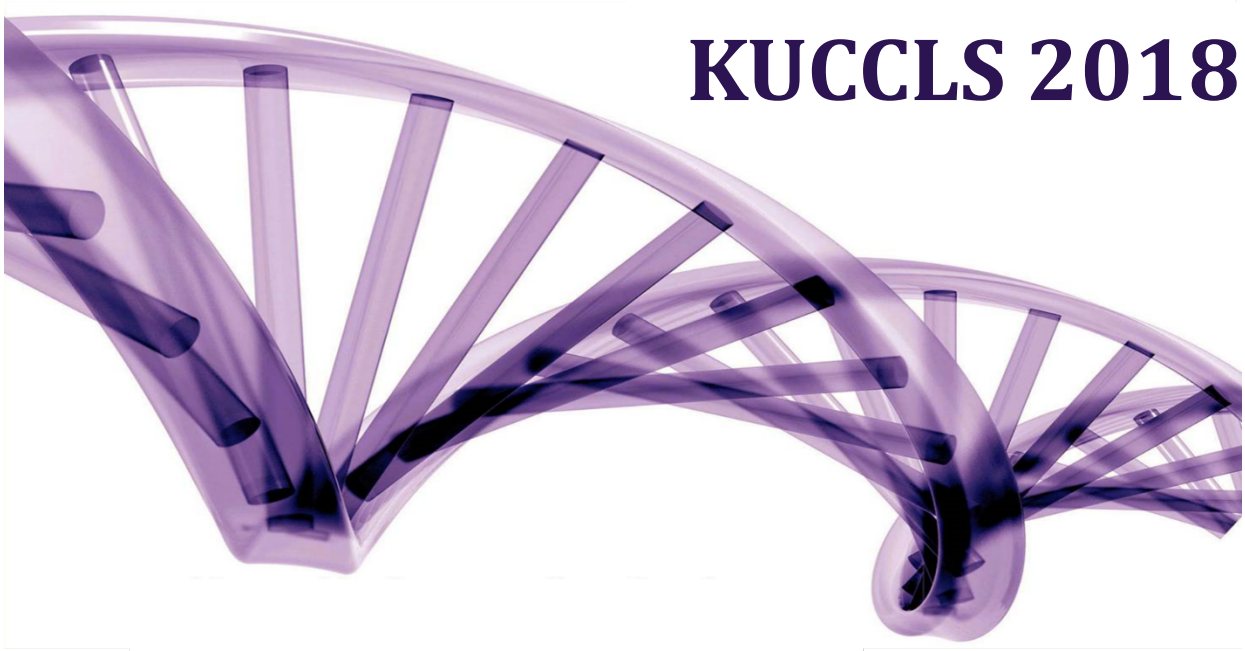
4th Korea-US Cooperative Conference for Life Science 2018

November 1 - 3, 2018

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



KUCCLS 2018

Collaboration and Innovation in Biosciences

Organized by

KAPAL
Korean-American Professional Association in Life Sciences

Hosted by

Embassy of the Republic of Korea in the USA

CHUNGCHEONGBUK-DO

KHIDI
Korea Health Industry Development Institute

beyond leading technology KIAT
Korea Institute for Advancement of Technology

Osong raises our hopes in the pursuit of the dream of
being a global biomedical center

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

Bio Pharmaceuticals 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

Welcome message

Dear Participants,

On behalf of the organizing committee, it is my great pleasure to welcome you to the 4th Annual Korea – US Cooperative Conference for Life Science (KUCCLS) 2018. Since the inaugural conference in 2015, the KUCCLS has grown steadily in connecting professionals in bioscience and cultivating a collaboration of Korean and American bioscience industries. We are very excited to see the Annual KUCCLS becoming a platform to promote innovation and advancement among Korea and American bio-companies, institutes, and scientists. Many experts including strategists, lawyers, investors are invited to the KUCCLS as a success of biopharmaceuticals depends on a multi-collaboration of key disciplines. The KUCCLS provides a broad perspective of biopharmaceutical innovation and addresses critical topics of the current bioscience.

The 4th KUCCLS will provide a unique opportunity for all participants to get connected and to share innovative ideas in bioscience and pharmaceuticals for a potential collaboration. We encourage all participants broadening their professional network and engaging dialogues during the conference. This year's KUCCLS offers a special regulatory session with FDA speakers, which will give the essential updated regulatory process for development of new therapeutics for unmet medical needs. Scientists and delegates from bio-companies will entertain pre-scheduled private business-to-business meetings during the conference. I anticipate many positive outcomes continue to move forward after the 4th KUCCLS as we have witnessed during the past few years.

The 4th annual KUCCLS is aligned with the NIH-Korean Scientists Association which has organized the 10th Annual Bioscience and Engineering Symposium (ABES). The 10th ABES will be held on November 3, 2018 at the same location. These two back-to-back events will provide a synergy between fundamental bioscience and applied biopharmaceutical R&D.

The 4th annual KUCCLS would have not been possible without the generous sponsorships from companies and institutes. We recognize the important contributions from multiple organizations including Chungcheongbuk-do and Embassy of the Republic of Korea. Lastly, we thank all speakers, organizing members, and participants and look forward to having a successful 4th Annual KUCCLS and 10th ABES.

Luke Yun Suk Oh, Ph.D.

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

KUCCLS+ABES 2018 Program

Program Chair: **JK Song, Ph.D.**

Thursday, November 1

5:00 – 6:00 pm — Registration & Networking

6:00 – 6:30 pm — **Opening Remarks**

Luke Oh, President of Korean-American Professional Association in Life Sciences
Cho, Yoon-je, Ambassador of the Republic of Korea
Benjamin Wu, Deputy Secretary, Maryland Department of Commerce
Myung Hee Park, President of NIH-Korean Scientist Association




6:30 – 6:35 pm — **Group photo**

6:35 – 7:40 pm — Dinner hosted by the Minister of the Korean Embassy

7:40 – 8:00 pm — **Hosting sponsor presentation**
Osong, the Best Bio-Cluster in Korea
Maeng Eun-young (Director, Chungcheongbuk-do)

8:00 – 9:10 pm — **Keynote presentation I & II**

Samsung Bioepis – Quo vadis? Past – Present – Future
Dr. Sang Jin Pak (COO, Samsung Bioepis)

Adoptive Cell Therapy 'Immuncell-LC'
Dr. Duckjoo Lee (CEO, Green Cross Cell)

9:10 – 10:30 pm — Networking & End of Day 1

Friday, November 2

8:00 – 8:50 am	Breakfast
8:50 – 10:20 am	**Session I: Emerging Korean Bio-innovation** ***Moderated by Dr. Byung Ha Lee*** ***Bestian Medi-Cluster*** Jae Hyuck Yang (Head of Dept., Bestian Hospital) ***Drug Development at Aribio*** Dr. Jai Jun Choung (Chairman, AriBio) ***Companion Diagnosis by using Multiplex IHC*** Dr. Dong-Jun Bae (CEO, BIOPRISM) ***Multifunctional In-vitro diagnostic device (IVD)*** Dr. Sang Yoon Lee (CEO, INTEK-PLUS) ***Radiolabeling in Drug Discovery and Development*** Sook Jung Shin (CEO, Curachem) ***CRISPR/Cas genome-editing technologies in G+FLAS*** Dr. Sunghwa Choe (CEO, G+FLAS Life Sciences)
10:20 – 10:30 am	Coffee Break
10:30 – 12:00 pm	**Session II: Legal & Investment strategy** ***Moderated by Mr. Bumrae Cho*** ***Legal Trends and Developing Topics in the Life Sciences Industry*** Adrian Mollo, Esq. (Partner, Dentons US LLP) ***Fundraising Considerations for Earlier Stage Life Sciences Companies*** Woojin Choi (Exe. Director, Nomura Securities International) ***Patent Right considerations in Licensing Transaction*** Sunhee Lee, Esq. (Partner, Sughrue Mion, PLLC)
12:00 – 1:00 pm	Lunch

1:00 – 2:10 pm

Keynote presentation III & IV

Stimulation of Immune Cells in the Tumor Microenvironment via Bispecific DART® and TRIDENT™ Molecules
Dr. Gundo Diedrich (Director, MacroGenics)

Leveraging expert guidance to scale drug development demands
Dr. Brian D. Furmanski (Senior Director, Nuventra Pharma Sciences)

2:10 – 2:30 pm

Coffee Break

2:30 – 4:45 pm

Special FDA Session: Early Stage Drug Development

Moderated by Dr. Hae-Young Ahn

CMC Regulatory Considerations for the Product Development Process
Dr. Sydney Choi (FDA)

Nonclinical studies of small molecules in the initial IND submission
Dr. Grace S. Lee (FDA)

Application of Clinical Pharmacokinetics and Pharmacodynamics in Drug Development
Dr. Seong Hoon Jang (FDA)

4:45 – 5:00 pm

Late-breaking presentation

Clonal Mesenchymal Stem Cells for the Treatment of Immune Diseases
Dr. Sun U. Song (CSO, SCM Lifescience)

5:00 – 6:00 pm

Session III: Strategic Approach: from Bench to Market

Moderated by Dr. JK Song

Preclinical Drug Development: From Inception to Prescription
Dr. Elise Lewis (Director, Charles River Laboratories)

Pathways to Commercialization
Ms. Maria Brazda (CEO, Panthera Global Solutions)

6:00 – 7:30 pm

Dinner

7:30 – 9:00 pm	**After-hour Round Table Discussion** 'Strategic approach' moderated by Ms. Maria Brazda 'Legal' moderated by Mr. Bumrae Cho 'Investment' moderated by Dr. Byung Ha Lee 'Regulatory' moderated by Dr. Hae-Young Ahn
9:00 pm	End of Day 2

Saturday, November 3

8:00 – 9:00 am	**Annual Bioscience and Engineering Symposium (ABES)** *Registration and Breakfast*	
9:00 – 9:10 am	**Opening Remarks** Dr. Myung Hee Park, NIH-KSA President	
9:10 – 9:50 am	**Keynote Lecture I** *Chair: Dr. Byoung-Joon Song (NIAAA)* ***Reactive oxygen species as the cause of eustress and distress*** Dr. Sue Goo Rhee (NHLBI)	
9:50 – 10:50 am	**Session 1** *Chair: Dr. Youngchan Kim (NIAAA)* 4 speakers (each 12 min + 3 min Q&A)	**K-Tag group meeting** *Chair: Pom Jin Lee (KIAT)*
10:50 – 11:00 am	Coffee Break	
11:00 – 12:00 pm	**Session 2** *Chair: Dr. Ji-Hoon Park (NHLBI)* 4 speakers (each 12 min + 3 min Q&A)	**K-Tag subgroup meeting** *Chair: Pom Jin Lee (KIAT)*
12:00 – 12:10 pm	**Group photo**	
12:10 – 1:00 pm	Lunch & Job Opening Announcement ***SCM Lifescience*** ***G+FLAS Life Sciences***	

1:00 – 1:40 pm	**Keynote Lecture II** *Chair: Dr. Hee-Yong Kim (NIAAA)* ***Cosmic journey*** Dr. Eun-Suk Seo (Univ. of Maryland)
1:40 – 2:40 pm	**Session 3** *Chair: Dr. Juhyung Lee (NIDDK)* 4 speakers (each 12 min + 3 min Q&A)
2:40 – 2:50 pm	Coffee Break
	Career Development Session
2:50 – 3:20 pm	**Keynote Speech** *Chair: Dr. Myung Hee Park (NIDCR)* ***What I have learned as professor and scientist*** Dr. Carl Hashimoto (OD, NIH)
3:20 – 4:20 pm	**Job Talks** **Dr. Seong Jae Yoo**, United States Pharmacopeial Convention (USP) **Dr. Youngsuk Oh**, NHLBI/NIH, Extramural **Dr. Sang Tae Park**, Macrogen Corporation **Dr. Kay Kim,** US patent and Trademark Office (USPTO) **Dr. Eun Hee Lee**, Virginia Commonwealth University **Dr. Seong Hoon Jang**, Food and Drug Administration (FDA)
4:20 – 5:00 pm	**Panel Discussion and Q & A Session** *Chair: Dr. Kyung Sang Lee (NCI)*
5:00 – 5:15 pm	**Closing Remarks and Award Presentation** **Johng S. Rhim Young Investigator Award and KAPAL Best Presentation Awards**
5:15 – 5:30 pm	Job Interview as appointed
5:30 – 7:00 pm	Dinner at **HoneyOne BBQ (19743 Frederick Rd, Germantown, MD)**

SPEAKERS

Osong, the Best Bio-Cluster in Korea

Maeng Eun-young
Director of Bio Policy Division, Chungbuk-province

Maeng Eun-young is the head of the Chungbuk-province delegation and currently serves as director of the Bio policy division, Chungbuk-province.

She started a civil service in Chungbuk-province and went through the Ministry of Strategy and Finance in charge of the national budget. Currently, as director of Bio policy division in Chungbuk-province, she is trying to expand the biotechnology industry that the whole world is paying attention to as a future industry to province wide and is trying to realize the goal of "Chungbuk-province, the land of life".

Samsung Bioepis – Quo vadis? Past – Present – Future

Sang Jin Pak; M.D., M.Sc.
COO, Samsung Bioepis

Dr. Pak is a medical doctor with more than 20 years experience in healthcare and pharmaceuticals and extensive overseas experience across three continents. Previously he was the Senior Vice President & General Manager Pharma Germany for GlaxoSmithKline (GSK) for 5 years, based in Munich, Germany.

He also was the President at AstraZeneca Korea for 3 years and the Regional Sales- and Marketing Director for the Asia Pacific region, based in Singapore. Next to his roles at GSK and AstraZeneca, Dr. Pak was actively engaged as a board member in various industry associations, e.g. vfa (German Industry Association), LAWG (Local Area Working Group) and KRPIA (Korean Research-Based Pharmaceutical Industry Association).
Dr. Pak graduated from medical school at Johannes-Gutenberg University, Mainz, Germany and was awarded a doctorate degree in medicine thereafter. He worked as a resident physician before joining the pharmaceutical industry.

Adoptive Cell Therapy 'Immuncell-LC'

Duck-Joo Lee, M.D., M.MSc., M.P.H., Ph.D.
CEO, Green Cross Cell

Dr. Lee has extensive experiences in both academia and industry. He 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, he was 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 Ph.D. degree from Korea University School of Medicine, earned M.P.H. from University of Minnesota, and earned M.S. from Yonsei University Postgraduate School of Medicine.

Companion Diagnosis by using Multiplex IHC

Dong-Jun Bae; Ph.D.
CEO, BIOPRISM CO., Ltd

Dr. Bae received his Ph.D. degree in biochemistry and cell biology from Kyungpook National University School of Medicine and completed a postdoctoral fellowship training at Asan Medical Center, University of Ulsan College of Medicine.

Multifunctional In-vitro diagnostic device (IVD)

Sang Yoon Lee; Ph.D.
CEO, INTEK-PLUS

Dr. Lee has a strong background in mechanical engineering and robotics. His research interests include Semiconductor Back-end & Mid-end Inspection, OLED 2D/3D Inspection, and In Vitro Diagnostics Using Bio-photonics.

Dr. Lee joined INTEK-PLUS in 1999 as a research engineer and was CTO of the company. Prior to joining INTEK he has worked as a research scientist at Korea Institute of Science and Technology (KIST).
He received his B.S. and M.S. in Mechanical Design and Production Engineering from Seoul National University, and Ph.D. in Mechanical Engineering from Korea Advanced Institute of Science and Technology (KAIST).

Radiolabeling in Drug Discovery and Development

Juhee Park; Ph.D.
Principal Scientist, Curachem Inc.

Dr. Park has specialty in the development of radiolabeling technology on bioorganic molecules

Dr. Park has started his professional career in the radiolabeling industry at Curachem in Korea since 2012. He made significant contributions to the development of 14C & 3H radiolabeling technology on the different types of molecules ranging from simple small molecules to complex biomolecules (*e.g.* peptide, oligonucleotides, proteins, antibodies). He also served as a production team leader for the GMP 14C radiolabeling for human ADME (absorption, distribution, metabolism, and excretion) study.
He was a research fellow at Pohang University of Science and Technology prior to industry career.
Dr. Park obtained his Ph.D. degree in Nano-bioorganic chemistry and completed a postdoctoral fellowship training in Chemistry from University of Maryland at College Park.

CRISPR/Cas genome-editing technologies in G+FLAS

Sunghwa Choe; Ph.D.
CEO, G+FLAS Life Sciences

Dr. Choe has substantial research experience in molecular genetics and precision genome editing with CRISPR technology. He is professor in Seoul National University School of Biological Sciences.

As CEO of G+FLAS Life Sciences, a startup company spun off from Seoul National University, he raised the series A and series B funding from major investors including Korea Development Bank and Ost Investment, and has been commercializing biologics mAb from Glyco-engineered plants.
Dr. Choe was vice president of Advanced Institutes of Convergence Technology, where he led a convergence Research Center for Functional Plant Products, and successfully developed DNA-free genome editing technology in plants with pre-assembled CRISPR/Cas9 ribonucleoproteins.
He was visiting professor in Purdue University and University of Wisconsin.
Dr. Choe obtained his B.S. and M.S. in botany from Seoul National University, and Ph.D. degree in Plant Sciences and Genetics from University of Arizona.

Clonal Mesenchymal Stem Cells for the Treatment of Immune Diseases

Sun U. Song; Ph.D.
Founder & CSO, SCM Lifescience

Dr. Song has special expertise in stem cell research and stem cell-based therapeutic development in both academia and industry. He is professor in Inha University School of Medicine and a director of Translational Research Center at Inha University Hospital.

Dr. Song has been an editor of World Journal of Stem Cells. He started his professional career in the industry as CSO at HomeoTherapy.
He received his Ph.D. degree in molecular biology from Johns Hopkins University and completed a postdoctoral fellowship training at Harvard University.

Legal Trends and Developing Topics in the Life Sciences Industry

Adrian Mollo; Esq.
Partner, Dentons US LLP

Adrian Mollo is a corporate and intellectual property lawyer, whose career has included acting as Co-Chair of the Intellectual Property Department of an AM Law 100 law firm and as General Counsel of a publicly traded life sciences company that focuses on researching, developing, and marketing regenerative medicine products, with a focus on applications of mesenchymal stem cells.

While in-house, Adrian's experiences included providing legal counsel for the development and launch of new HCT/Ps and biologics, directing the licensing and sale of the company's intellectual property holdings, providing legal guidance for the company's nationwide sales force, assisting with management of OEM and distribution relationships, and day-to-day collaboration with the company's research and development team.

Life sciences companies are similar to many others, in that a life sciences company goes through a similar life cycle to that of other companies: formation, internal growth, securing an IP position, external partnerships, market assessment and entry. A distinguishing feature of the life sciences company, however, is the focus on scientific discovery and patient care. Having recently returned to private practice, Adrian's practice focuses on the special nature of life sciences companies, assisting with matters ranging from licensing technology from a university to aid in the client's scientific development, assessing trade secrets controls for joint venture operations, providing guidance concerning enforcement trends, and monitoring and counseling concerning the FDA's evolving position concerning digital health products.

Fundraising Considerations for Earlier Stage Life Sciences Companies

Woojin Choi
Executive Director, Healthcare Investment Banking, America

Woojin Choi is a member of Nomura's Healthcare Investment Banking team based in New York. He has over 12 years of investment banking experience where his current focus is on M&A, divestitures, equity and debt capital raising, private placements, and specialty financings in the healthcare industry.

Prior to joining Nomura in 2017, Mr. Choi worked at Morgan Stanley, Jefferies, and Goldman Sachs as part of investment banking coverage teams providing M&A, capital raising, and advisory services to clients in the healthcare and real estate sectors.

Mr. Choi holds a B.S. in Management and a minor in Mathematics from M.I.T.

Patent Right considerations in Licensing Transaction

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.

Stimulation of Immune Cells in the Tumor Microenvironment via Bispecific DART® and TRIDENT™ Molecules

Gundo Diedrich; Ph.D.
Director of Antibody Engineering, MacroGenics

Dr. Diedrich has special expertise in antibody engineering and the development of antibody-based molecules.

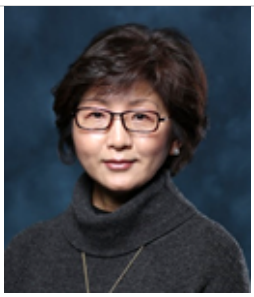
Dr. Diedrich previously worked as a Research Scientist in antibody discovery at Targeted Molecules, diaDexus, and Medimmune. In 2015, he joined MarcoGenics as Director Antibody Engineering.
Dr. Diedrich received his Ph.D. in Chemistry from the Max-Planck Institute for Molecular Genetics in Berlin and completed his postdoctoral training in immunology at Yale University.

Leveraging expert guidance to scale drug development demands

Brian D. Furmanski; Ph.D.
Senior Director of Clinical Pharmacology & Pharmacokinetics, Nuventra

Dr. Furmanski has over 8 years of experience in the development of small molecule, oligonucleotide, radiopharmaceutical, and biologic therapeutics from an industrial and regulatory perspective.

He has provided expert guidance on the design and interpretation of human clinical pharmacology, toxicokinetic, drug metabolism, bioanalytical and biopharmaceutical quality findings through the examination of pharmacokinetic and pharmacodynamic analyses across multiple therapeutic areas. He has also presented key regulatory findings at an oncology drug advisory committee meeting, scientific conferences and to other health agencies (EMA, Health Canada, PMDA, TGA and Swissmedic). His therapeutic focus areas are oncology, immuno-oncology, muscular disorders, and infectious diseases.
Dr. Furmanski obtained his Ph.D. degree in Biochemistry from University of South Carolina.



Special FDA session: Early Stage Drug Development

Hae-Young Ahn; Ph.D., RAC
CEO & President, AhnBio Consulting, Inc.

Dr. Ahn is the principal consultant as well and her expertise is on building drug development strategies and regulatory strategies. Prior to founding AhnBio in January, 2018, she was the deputy director in Division of Clinical Pharmacology 3, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

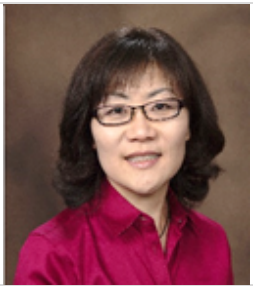
She joined the FDA in 1990 as a research scientist. During her tenure at the FDA, she held several positions in the Office of Clinical Pharmacology including a clinical pharmacology and biopharmaceutic reviewer, the metabolic and endocrine clinical pharmacology team leader and deputy division director. She also served as a senior advisor to the Office of New Drugs (OND) Associate Director for Therapeutic Biologics on broad policy and strategic initiatives related to biosimilars, follow-on protein products, and other related complex products. She participated in many important CDER coordinating committees and working groups such as Complex Drug Substance Coordinating Committee, Biopharmaceutical Coordinating Committee, Non-glycosylated peptide

working group, Biosimilar Implement Committee, Biologic Oversight Board, and Hepatic Impairment working group.
She received her B.S. in pharmacy from Ewha Womans University, M.S. in pharmaceutics from Seoul National University, and Ph.D. in pharmaceutics from West Virginia University. She also received a postdoctoral training in pharmaceutics at the University of Michigan.

CMC Regulatory Considerations for the Product Development Process

Sydney Choi; Ph.D.
Chemist, U.S. Food and Drug Administration

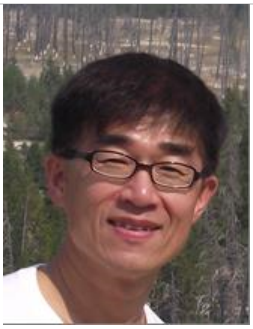
Dr. Choi is a chemist in the Division of Process Assessment in CDER/OPQ at the FDA. In her current role as a process and facility reviewer, she reviews submissions of IND, NDA and ANDA applications.
She received her Bachelors and Masters in Chemistry from the Changwon University, South Korea and a Ph.D. in Physical Chemistry from the University of Missouri-Kansas City. She completed her post-doctoral fellowship at the University of Maryland-Baltimore, School of Pharmacy. Dr. Choi started her FDA career in 2006 and she worked as a Science and Research staff prior to joining CMC review division in Office of Lifecycle Drug Product in 2013. She was also actively involved in different working groups including Phospholipidosis working group, Nanotechnology working group and Computational Toxicology Subcommittee.



Nonclinical studies of small molecules in the initial IND submission

Grace S. Lee; Ph.D.
Pharmacologist, U.S. Food and Drug Administration

Dr. Lee is a Pharmacology Toxicology Reviewer at Division of Anesthesia, Analgesia, and Addiction Products, USFDA.
Previously she worked at the Division of Pulmonary, Allergy, and Rheumatology Products. At CDER/FDA, she has been participating in three PharmTox subcommittees: Reproductive and Developmental Toxicity Subcommittee, Biologics Subcommittee, and Nonclinical Safety Testing for Pediatric Drugs Subcommittee.
Prior to joining the FDA, she has worked as a reproductive toxicologist at Schering-Plough for 4 years. At Schering-Plough, she was a study director/monitor for reproductive and developmental toxicology studies and a compound director representing Drug Safety in drug development teams.
Dr. Lee received both B.S. in Biochemistry and Ph.D. in Molecular Toxicology from UCLA.



Application of Clinical Pharmacokinetics and Pharmacodynamics in Drug Development

Seong Hoon Jang; Ph.D.
Team leader, U.S. Food and Drug Administration

Dr. Jang works in the Office of Clinical Pharmacology, the Center for Drug Evaluation and Research, FDA, as a team leader. His review team oversees all Clinical Pharmacology studies in the New Drug Applications (NDAs) and the Investigational New Drug

	Applications (INDs) submitted to the Division of Anti-Infective Products in the Office of New Drugs.

He joined FDA as a clinical pharmacology reviewer in 2002, after completing a three-year postdoctoral research fellowship at the Ohio State University.
Dr. Jang received his Ph.D. in Pharmacology from the Ohio State University in 1999, focusing on studies of pharmacokinetics and pharmacodynamics of anticancer drugs. He received his B.S. in pharmacy and M.S. in Pharmacokinetics from Seoul National University.

Preclinical Drug Development: From Inception to Prescription

Elise Lewis; Ph.D.
Senior Director of Toxicology, Charles River Laboratories

Dr. Lewis joined Charles River Laboratories, Horsham, PA in 2001, and in her role as a Scientific Director, she is responsible for recruiting and supervising study directors, and she has an integral role in implementing and overseeing the science and systems to ensure that Charles River maintains its' leadership position in the field of Developmental, Reproductive, and Juvenile Toxicology.

She interacts with clients in the pharmaceutical, chemical, cosmetic and food industries throughout the world to serve their reproductive and developmental toxicology testing needs and ensure compliance with the governing regulations for this testing.
Dr. Lewis has authored or co-authored multiple publications, books, and book chapters in various areas of developmental, reproductive, juvenile toxicology. She is a member of the Teratology Society, the European Teratology Society, the Society of Toxicology, the American College of Toxicology, the Mid-Atlantic Reproductive Toxicology Association, and the Association for Women in Science (Philadelphia Chapter). She is also the Vice President-elect for the Teratology Society.
Dr. Elise Lewis received her undergraduate degree in biological sciences and did her graduate work in Developmental Toxicology at the University of Alabama in Tuscaloosa, Alabama.

Pathways to Commercialization

Maria Brazda
CEO, Panthera Global Solutions

Maria is a Senior Strategic Marketing Communications, International Development, Media Specialist, and Business Development Executive.

Maria employs the best practices in all areas by fortifying strong strategic alliances, capitalizing on relationships, and honing partnerships which will yield endorsements, corporate enterprise and critical funding. She has 20+ years' experience in business development and past performance in the Federal Government space. Maria runs strategic teams for fundraising, business development, commercialization, and communication initiatives. She designed and executed direct marketing, interactive media, sales promotions and PR strategies for government agencies, nonprofits and Fortune 500 companies. Maria helped create multi-million dollar training modules for the International Training Institute. She is a C-Level Strategic Alignment Strategist and has advised senior management and government
leadership in media, crisis communication, staffing protocols, business strategy, and leadership challenges.
Maria holds a B.A. in Liberal Studies from Georgetown University.

Conference Organizers

Luke YS Oh, Ph.D.
President, KAPAL

Over 14 years of experience in biopharmaceuticals for small molecules and antibodies
Worked as associate director at Questcor Pharma and Mallinckrodt Pharmaceuticals
Spearheaded immunology research group in Human Genome Sciences.
Research scientist and council member at Vertex Pharmaceuticals.
PhD in Neuroimmunology at McGill University and postdoctoral fellowship at UCONN.

Jeong Kuen (JK) Song, Ph.D.
Vice President, KAPAL
Senior Scientist, L&J Biosciences
Postdoc & Research Fellow, NINDS, NIH
Ph.D. in Neuroscience, Vanderbilt University School of Medicine

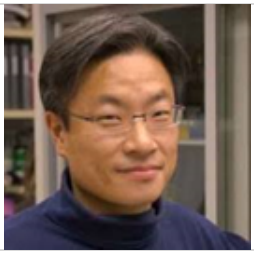
Helena Hyesook Ahn, Ph.D.
Financial Director, KAPAL
Program Specialist, NCCIH, NIH
Project & Regulatory Associate, KCRN Research
Biologist, NCCIH, NIH
Postdoc, Yale University
Ph.D. in Neurobiology, The Catholic University of Korea

Byung Ha Lee, Ph.D.
General Director, KAPAL
Principal Scientist, NeoImmuneTech, Inc.
Senior manager, Corporate Development, Genexine, Inc.
IRTA fellow, NIAID, NIH
Postdoc, The University of Florida College of Dentistry
Ph.D. in Immunology and Microbiology, The University of Florida College of Medicine

Bumrae Cho, J.D./LL.M.
Program Director, KAPAL
Senior Managing Associate, Dentons US LLP.
J.D. / LL.M., Franklin Pierce Law Center (University of New Hampshire)
LL.M., Yonsei University
B.S., Yonsei University
Admitted in DC and MA

Juny Kim, MBA
Public Affairs Director, KAPAL
Vice President, CRScube America, Inc
Director, Clinical Research Marketing, Inc
Associate Director, KCRN Research, LLC
Team Leader, Bison Medical co,. Ltd
MBA, Hood College

Suntae Kim, Ph.D.
IT Director, KAPAL
Principal Scientist, G+FLAS Lifesciences
Postdoc & Research Fellow, NCI, NIH
Ph.D. in Biochemistry & Molecular Biology, Environmental Toxicology, Michigan State University



Cheol Lee, Ph.D.
Science Director, KAPAL
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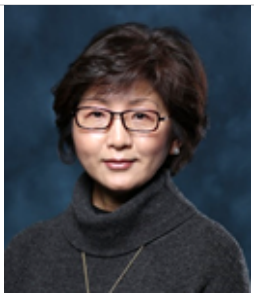

Hae-Young Ahn; Ph.D., RAC
CEO & President, AhnBio Consulting, Inc**.**

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B.S. in pharmacy from Ewha Womans University,
M.S. in pharmaceutics from Seoul National University,
Ph.D. in pharmaceutics from West Virginia University.
Postdoctoral training in pharmaceutics at the University of Michigan

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CEO, Macrogen Corporation

Previously worked at Children's Hospital Boston, Macrogen Clinical Lab, and Axeq Technologies
Postdoc, Harvard Medical School
Ph.D. in Molecular Microbiology, Yonsei University

Hong-Woon Yang, Ph.D.
Senior Scientist, Sanofi

Over 16 years of experience in small molecule-based drug discovery
Previously worked at Array BioPharma, CoMentis, and GlycoMimetics
Postdoc, Johns Hopkins University
PhD in Chemistry, Texas A&M University

The 10th Annual Bioscience and Engineering Symposium, 2018

Dear Participants of the 2018 ABES,

On behalf of the ABES 2018 Organizing Committee, I would like to welcome all of you to the 2018 Annual Bioscience and Engineering Symposium (ABES). ABES is an annual flagship event organized by the NIH-KSA (Korean Scientists Association) to promote scientific exchange and networking among Korean and Korean-American Scientists and Engineers in the Washington D.C. Metropolitan area and vicinity.

I am pleased that ABES 2018 will be held jointly with KUCCLS (Korea-US Cooperative Conference for Life Science). This year, we are honored to have three high profile key note speakers, Dr. Sue Goo Rhee (NIH), Dr. Eun-Suk Seo (University of Maryland) and Dr. Carl Hashimoto (NIH).
In addition, we have invited twelve young Korean-American Scientists and engineers to present their exciting research. We also have a Career Development Session where Dr. Carl Hashimoto will give career advice to junior scientists. Subsequently, 6 panelists will discuss career aspects in NIH extramural (NHLBI, NIH. Dr. Young Suk Oh) academia (Virginia Commonwealth University, Dr. Eun Hee Lee), industry (Macrogen, Dr. Sang Tae Park), FDA (Food and Drug Administration, Dr. Seong Hoon Jang), USP (US Pharmacopeial Convention, Dr. Seong Jae Yoo) and USPTO (US Patent and Trademark office, Dr. Kay Kim) and there will be a panel discussion with a Q & A session. There will also be job recruitments and opportunities for job interviews.

Finally, I would like to thank the following sponsors who have provided generous support for the 2018 ABES and NIH-KSA monthly seminar series: KSEA (Korean American Scientists and Engineers Association), KUSCO (Korea-US Science Cooperation Center), Macrogen-USA, KAPAL (Korean-American Professional Association in Life Sciences), and other private sponsors.
I hope that the symposium will provide you with valuable opportunities for scientific exchange, collaboration and networking with other fellow scientists and engineers.

Myung Hee Park, Ph.D.
President of NIH-Korean Scientists Association

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Co-Chair: Ga-Yeon Son, Ph.D. (NIDCR/NIH)
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Youngchan Kim, PhD (NIAAA)
Juhyung Lee, PhD (NIDDK)
Hye Kyung Lee, PhD (NIDDK)
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Jaewoo Choi (NCI)
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1993	**Dr. Soo-Il Chung**
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2018	**Dr. Myung Hee Park**

Keynote Speakers

Dr. Sue Goo Rhee received his B.S. degree from Seoul National University in 1965 and Ph.D. degree in organic chemistry from the Catholic University of America in 1972. He then joined the Laboratory of Biochemistry at the NHLBI, National Institutes of Health, where he was awarded tenure in 1979, and promoted first to chief of the section of Signal Transduction in 1988 and then to chief of the Laboratory of Cell Signaling in 1994. In the fall of 2005, he returned to his native South Korea to join the faculty of Ewha Women's University and then in 2013 moved to Yonsei University College of Medicine, from which he retired in 2017. Dr. Rhee discovered three prototypical phospholipase C enzymes and elucidated their regulatory mechanisms; uncovered peroxiredoxins (peroxidases) and their participation in cell signaling through control of intracellular H_2O_2 concentration; and identified cysteine hyperoxidation as a novel, reversible post-translational modification.

Dr. Eun-Suk Seo is Professor of Physics in the University of Maryland's Department of Physics and Institute for Physical Science and Technology. She is a Fellow of the American Physical Society. She has been leading development of particle detectors for space-based experiments to investigate cosmic ray origin, acceleration and propagation, especially as Principal Investigator of Cosmic Ray Energetics and Mass, the highest energy frontier of cosmic ray direct measurements. Her research includes searching for dark matter, antimatter and other exotic matter. She received many prestigious awards including Presidential Early Career Award for Scientists and Engineers (1997), NASA Group Achievement Award (2006), Antarctica Service Medal of the United States of America (NSF, 2008), Scientist of the Year Award (KSEA/KOFST, 2015) and Korean-American Day Honoree (KEI, 2017). She served as the 46th President of KSEA; the 29th President of the AKPA; the 4th President of KWiSE. She is currently serving on the Executive Committee of the KUSCO.

Dr. Carl Hashimoto is senior advisor for faculty development in the Office of Intramural Research and in the Office of Scientific Workforce Diversity. His principal responsibility in this role is to support the professional and career development of early career stage investigators in the NIH intramural research program. He was a faculty member for 26 years at the Yale School of Medicine, before retiring as Professor Emeritus of Cell Biology and joining the NIH in 2017. At Yale, in addition to teaching medical and graduate students and undergraduates, he conducted research in the molecular biology of early embryonic development. He also served in diverse administrative roles from directing the Cell Biology PhD program to overseeing research training and diversity programs at Yale College and Graduate School as an Assistant Dean.

2018 ABES Program Schedule

08:00 Registration and Breakfast

09:00 Opening Remarks (Dr. Myung Hee Park, NIH-KSA President)

09:10 **Keynote Lecture I: Dr. Sue Goo Rhee**, NHLBI, NIH (Chair: Dr. Byoung-Joon Song)
"Reactive oxygen species as the cause of eustress and distress"

09:50 **Session 1, Chair: Dr. Youngchan Kim** (NIAAA) (4 speakers; each 12 min + 3 min Q&A)

10:50 Coffee Break

11:00 **Session 2, Chair: Dr. Ji-Hoon Park** (NHLBI) (4 speakers; each 12 min + 3 min Q&A)

12:00 Group photo

12:10 Lunch & Job Opening Announcement

13:00 **Keynote Lecture II: Dr. Eun-Suk Seo**, Univ. of Maryland (Chair, Dr. Hee-Yong Kim)
"Cosmic journey"

13:40 **Session 3, Chair: Dr. Juhyung Lee** (NIDDK) (4 speakers; each 12 min + 3 min Q&A)

14:40 Coffee Break

14:50 **Career Development Session,**
Keynote Speech: Dr. Carl Hashimoto (OD, NIH) (Chair, Dr. Myung Hee Park)
"What I have learned as professor and scientist"

15:20 Job Talks
Dr. Seong Jae Yoo: United States Pharmacopeial Convention (USP)
Dr. Youngsuk Oh: NHLBI/NIH, Extramural
Dr. Sang Tae Park: Macrogen Corporation
Dr. Kay Kim: US patent and Trademark Office (USPTO)
Dr. Eun Hee Lee, Virginia Commonwealth University
Dr. Seong Hoon Jang, Food and Drug Administration (FDA)

16:20 Panel discussion and Q & A session (Chair: Dr. Kyung Sang Lee)

17:00 Closing Remarks and Award Presentation
: Johng S. Rhim Young Investigator Award and KAPAL Awards

17:15 Job Interview

17:30 Dinner and Networking at Ichiban Restaurant (637 N. Frederick Ave, Gaithersburg, MD)

The List of Short Talks

Session 1, Chair: Dr. Youngchan Kim (NIAAA) (4 speakers; each 12 min + 3 min Q&A)

1. Tumor suppressive role of KLHL6 in diffuse large B-cell lymphoma
   ----------Jaewoo Choi, Ph.D., NCI

2. TBC1d24-ephrinB2 interaction regulates contact inhibition of locomotion in neural crest cell migration
   ----------Jaeho Yoon, Ph.D., NCI

3. MAP kinase phosphatase 3 regulates myogenic differentiation in old primary myoblasts
   ----------Young Jae Bahn, Ph.D., NIDDK

4. Oxygen tension regulates lysosomal activation and receptor tyrosine kinase degradation
   ----------Jaewoo Hong, D.V.M., Ph.D., NCI

Session 2, Chair: Dr. Ji-Hoon Park (NHLBI) (4 speakers; each 12 min + 3 min Q&A)

5. MicroRNA-mediated control of developmental lymph-angiogenesis
   ----------Hyun Min Jung, Ph.D., NICHD

6. The cytokine receptor IL-7Rα is a negative regulator of IL-2 receptor signaling
   ----------Tae-hyoun Kim, Ph.D., NCI

7. Quantitative difference in PLZF protein expression determines *i*NKT lineage fate and controls innate CD8 T cell generation
   ----------Juntae Kwon, Ph.D., NCI

8. Molecular architecture of a cylindrical self-assembly at human centrosomes
   ----------Liang Zhang, Ph.D., NCI

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

9. Pygmy Pigs: High Mobility Group A2 (HMGA2) deficiency in pigs leads to dwarfism, abnormal fetal resource allocation and cryptorchidism
   ----------Jaewook Chung, Ph.D., University of Maryland

10. Adaptive mapping of visual scenes to a heading representation via competitive anti-Hebbian plasticity in the *Drosophila* central brain
    ----------Sung Soo Kim, Ph.D., HHMI

11. CRISPR/Cas9-mediated introduction of the sodium/iodide symporter gene enables noninvasive in vivo tracking of iPSC-derived cardiomyocytes in murine model of myocardial infarction
    ----------So Gun Hong, D.V.M., Ph.D., NHLBI

12. Discovery of URAT1 and GLUT9 novel variant in hypouricemia subjects using whole exome sequencing analysis
    ----------Sung Kweon Cho, M.D., Ph.D, NCI

Abstracts (Keynote Speeches)

Dr. Sue Goo Rhee (NHLBI, NIH)

Title: Reactive oxygen species as the cause of eustress and distress.

Reactive Oxygen Species (ROS) are chemically reactive species derived from molecular oxygen. Examples include superoxide, hydrogen peroxide, hydroxyl radical, singlet oxygen**. ROS** cause oxidative damage to lipids, proteins and DNA and has been linked to a myriad of pathologies. There is also a growing consensus that ROS act as physiological redox signaling messenger with important regulatory functions. Thus, ROS is the source of both oxidative distress (negative form of stress that causes oxidative damage) and oxidative eustress (positive type of stress that enhances cellular function). Switch between these two-opposite type of stresses is intrically regulated by various antioxidant enzymes.

Dr. Eun-Suk Seo (University of Maryland, College Park)

Title: Cosmic journey

Professor Seo's research focuses on cosmic ray origin, acceleration, and propagation including searches for exotic matter, such as antimatter and dark matter using direct measurements of galactic cosmic rays by flying instruments on balloons or spacecraft. She has worked on numerous projects for the detection and characterization of cosmic rays, including four major international collaborations: ATIC (the Advanced Thin Ionization Calorimeter), AMS (the Alpha Magnetic Spectrometer on the International Space Station), BESS (the Balloon-borne Experiment with a Superconducting Magnet Spectrometer) and CREAM (the Cosmic Ray Energetics and Mass program).

Dr. Carl Hashimoto (OD, NIH)

Title: What I′ve learned as professor and scientist

Like the processes studied by developmental biologists, a career takes shape over time. But unlike, say, the development of a human organ, a career does not just naturally unfold (except maybe for a very few fortunate individuals). Rather, a career involves planning and management, with intentional acquisition of critical knowledge and skills. Guidance and support from others also play an important role in shaping a satisfying career. I will share what I've learned from being a professor and scientist about some important ingredients for professional and career success.

Abstracts (**Short talks.** #1 - 4: Session 1, #5 - 8: Session 2, #9 - 12: Session 3)

1. Tumor suppressive role of KLHL6 in diffuse large B-cell lymphoma

Jaewoo Choi, Ph.D., NCI

Mature B-cell cancers afflict thousands every year in the United States. Cancer is a genetic disease where abnormal gene changes affect cell growth and division. Progressive accumulation of somatic mutations is central to the process of cancer development. Recently, high-throughput genome sequencing studies have transformed our understanding the genetics of cancer, uncovering new insights into cancer evolution. By leveraging the knowledge of genomic rearrangements, we have studied the molecular targets in the oncogenic pathways leading a research area of potential therapeutic intervention in mature B-cell malignancies, specifically in diffuse large B-cell lymphoma (DLBCL). Combining biochemistry, genetics, proteomics, and mouse models, we present the function of unknown ubiquitin ligase gene, KLHL6. Analysis of genomic databases of B-cell cancer patients demonstrates that the highest mutation frequency of KLHL6 is observed in DLBCLs. Interestingly, cancer-associated somatic mutations of KLHL6 inhibit its ubiquitin ligase activity resulting in its loss of function. In malignant DLBCLs, knockout of KLHL6 gene increases cancer cell proliferation and decreases apoptosis rates, supporting KLHL6 is a tumor suppressor. Mechanistically, loss of KLHL6 or mutation of KLHL6 results in accumulation of its key substrate, an RNA binding protein that regulates mRNA decay. Stabilization of this essential mRNA decay factor results in an aberrant transcription program that promotes DLBCL growth and survival. Specifically, RNA sequencing analysis has revealed that multiple mRNA transcripts implicated as the NF-κB pathway inhibitors are affected by the KLHL6-dependent proteolysis. Thus, loss of KLHL6 further activates the NF-κB pathway through modulation of mRNA decay processes. Correspondingly, DLBCL patients with loss of function mutation of KLHL6 have a higher NF-κB activity and poorer survival rates than those without mutation. We have uncovered the tumor suppressing mechanism of KLHL6 whereby the ubiquitin pathways regulate effective mRNA turnover and contribute to pathogenesis of DLBCL. This innovative discovery can lead to a better understanding of ubiquitin-based regulation in DLBCL progression and advances in therapeutic approaches for targeting ubiquitin ligases. Furthermore, identification of novel genomic and molecular features of DLBCL tumors in this study will contribute to the development of an effective precision medicine.

2. TBC1d24-ephrinB2 interaction regulates contact inhibition of locomotion in neural crest cell migration

Jaeho Yoon, Ph.D., NCI

Although Eph-ephrin signalling has been implicated in the migration of cranial neural crest (CNC) cells, it is still unclear how ephrinB transduces signals regulating this event. We provide evidence that TBC1d24, a putative Rab35-GTPase activating protein (Rab35 GAP), complexes with ephrinB2 via the scaffold Dishevelled (Dsh), and mediates a signal affecting contact inhibition of locomotion (CIL) in CNC cells. Moreover, we found that in migrating CNC, the interaction between ephrinB2 and TBC1d24 negatively regulates E-cadherin recycling in these cells via Rab35. Upon engagement of the cognate Eph receptor, ephrinB2 is tyrosine phosphorylated, which disrupts the ephrinB2/Dsh/TBC1d24 complex. The dissolution of this complex leads to increasing E-cadherin levels at the plasma membrane, resulting in loss of CIL, and disrupted CNC migration. Our results indicate that TBC1d24 is a critical player in ephrinB2 control of CNC cell migration via CIL.

3. MAP kinase phosphatase 3 regulates myogenic differentiation in old primary myoblasts

Young Jae Bahn, Ph.D., NIDDK

Although several MAP kinase phosphatases (MKPs) are involved in muscle maintenance and myogenic differentiation, the regulatory function of MKP3 underlying myoblast differentiation are not fully understood. Here, we showed that MAP kinase phosphatase 3 (MKP3) is decreased in aged muscle and old primary myoblast. Expression of MKP3 was increased in late stage of myogenic differentiation in young primary myoblast but not in old primary myoblast. We confirmed that ectopic expression of MKP3 in primary myoblast markedly stimulated the myogenic differentiation, whereas the knock-down of endogenous MKP3 inhibited the differentiation. Consistently, we found a repressed myoblast differentiation in MKP3-null MEF cells. Overexpression of MKP3 in old primary myoblast significantly restores myogenic differentiation of old primary myoblast. In in vivo studies, we revealed that MKP3 promoted the CTX injury-induced muscle regeneration. We identified that, with MKP3 decrease, phosphorylation of ERK1/2 was increased in aged muscle compared to young muscle. Taken together, we suggest that decreased MKP3 is associated with myoblast differentiation in aged muscle and MKP3 could act as a regulator of myogenic differentiation.

4. Oxygen tension regulates lysosomal activation and receptor tyrosine kinase degradation

Jaewoo Hong, D.V.M., Ph.D., NCI

Oxygen sensing is crucial for adaptation to variable habitats and physiological conditions. Low oxygen tension, or hypoxia, is a common feature of solid tumors and hypoxic tumors are often more aggressive and resistant to therapy. Here we show that, in mammalian tissue culture cells, hypoxia suppressed lysosomal acidification/activation and receptor tyrosine kinase (RTK) degradation. Hypoxia down-regulated mTORc1, reducing its ability to activate transcription factor EB (TFEB), a master regulator of v-ATPase, the lysosomal proton pump. Hypoxia prevented epidermal growth factor receptor (EGFR) degradation in tumor tissues, whereas activation of lysosomes enhanced tumor cell response to anti-EGFR treatment. Our results link oxygen tension and lysosomal activity, provide a molecular explanation of the malignant phenotype associated with hypoxic tumors, and suggest activation of lysosomes may provide therapeutic benefit in RTK-targeted cancer therapy.

5. MicroRNA-mediated control of developmental lymph-angiogenesis

Hyun Min Jung, Ph.D., NICHD

The lymphatic vascular system is essential for tissue fluid homeostasis, immune trafficking, and absorption of dietary fats. It is involved in a wide range of clinical complications such as lymphedema, cancer metastasis, inflammatory and immunological disorders, and metabolic disease. Despite its importance, our understanding of the essential molecules that build the lymphatic system and regulate its function is still very limited. In particular, the post-transcriptional regulatory mechanisms in lymphatic endothelial cells are largely elusive. In this study, we used high throughput small RNA sequencing to identify miRNAs enriched in lymphatic endothelial cells. We present a highly conserved miRNA (100% identical sequence among various species), miR-204 that plays critical function in regulating lymphatic vessel formation during embryonic development. Using morpholino antisense oligomers and CRISPR-mediated genome editing strategies to silence mature miR-204 activity or blocking miR-204 biogenesis in developing zebrafish embryos, we show that miR-204 is an important component for developmental lymph-angiogenesis. Moreover, overproduction of miR-204 in lymphatic vessels accelerates the development of lymphatic vessel formation suggesting its positive regulator activity. These events were monitored using high-resolution real-time live imaging of developing zebrafish embryos. We identified NFATC1 as a novel target for miR-204, which is a known player for lymphatic vessel development. Loss of miR-204 in embryos caused amorphic lymphatic phenotype whereas loss of its target NFATC1 led to lymphatic hyperplasia. The amorphic lymphatic phenotype in miR-204-deficient embryos was rescued by NFACT1 knockdown indicating the importance of proper balance of these two

molecules for lymph-angiogenesis. These results were also reproducible in human lymphatic endothelial cell culture system suggesting an evolutionarily conserved mechanism for this process. Together, these data suggest that miR-204 plays a key role in fine-tuning NFATC1 levels during lymphatic vascular development.

6. The cytokine receptor IL-7Rα is a negative regulator of IL-2 receptor signaling

Tae-hyoun Kim, Ph.D., NCI

IL-2 is a member of the common γ chain (γc) cytokine family that plays an important role in T cell homeostasis. IL-2 is required for the development and survival of $Foxp3^{+}$ regulatory T cells (Treg). This contrasts to IL-7, which is required by conventional T cells. Because IL-2 and IL-7 receptors share γc, they compete for γc whose availability is limited. How IL-7 and IL-2 signaling is controlled under such competing condition is not well understood. Here, we show that IL-7Rα acts as a negative regulator of IL-2 signaling. We found that IL-7Rα has much higher binding affinity to the γc subunit than IL-2Rβ, leading us to question how Treg can receive IL-2 signaling if the γc subunit is sequestered by IL-7Rα. As a potential solution, we demonstrated that the number of IL-7Rα on Tregs is significantly decreased compared to naive CD4 T cells. These data suggest that reduction of IL-7Rα maximizes IL-2 signaling in Tregs. To test this idea, we overexpressed IL-7Rα protein on Treg cells. In IL-7Rα transgenic Tregs, the number of IL-7Rα molecules on cell surface is increased, but IL-2 receptor signaling is suppressed. Notably, enforced expression of a truncated IL-7Rα that contains only the ectodomain, and which is impaired in intracellular signaling, still suppressed IL-2 signaling. This suggests that the extracellular domain of IL-7Rα is sufficient to suppress IL-2 signaling. Collectively, these results unveil a novel trans-regulatory mechanism of IL-2 receptor signaling by IL-7Rα protein.

7. Quantitative difference in PLZF protein expression determines *i*NKT lineage fate and controls innate CD8 T cell generation

Juntae Kwon, Ph.D., NCI

Zbtb16 encodes the zinc finger protein PLZF, which is a transcription factor expressed in innate-like T cells including invariant NKT (*i*NKT) cells, γδ T cells, and mucosal associated invariant T (MAIT) cells. PLZF is specifically required for thymic invariant NKT (*i*NKT) cell generation and their effector function. Here, we show that not only PLZF expression itself, but also the abundance of PLZF protein plays a crucial role in *i*NKT cell development. Utilizing a *Zbtb16* hypomorphic allele, *i.e.* $PLZF^{GFPCre}$, that produces only at half the amount of the wildtype allele, we report that decreased PLZF expression resulted in significant loss of *i*NKT cell numbers in the thymus and in peripheral tissues. Notably, dosage of PLZF is important not only for *i*NKT generation but also for *i*NKT lineage choice. Consequently, in $PLZF^{GFPcre+/wt}$ mice, *i*NKT lineage choice was heavily skewed towards NKT1 cells while NKT2 cell numbers were significantly reduced. Moreover, impaired *i*NKT lineage choice resulted in attenuation of innate CD8 T cell generation. These results demonstrate that the quantitative regulation of PLZF protein is a critical factor for both effective *i*NKT cell generation and determining their lineage choice.

8. Molecular architecture of a cylindrical self-assembly at human centrosomes

Liang Zhang, Ph.D., NCI

The centrosome is a membraneless organelle composed of two microtubule-derived structures called centrioles and an amorphous mass of pericentriolar material (PCM). Super-resolution microscopic analyses in various organisms revealed that diverse PCM proteins are concentrically localized around a centriole in a highly organized manner.

However, the molecular nature underlying these organizations remains unknown. Combining various *in vitro* biophysical and reconstitution assays, X-ray crystallography, and *in vivo* self-assembly assays, we showed that two human pericentriolar scaffolds, Cep63 and Cep152, cooperatively interact with each other to generate an antiparallel four-helix bundle, which in turn self-assembles into a higher-order cylindrical architecture that resembles their endogenous localization patterns around a centriole. The resulting cylindrical self-assembly was capable of recruiting downstream components, including Plk4, a key regulator for centriole duplication. Mutations disrupting either the formation of the four-helix bundle or the inter-building block interaction abrogated not only the self-assembly but also Plk4-mediated centriole duplication. Subsequent characterization of self-assembled cylinders revealed that Cep63 and Cep152 proteins are radially arranged from the axis of the cylindrical self-assembly with the Cep63 N-terminus pointing inward and the Cep152 N-terminus pointing outward, thus allowing to recruit Plk4 and Sas6, a pivotal structural element of a centriolar cartwheel architecture, to the outskirts of the self-assembly. Unlike actin or tubulins, which harness the energy from the hydrolysis of ATP or GTP, respectively, to generate filamentous polymers, the entire assembly process occurs spontaneously without consuming any external energy. SIM-total internal reflection fluorescence (TIRF) time-lapse revealed that early ring-like assemblies were detectable as early as t = ~50 minutes, and their signals steadily increased until t = ~100 minutes after incubation. Fluorescent recovery after photobleaching (FRAP) revealed that the self-assembly undergoes a dynamic exchange of its components with those in the surroundings. Given various mutations in Cep63 and Cep152 are associated with the development of human diseases, such as cancer and microcephaly, further investigation into how these mutations alter the structure and function of the self-assembly may provide new insights into how a defect in centrosomal architecture contributes to the development of these disorders. In addition, because PCM organization is evolutionarily conserved, this work may offer a paradigm for investigating the assembly and function of other centrosomal scaffolds in various organisms.

9. Pygmy Pigs: High Mobility Group A2 (HMGA2) deficiency in pigs leads to dwarfism, abnormal fetal resource allocation and cryptorchidism

Jaewook Chung, Ph.D., University of Maryland

High Mobility Group AT-hook 2 (HMGA2), acting as architectural enhanceosome, is strongly associated with body size and growth in mice and humans, suggesting the function of the HMGA2 protein is conserved among mammals. To test this hypothesis, we generated *HMGA2*-KO cell lines via gene editing with TALEN and HMGA2-deficient pig clones using SCNT. Mutations in *HMGA2* gene affected the size of pigs. Lack of HMGA2 showed significant size reduction ranging from 35 to 85% of controls depending on age ($P<0.05$), and organ weights were also affected ($P<0.05$). Cross-breeding of $HMGA2^{-/+}$ generated healthy $HMGA2^{-/-}$ fetuses present at the expected Mendelian ratio. However, the $HMGA2^{-/-}$ fetuses showed placental abnormality at D78. $HMGA2^{-/-}$ cloned boars exhibited normal development but sterile due to undescended testes. Our results show that the effect of *HMGA2* with respect to growth regulation is highly conserved and HMGA2 is a potential target for gene modification that can be used to modulate size in other mammalian species. This can have an implication in biomedical regenerative medicine for organ-size regulation in xenotransplantation.

10. Adaptive mapping of visual scenes to a heading representation via competitive anti-Hebbian plasticity in the *Drosophila* central brain

Sung Soo Kim, Ph.D., HHMI

In flies, so-called E-PG neurons, each arborizing in a single sector of the torus-shaped ellipsoid body (EB), carry an internal representation of the animal's heading. The E-PG neurons are thought to be part of a ring attractor, winner-take-all dynamics that ensure a unique localized bump-like E-PG population activity in the EB. This 'bump' spans

about 90 degrees and its angular position in the EB represents the animal's heading in visual environments as well as in darkness, a state in which angular velocity inputs —from a different population of so-called P-EN neurons that are driven by the fly's turning movements— are integrated to move the bump. The bump moves smoothly around the EB as the fly turns in a visual environment, suggesting that angular velocity integration is well-matched to landmark-driven movement of the bump. However, the E-PG bump position in the same visual environment varies across flies, strongly suggesting that the pinning 'offset' between landmarks and the bump position is not stereotypical or genetically determined but develops over time with experience. Visual input to the E-PG neurons comes from a population of visual-feature-selective, GABA-ergic neurons called ring neurons, which electron microscopic (EM) reconstrution reveals to be directly presynaptic to the E-PGs. In dramatic contrast with earlier stages of this visual pathway, ring neuron axonal projections in the EB are not local or retinotopic—individual ring neurons make synapses with E-PG neurons in all the different sectors of the EB. We propose that both the development of an arbitrary pinning 'offset' and the continuous movement of the bump in a visual environment despite the loss of retinotopy in ring neuron projections to the EB are simultaneously realized via competitive anti-Hebbian plasticity between ring neurons and E-PG neurons. That is, that synaptic weights from ring neurons to E-PG neurons are depressed when they are simultaneously active. To test this hypothesis, we tethered flies, put them in a virtual reality arena and used two-photon calcium imaging and optogenetics to enforce an artificial offset between the E-PG bump position and landmarks in a visual environment for a short period of time. As our model predicts, the natural E-PG offset to landmark cues was perturbed and shifted towards the artificially enforced offset, supporting the idea of competitive anti-Hebbian plasticity between E-PG neurons and ring neurons. Our simulations showed that the same plasticity rule also recovers the continuity of E-PG bump flow. Our results provide direct physiological evidence of a population-level anti-Hebbian plasticity in the fly compass system. This relatively fast plasticity of synaptic weights may allow animals to quickly reconcile and register self-motion- and landmark-based cues to maintain and update their heading in visual environments.

11. CRISPR/Cas9-mediated introduction of the sodium/iodide symporter gene enables noninvasive in vivo tracking of iPSC-derived cardiomyocytes in murine model of myocardial infarction

So Gun Hong, D.V.M., Ph.D., NHLBI

Non-human primate (NHP) induced pluripotent stem cells (iPSCs) offer the opportunity to investigate safety, potential immunogenicity and functional integration of iPSC-derived cells and tissues in clinically relevant models. However, there have been limited preclinical longitudinal studies incorporating *in vivo* molecular imaging for long-term assessment of localization and persistence of iPSC-derived cells. Sodium-iodide symporter (NIS)–based *in vivo* imaging has many advantages, including predicted safety and immunotolerance due to reliance on an endogenous gene, and on widely available imaging technologies. We report the development of NIS-based *in vivo* imaging to detect and track rhesus iPSC (RhiPSC)-derived cardiomyocytes (CMs) in a murine model of myocardial infarction (MI). Rhesus NIS cDNA was incorporated into Rhesus iPSCs at the AAVS1 safe harbor site via CRISPR/Cas9, and NIS-positive RhiPSCs underwent cardiac differentiation. NIS-RhiPSC-CMs were derived with high purity, exhibited spontaneous beating in culture, and retained functional NIS expression. All electrophysiologic parameters of NIS-RhiPSC-CMs accessed by whole-cell patch clamp were within normal limits. Mice were injected intramyocardially with 2 million NIS-RhiPSC-CMs immediately following MI. To track the injected cells *in vivo*, positron emission tomography/computed tomography was used with ^{18}F-TFB. Transplanted cells could be clearly visualized for up to ten weeks post-injection. Taken together, our results further demonstrate the utility of NIS as a safe and robust tool for imaging of iPSC-based cell therapies.

12. Discovery of URAT1 and GLUT9 novel variant in hypouricemia subjects using whole exome sequencing analysis

Sung Kweon Cho, M.D., Ph.D, NCI

Renal hypouricemia is a rare disorder associated with genetic mutant of renal transporters. Differentiating between inherited renal hypouricemia and asymptomatic hypouricemia is challenging. Here, we aimed to describe the genetic background of hypouricemia patients using whole-exome sequencing and assess the feasibility for genetic diagnosis in the primary screening. Korean cases (N= 31) with extreme hypouricemia (<1.2mg/dl) were selected from an urban cohort of 179,381 subjects; selection criteria included 1) abstinence from alcohol or smoking and 2) an absence of underlying conditions (i.e., hypertension, diabetes and taking anti-hypertensive medication). Whole-exome sequencing was performed for the discovery of diagnostic markers. Two known genetic marker (*SLC22A12* c.774G>A (p.Trp258*) and *SLC22A12* c.269G>A (p.Arg90His) were identified, explaining 90.32 % (28/31) renal hypouricemia in Koreans. We used SNaPshot for the 2 *SLC22A12* SNPs and screened 50 additional hypouricemia subjects from the Korean Cancer Prevention Study. 47 carried known SLC22A12 markers; the unexplained three hypouremic cases were whole-exome sequenced. In total, we conducted whole-exome sequencing (WES) of 34 individuals with extreme hypouricemia. 82.35 % (28/34) carried known hypouricemia variants. Average of 1,382 (1,020-1,555), non-synonymous and splice-site variants were identified after filtering out common variants (>1%) and variants from 46 healthy internal control in each subject. 4 novel variants of *SLC22A12* (c.408C>A (p.Asn136Lys), c.674C>A (p.Thr225Lys), c.851G>A (p.Arg284Gln) and c.1285G>A (p.Glu429Lys) were found and one novel variant c. 376A>G (p.Met155Val) of *SLC2A9* were identified. *In silico* prediction and molecular dynamics confirmed that all newly discovered variants are functionally related to uric acid transport. After filtering out known genes of renal hypouricemia (*SLC22A12* and *SLC2A9*), 6 unsolved patients remained and novel causative candidate genes were identified among them. Among the candidate genes, p.Arg78His variant in *ASB12* was overlapped in two unexplained patients. This is the first attempt to determine the value of genetic diagnostic screening of patients for hypouricemia in the clinical setting. Screening of just 2 SNPs (p.Trp258* and p.Arg90His) identified 71/81 (87.7%)of patients with hypouricemia. Early identification and intervention of hypouricemia (hydration and cautious exercise) may prevent acute kidney injury.

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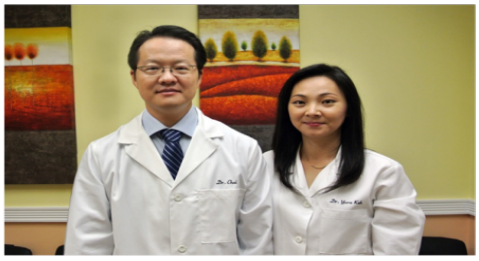

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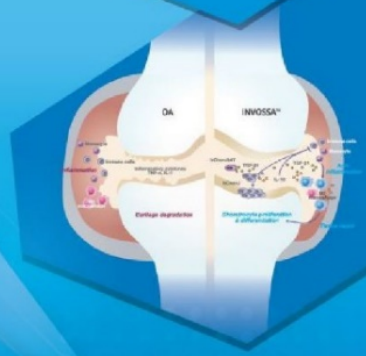

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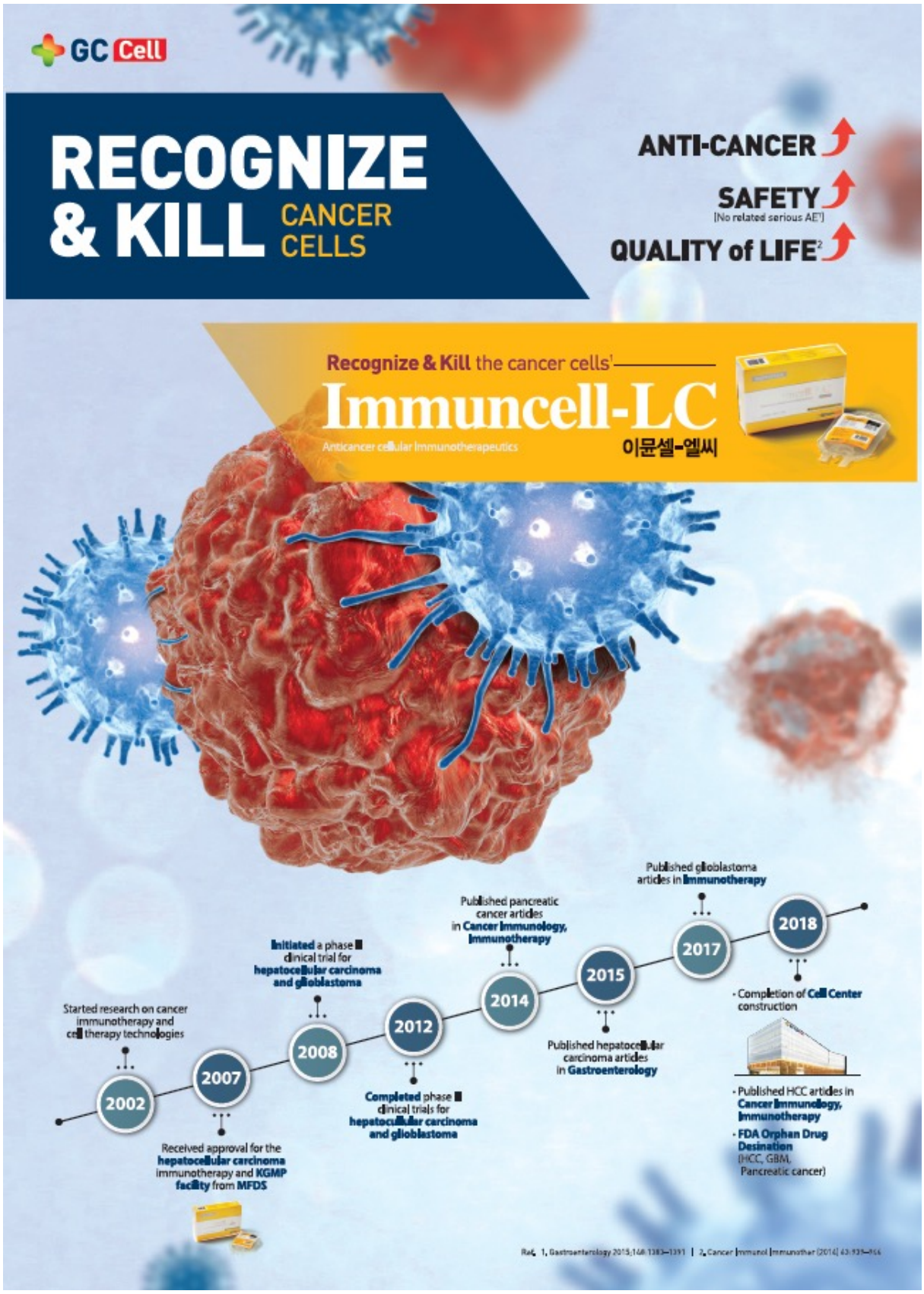
[OMERACT[1]-OARSI[2] RESPONSE RATE (%)]

Source: US Phase II Clinical Trial (TGC09201)
1 OMERACT: Outcome Measures in Rheumatology
2 OARSI: Osteoarthritis Research Society International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ANTI-CANCER
SAFETY
[No related serious AE']
QUALITY of LIFE[2]
Recognize & Kill the cancer cells'
Immuncell-LC
Anticancer cellular Immunotherapeutics
이뮨셀-엘씨
2002
Started research on cancer immunotherapy and cell therapy technologies
2007
Received approval for the hepatocellular carcinoma immunotherapy and KGMP facility from MFDS
2008
Initiated a phase I clinical trial for hepatocellular carcinoma and glioblastoma
2012
Completed phase I clinical trials for hepatocellular carcinoma and glioblastoma
2014
Published pancreatic cancer articles in Cancer Immunology, Immunotherapy
2015
Published hepatocellular carcinoma articles in Gastroenterology
2017
Published glioblastoma articles in Immunotherapy
2018
- Completion of Cell Center construction
- Published HCC articles in Cancer Immunology, Immunotherapy
- FDA Orphan Drug Desination (HCC, GBM, Pancreatic cancer)
Ref. 1. Gastroenterology 2015;148:1383–1391 | 2. Cancer Immunol Immunother (2014) 63:935–946

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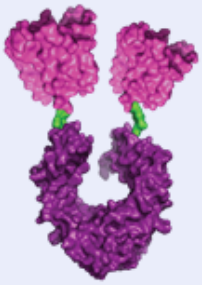

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Hyleukin-7 is built on the **hyFc®** platform technology, created by NIT's related company, Genexine, Inc.

hyFc® is used to construct a long-acting fusion protein composed of the engineered IL-7 moiety hybridized with IgD and IgG4 Fc fragments that serve as non-cytolytic and non-immunogenic carriers.

Hyleukin-7 Clinical Development Status and Plan

	Indications	Target Patients	Pre IND	Phase 1b/2a
Oncology	Advanced Solid Tumors	Advanced, Metastatic		
	Glioblastoma	Newly Diagnosed		
	High-risk Skin Cancer (MCC, cSCC, Melanoma)	Advanced, Metastatic		
	Triple Negative Breast Cancer (TNBC)	Advanced, Metastatic		
Infectious Diseases	Vaccine Adjuvant	Aged Cancer Survivors (post-chemo)		
Lymphopenia	Idiopathic CD4 Lymphopenia[1]	CD4<200/μL		
	Acute Radiation Syndrome[2]	Radiation-Induced Lymphopenia		

1. Orphan drug designation in EU achieved, 2. BARDA (Biomedical Advanced Research and Development Authority) project to be applied