reported with substantial experimental evidence before. Recently, we identified a unique somatic mutation in GTF2I with high frequency in indolent thymomas. There are currently at least five known splice variants of GTF2I in the human genome, and we detected β and δ isoform of TF2I were expressed in thymic epithelial tumor cells (TETs) [Nat Genet. 2014 Aug;46(8):844-9]. I have been trying to define the molecular process underlying the development of TETs through functional characterization of GTF2I mutation in normal mouse thymic epithelial cells using knock-in mediated by CRISPR/Cas9n and doxycycline-inducible system. I found that mutation of GTF2I leads to oncogenic transcriptome networks, and induces EMT-like cell transformation in mouse normal thymic epithelial cell.

GR, KLF4 and Krox20 are dispensable for adipogenesis

Young-Kwon Park, PhD, NIDDK

Much of our knowledge on adipogenesis comes from cell culture models of preadipocyte differentiation. Adipogenesis is induced by treating confluent preadipocytes with the adipogenic cocktail, which activates transcription factors (TFs) glucocorticoid receptor (GR) and CREB within minutes and increases expression of TFs C/EBP, C/EBP, KLF4 and Krox20 within hours. However, it has remained unclear whether endogenous GR, KLF4 and Krox20 are required for adipogenesis in culture and in vivo. By deleting GR in precursors of brown adipocytes, we found unexpectedly that GR is dispensable for brown adipose tissue (BAT) development in mice. In culture, GR-deficient preadipocytes showed severely delayed adipogenesis at one week after induction of differentiation. However, when differentiation was extended to 3 weeks, GR-deficient preadipocytes showed similar levels of adipogenesis marker expression and lipid accumulation as the wild type cells, indicating that GR accelerates, but is dispensable for, adipogenesis. Mechanistically, GR recruits histone H3K27 acetyltransferase CBP to promote activation of C/EBP-primed enhancers of adipogenic genes. Using conditional knockout mice and derived

preadipocytes, we also show that endogenous KLF4 and Krox20 are dispensable for adipogenesis in culture and BAT development in mice. In contrast, the master adipogenic TF PPAR is essential. Together, these results challenge the existing model on transcriptional regulation in the early phase of adipogenesis and highlight the need of studying adipogenesis in vivo.

Inhibiting enzymatic activities or deleting SET domains destabilizes MLL3/MLL4 proteins and prevents enhancer activation in cell differentiation

Younghoon Jang, PhD, NIDDK

Transcriptional enhancers play a key role in cell type-specific gene expression and cell fate transition. Enhancers are marked by histone H3K4 mono- and di-methylation (H3K4me1/2). The tumor suppressor MLL4 (KMT2D) is a major enhancer H3K4 mono- and di-methyltransferase with a partial functional redundancy with MLL3 (KMT2C). However, the functional role of MLL4 enzymatic activity remains elusive. To address this issue, we have generated MLL4 enzyme-dead knock-in (KI) embryonic stem (ES) cells and mice, which carry Y5477A/Y5523A/Y5563A mutations in the enzymatic SET domain of the MLL4 protein. Homozygous MLL4 enzyme-dead KI (Mll4KI/KI) mice are embryonic lethal and die around E10.5, which pheno-copies Mll4 knockout (KO) mice. Interestingly, enzyme-dead MLL4 protein in ES cells is highly unstable. Like Mll4 KO ES cells, Mll4KI/KI ES cells show reduced levels of H3K4me1/2. Further, we show that ectopic expression of histone H3.3 lysine 4 to methionine (K4M) mutant, which reduces endogenous H3K4 methylation levels in ES cells, decreases protein stability of MLL3 and MLL4 but not that of H3K4 methyltransferases SET1A (KMT2F) and SET1B (KMT2G). Taken together, our findings indicate that MLL4 protein stability is tightly regulated by its H3K4 methyltransferase activity.

Special Session

NIH Funding Opportunities for Career Development Awards and Other Research Grants

Minkyung Song, PhD, NCI

The National Institutes of Health (NIH) conduct, promote, and support biomedical and behavioral research to improve human health. Over 80% of the NIH budget is used to fund projects carried out by the extramural research community. During this presentation, information will be provided and discussed on: NIH extramural research funding mechanisms; Funding Opportunity Announcements and Notices; Career Development Awards for the NIH intramural investigators; Widely-used NIH research grant mechanisms;

NIH grant application, peer review, and award process; Roles and responsibilities of Scientific Review Officers and Program Officers; Advice on preparing grant applications; Problem areas in biomedical research grant applications; and Useful web links to the NIH Office of Extramural Research.

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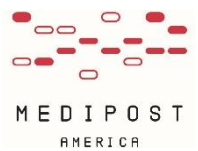
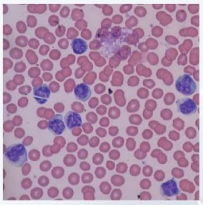


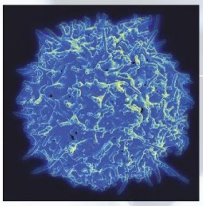
NeoImmuneTech

Developing next generation immunotherapy by reconstituting T cell system for cancer patients



LYMPHOCYTES

- **NeoImmuneTech, Inc. (NIT)** is a clinical-stage private biotech company primarily focused on development of T cell growth factor, **Interleukin-7-hyFc (IL-7-hyFc)**.
- IL-7-hyFc is an optimal partner for reinvigoration of T cell immunity to overcome challenges in cancer immunotherapy



T CELL

- The recent publications in immune-oncology field indicate that cancer patients with lower absolute numbers & higher numbers of non-functioning (exhausted) T cells exhibit shorter survival and low response rate to chemo/radiotherapy or immunotherapy.
- IL-7-hyFc is a non-redundant T cell growth factor and immunotherapeutics with a targeted potential to substantially improve the clinical response and survival in patients with cancers.

IL-7-hyFc

- Currently, there is no standard treatment for reconstituting T cell system, and NIT intends to introduce a first-in-class drug to this new market.

NeoImmuneTech

NeoImmuneTech is honored to sponsor the Korea-US Cooperative Conference for Life Science!

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