

Korean Society For Extracellular Vesicles (KSEV)



KSEV 2022
하계 산업체 워크숍



KOREAN SOCIETY FOR
EXTRACELLULAR
VESICLES



엑소좀산업협의회

Extracellular Vesicles Industry Association

엑소좀산업협의회는 국내 엑소좀 산업이 성장하는데 필요한 토대를 마련하기 위해 설립되었습니다.

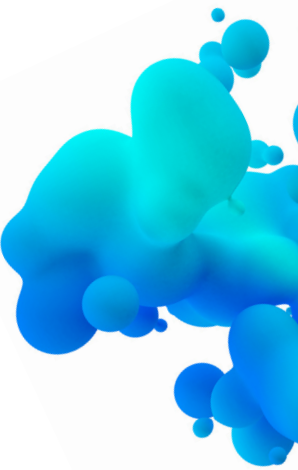
엑소좀산업협의회는 엑소좀 개발 기업의 산업 생태계를 조성하고
국내외 산업계, 학계와의 오픈 이노베이션을 지원하며, 엑소좀 분야의 글로벌 파트너십 및 네트워크를 구축합니다.

회장 | 배신규(엠디문 대표) 부회장 | 최철희(일리아스바이오로직스 대표)



Korean Society
For Extracellular Vesicles

KSEV 2022
하계 산업체 워크숍



회원사 가입 문의
강종희 총무(일리아스바이오로직스 상무) | 070-4060-1521 | jkang@iliiasbio.com

Greeting



세상이 초록으로 바뀌는 계절! 여름이 다가오고 있습니다.
더워지지만 유쾌할 수 있는 자리를 마련해 보려 합니다.

세포박소포체의 사업화에 노력하시는 기업들의 최신 업적을
경청하고 사업화에 대한 아이디어를 공유하기 위해 한국세포
박소포체학회와 한국엑소좀산업협의회가 공동으로 산학 워크
숍을 개최하려 합니다.

아무쪼록 회원님들의 많은 참여와 성원을 부탁드립니다. 본 하계
워크숍이 성공적으로 개최될 수 있기를 기원합니다.

한국세포박소포체학회 회장
정 효 일



차세대 바이오의약품 및 진단기술로 주목받고 있는 엑소좀 산
업 발전을 도모하기 위해 관련 기업들이 뜻을 모아 2021년 ‘엑
소좀산업협의회’를 설립하였으며, 산업계와 학계 그리고 식약
처가 함께 협력해가는 일이 무엇보다 중요하다고 판단되어 이
번 워크숍을 개최하게 되었습니다.

코로나 거리두기가 해제되면서 대면으로 모일 수 있어서 기쁘
게 생각하고, 이번 첫 산학 협력 워크숍을 계기로 제약/바이오
기업들의 관심과 실질적인 산학 협력 연구가 활발해지기를 기
대합니다.

또한 앞으로 국내 엑소좀 산업을 성장시키면서 글로벌 시장에서
K-BIO의 한 축을 담당하기 위해 함께 노력해가겠습니다.

감사합니다.

한국세포박소포체학회 산학협력위원장
엑소좀산업협의회 회장
배 신 규

General Information

Overview

Title	KSEV 2022 하계 산업체 워크숍
Date	2022. 06. 28. (화)
Organized by	한국세포막소포체학회 (Korean Society for Extracellular Vesicles)

Venue



COEX 회의실 402호

Program at a Glance

Session 1	MFDS Guideline & Chemistry, Manufacturing and Controls (CMC)
Session 2	EV Isolation & Theragnostics

Secretariat

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E-mail. ksev2021@gmail.com
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Program at a Glance

2022. 06. 28. 화 / COEX 회의실 402호

사회: 문지숙 (차의과학대학교)

시간	내용	연사	좌장
13:30-14:00	등록		
13:50-13:55	인사말	배신규	
13:55-14:00	축사	이정석	
Session 1: MFDS Guideline & Chemistry, Manufacturing and Controls (CMC)			
14:00-14:30	강연 1: 식품의약품안전처 Regulatory Perspectives for Clinical Entry of Therapeutic Extracellular Vesicles	오일웅	
14:30-15:00	강연 2: 일리아스바이오로직스 Potential and Application of Exosome-based Intracellular Delivery of Therapeutic Proteins	박준태	김창수 (뉴메이스)
15:00-15:30	강연 3: 엑소시스템텍 Development of stem cell exosome-based therapeutics	최지숙	
15:30-16:00	강연 4: 싸토리우스코리아바이오텍 Generic Exosome “Blue Print” Scalable, Flexible and Reliable Solutions to Simplify Your Extracellular Vesicle Process	류준혁	
16:00-16:30	Break Time		
Session 2: EV Isolation & Theragnostics			
16:30-17:00	강연 5: 로제타엑소좀 Scalable mass production of Gram-negative bacterial outer membrane vesicles for the next-generation cancer immunotherapeutic agents	고용송	
17:00-17:30	강연 6: 엠디헬스케어 Microbial EV therapy for the treatment of CNS disorders	김윤근	김 수 (브렉소젠)
17:30-18:00	강연 7: 솔바이오 The Art of Exosome-based Liquid Biopsy	백세환	
18:00-18:10	맺음말/폐회	정효일	
18:30	만찬 (COEX 317호)		

Session 1

MFDS Guideline & Chemistry, Manufacturing and Controls (CMC)



Regulatory Perspectives for Clinical Entry of Therapeutic Extracellular Vesicles

오일웅 식품의약품안전처



Potential and Application of Exosome-based Intracellular Delivery of Therapeutic Proteins

박준태 일리아스바이오토크



Development of stem cell exosome-based therapeutics

최지숙 엑소시스템텍



Generic Exosome “Blue Print” Scalable, Flexible and Reliable Solutions to Simplify Your Extracellular Vesicle Process

류준혁 싸토리우스코리아바이오텍



Oh Ilung

Cell and Gene Therapy Products Division
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Educational
Background &
Professional
Experience

2020-	MFDS	Director
2006-2020	MFDS	Senior Scientific Officer
1997-2006	KFDA	Scientific Officer
1992-1997	Kyungpook National University	PhD. Molecular Biology
1990-1991	Kyungpook National University	MS. Microbial Genetics
1985-1989	Kyungpook National University	BS. Genetic Engineering

Research
Interests

Cell & Gene therapy, LBP (Live Biotherapeutic Products), Exosome, Biosimilar

List of Major
Publications

1. Validation of Monosaccharide Composition Assay Using HPLC-UV Platform for Monoclonal Antibody Products in Compliance with ICH Guideline *Bull. Korean Chem. Soc.* 39, 1394-1399 (2018)
2. Human amniotic membrane-derived stromal cells (hAMSC) interact depending on breast cancer cell type through secreted molecules. *Tissue and Cell* 47, 10-16 (2015)
3. Character Comparison of Abdomen-derived and Eyelid-derived Mesenchymal Stem Cells. *Cell Prolif.* 46, pp. 291-299 (2013)
4. 「유전자재조합의약품 동등생물의약품의 품목별 비임상 및 임상평가 가이드라인에 관한 연구」 *FDC 법제연구 제8권 제1. 2호*, 1-12 (2013)
5. Possible Role of Phosphoinositide-3-Kinase in Mx1 Protein Translation and Antiviral Activity of Interferon-Omega-Stimulated HeLa Cells. *Pharmacology* 87, pp.224-231 (2011)

Regulatory Perspectives for Clinical Entry of
Therapeutic Extracellular Vesicles

Oh Ilung¹

Cell and Gene Therapy Products Division, Ministry of Food and Drug Safety

Currently, stem cells have applications ranging from regeneration of various types of tissues and treatment of intractable or rare conditions. However, there exist a variety of side effects caused by stem cell therapies (immune reponse, tumor formation, etc.) in addition to other issues such as low bioviability of stem cells and their *in vivo* stability post-injection. While research has been actively underway to find ways to address such accompanying side effects, Extracellular Vesicles (EVs) secreted by stem cells were found to be a considerable contributory factor to the therapeutic effects delivered by stem cell therapies, which has fueled vigorous research on the potential roles of EVs and active development of EV-based therapeutic products. To respond to these trends in a proactive manner, Korea Ministry of Food and Drug Safety (MFDS) published *Guideline on Quality, Non-clinical and Clinical Assessment of Extracellular Vesicles Therapy Products* in 2018 to provide the industry with considerations in developing EV-based therapy products; in the guideline, quality, nonclinical and clinical considerations are presented to assist the development of EV therapy products with consistent quality, safety and efficacy. Also, up until next year, this guideline will be revised with comments and feedback from the industry incorporated into the existing version. My presentation today will cover basic principles for EV product developers to consider to successfully advance into clinical trials and also the types of quality, nonclinical and clinical data expected by the MFDS for regulatory review. Last but not least, we will take a look at the programs in place at the MFDS to support the commercialization of EV therapy products.



Jun Park

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Educational
Background &
Professional
Experience

2020-Present	ILIAS Biologics	CTO/EVP
2017-2019	Helixmith Co.	SVP/Head of CMC
2006-2017	FDA/CDER/Office of Biotechnology Products	CMC Reviewer
1999-2006	US Department of Defense, ECBC	Biochemical Engineer
1989-1999	Alpha-Beta Technology Inc.	Group Leader
1983-1989	Worcester Polytechnic Institute	Ph.D., Biochemical Engineering
1977-1979	KAIST	M.S., Chemical Engineering
1973-1977	Yonsei University	B.S., Chemical Engineering

Research
Interests

Drug development for biologics, Regulatory strategy, CMC development

List of Major
Publications

1. So-Hee Ahn, Seungwook Ryu, Hojun Choi, Sangmin You, Jun Park, Chulhee Choi, "Manufacturing Therapeutic Exosomes: from Bench to Industry," Mol. Cells, 45(5): 284-290, 2022
2. Sarah Rogstad, Anneliese Faustino, Ashley Ruth, David Keire, Michael Boyne, Jun Park, "A Retrospective Evaluation of the Use of Mass Spectrometry in FDA Biologics License Applications," J. American Society of Mass Spectrometry, Nov. 2016
3. Bo Chi, Julia Edwards, Jun Park, Stefanie Pluschkell, Nancy Waites, Elizabeth Yamashita, Siddharth Advant, and Wassim Nashabeh, with Lorna D. McLeod, "Multiproduct Facility Design and Control for Biologics: Challenges and Considerations," BioProcess Int., 10: 48-53, 2012
4. Joseph Siemiatkoski, Stacey Ma, Jun Park, Kurt Brorson, and Patrick Swann, "Glycosylation of Therapeutic Proteins: Current Understanding of Structure-Function Relationships," BioProcess Int., 9: 48-53, 2011
5. E.K. Read, J.T. Park, R.B. Shah, B.S. Riley, K.A. Brorson, A.S. Rathore, "Process Analytical Technology (PAT) for Biopharmaceutical Products: Part I. Concepts and Applications," Biotechnology & Bioengineering, 105 (2): 276-84, 2009
6. E.K. Read, R.B. Shah, B.S. Riley, J.T. Park, K.A. Brorson, A.S. Rathore, "Process Analytical Technology (PAT) for Biopharmaceutical Products: Part II. Concepts and Applications," Biotechnology & Bioengineering, 105 (2): 285-295, 2009

Potential and Application of Exosome-based
Intracellular Delivery of Therapeutic Proteins

Jun Park, Ph.D.

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As extracellular vesicles that play an active role in intercellular communication by transferring cellular materials to recipient cells, exosomes offer great potential as a natural therapeutic drug delivery vehicle. Currently, both academia and industry try to develop exosome platform - based therapeutics for disease management, some of which are already in clinical trials. An opto-genetically engineered exosome system (EXPLOR®) that we previously developed was implemented for loading therapeutic cargo into exosomes which can deliver therapeutic cargos into target cells in free form. We are studying the clinical potential of therapeutic exosomes with EXPLOR technology in multiple disease areas including inflammatory diseases. For targeted delivery, exosomes have natural tropisms specific to certain tissues and cells depending on their mother cell line. On the other hand, it can also mean that you may not deliver to a specific target of your interest if exosomes are not naturally distributed in that tissue. To overcome this problem and increase the versatility of exosomes, we are developing exosome surface engineering technology (Exo-Target®) for targeting moiety displaying. Exosomes are a very stable drug delivery tool because they maintain their physical structure under various conditions and keep protein cargoes safely in the bloodstream. However, for actual commercialization, scalable production and quality control steps are crucial. We successfully established industry-level production of cGMP-grade exosomes with acceptable QC attributes ready for pre-clinical and clinical trials (Pure-Exo®).



Jisuk Choi

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Educational
Background &
Professional
Experience

2016-Present	Exostemtech, Inc.	Director of Research Institute
2016-2019	Hanyang University	Research Professor
2011-2015	Hanyang University	Postdoctoral Researcher

Research
Interests

Exosomes, Extracellular vesicles, Stem cells, Regenerative medicine

List of Major
Publications

1. Lee KS, et al. Extracellular vesicles from adipose tissue-derived stem cells alleviate osteoporosis through osteoprotegerin and miR-21-5p. Journal of Extracellular Vesicles 2021;10:e12152
2. Woo CH, et al. Small extracellular vesicles from human adipose-derived stem cells attenuate cartilage degeneration. Journal of Extracellular Vesicles 2020;9:1735249
- 3.. Jung YJ, et al. Cell reprogramming using extracellular vesicles from differentiating stem cells into white/beige adipocytes. Science Advances 2020;6:eaay6721
4. Choi JS, et al. Functional recovery in photo-damaged human dermal fibroblasts by human adipose-derived stem cell extracellular vesicles. Journal of Extracellular Vesicles 2019;8:1565885
5. Choi JS, et al. Exosomes from differentiating human skeletal muscle cells trigger myogenesis of stem cells and provide biochemical cues for skeletal muscle regeneration. Journal of Controlled Release 2016;222:107-115

Development of stem cell
exosome-based therapeutics

Ji Suk Choi

ExoStemTech Inc, Ansan, Gyeonggi-do 15588, Republic of Korea

Exosomes are nano-sized vesicles involved in the paracrine effects of mesenchymal stem cells (MSCs). Exosomes contain cytosolic proteins, lipids, and genetic factors and they have therapeutic functions like those of their parent stem cells. MSC exosomes are attracting attention as novel cell-free therapeutics that have advantages over parental stem cells. Currently, academia and industry try to develop MSC exosome - based therapeutics in diverse disease areas and several clinical trials are ongoing in USA and abroad. Exostemtech is developing therapeutics using stem cell-derived exosomes for the treatment of various diseases. As the first pipeline, Exostemtech is developing ‘CARTISOME’, a treatment candidate for osteoarthritis, and has applied for an IND to the MFDS in April 2022 for a clinical trial. In this presentation, I would like to briefly introduce the development process of CARTISOME for the treatment of osteoarthritis and discuss strategies in the requirements including efficacy, safety, manufacturing, and quality to be considered when developing MSC exosome-based therapeutics.



Junhyuk YOO

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Educational
Background &
Professional
Experience

N/A

Research
Interests

N/A

List of Major
Publications

N/A

Generic Exosome “Blue Print” Scalable,
Flexible and Reliable Solutions to Simplify
Your Extracellular Vesicle Process

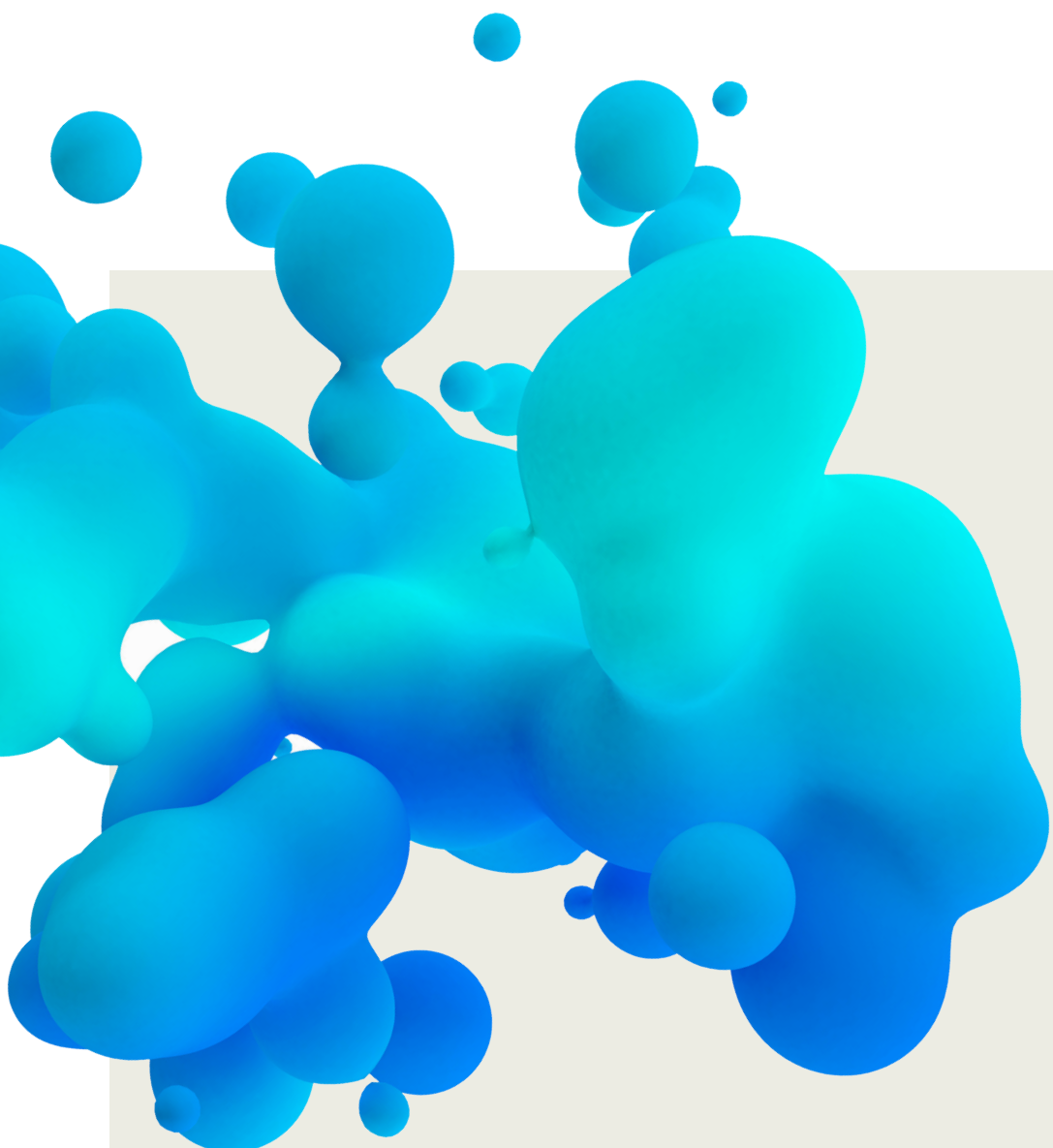
Junhyuk YOO

Sartorius Korea Biotech

The global exosomes market size is expected to reach USD 2.28 billion by 2030, according to a new report by Grand View Research, Inc., exhibiting a CAGR of 18.8% during the forecast period. Nanovesicles, which play a major role in intercellular communication, are anticipated to witness a significant rise in R&D, thus leading to revenue growth in the coming years. Application of these vesicles as carriers of functional content such as circulating nucleic acids, lipids, and proteins can be attributed to market growth. In addition, exosomes play an important role in immunosurveillance and tumor pathogenesis. Increasing research programs focusing on determining the role of exosomes in hepatocellular carcinoma (HCC) is estimated to drive the market. However, as of 2022, there is no clear production solution for EVs. We will take this opportunity to find out a solution that can become a blueprint for future EV-related production and to think about its application together.

Session 2

EV Isolation & Theragnostics



Scalable mass production of Gram-negative bacterial outer membrane vesicles for the next-generation cancer immunotherapeutic agents

고용승 로제타엑소좀



Microbial EV therapy for the treatment of CNS disorders

김윤근 엠디헬스케어



The Art of Exosome-based Liquid Biopsy

백세환 솔바이오



Yong Song Gho

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Educational Background & Professional Experience

2004-Present	Department of Life Sciences, POSTECH	Professor
2017-Present	Rosetta Exosome, Co., Ltd	Founder & CEO
2019-Present	Asian Pacific Societies for Extracellular Vesicles	President
2018-2019	Korean Society for Extracellular Vesicles	President
2015-2018	Department of Internal Medicine and Clinical Nutrition, University of Gothenburg, Gothenburg, Sweden	Guest Professor
2014-2016 2012-2014	International Society for Extracellular Vesicles	Executive Chair of Education
2012-2018	Journal of Extracellular Vesicles (2020 Impact factor=25.841)	Editors-in-Chief
1991-1997	University of North Carolina, Chapel Hill, North Carolina, USA	Ph.D. in Biochemistry and Biophysics

Research Interests

Extracellular vesicles (EVs), Exosome, Outer membrane vesicles (OMVs), Exosome
Mimetics

List of Major Publications

1. Extracellular vesicles from in vivo liver tissue accelerate recovery of liver necrosis induced by carbon tetrachloride. Lee, J, Kim, S R, Lee, C, Jun, YI, Bae, S, Yoon, YJ, Kim, O*, Gho, YS. *Journal of Extracellular Vesicles*, 2021;10, e12133

2. Quantitative proteomic analysis of trypsin-treated extracellular vesicles to identify the real-vesicular proteins. Choi D*, Go G, Kim DK, Lee J, Park SM, Di Vizio D, Gho YS. *Journal of Extracellular Vesicles*, 2020;9(1): 1757209

3. Indoor dust extracellular vesicles promote cancer lung metastasis by inducing tumor necrosis factor- α . Dinh NT, Lee J, Lee J, Kim SS, Go G, Bae S, Jun YI, Yoon YJ, Roh TY, Yong Song Gho YS. *Journal of Extracellular Vesicles*, 2020;9(1):1766821

4. Bacterial outer membrane vesicles suppress tumor by interferon- γ -mediated antitumor response. Kim OY, Park HT, Dinh NTH, Choi SJ, Lee J, Kim JH, Lee SW, Gho YS. *Nature Communications*. 2017;8(1):626

5. EVpedia: a community web portal for extracellular vesicles research. Kim DK, Lee J, Kim SR, Choi DS, Yoon YJ, Kim JH, Go G, Nhung D, Hong K, Jang SC, Kim SH, Park KS, Kim OY, Park HT, Seo JH, Aikawa E, Bai-Krzyworzeka M, van Balkom BW, Belting M, Blanc L, Bond V, Bongiovanni A, Borràs FE, Buée L, Buzás EI, Cheng L, Clayton A, Cocucci E, Dela Cruz CS, Desiderio DM, Di Vizio D, Ekström K, Falcon-Perez JM, Gardiner C, Giebel B, Greening DW, Gross JC, Gupta D, Hendrix A, Hill AF, Hill MM, Nolte- τ Hoen E, Hwang DW, Inal J, Jagannadham MV, Jayachandran M, Jee YK, Jørgensen M, Kim KP, Kim YK, Kislinger T, Lässer C, Lee DS, Lee H, van Leeuwen J, Lener T, Liu ML, Lötvall J, Marcilla A, Mathivanan S, Möller A, Morhayim J, Muller F, Nazarenko I, Nieuwland R, Nunes DN, Pang K, Park J, Patel T, Pocsfalvi G, Del Portillo H, Putz U, Ramirez MI, Rodrigues ML, Roh TY, Royo F, Sahoo S, Schiffelers R, Sharma S, Siljander P, Simpson RJ, Soekmadji C, Stahl P, Stensballe A, Stepień E, Tahara H, Trummer A, Valadi H, Vella LJ, Wai SN, Witwer K, Yáñez-Mó M, Yoon H, Zeidler R, Gho YS. *Bioinformatics*. 2015;31(6):933-9

6. Bioinspired exosome-mimetic nanovesicles for targeted delivery of chemotherapeutics to malignant tumors. Jang SC, Kim OY, Yoon CM, Choi DS, Roh TY, Park J, Nilsson J, Lötvall J, Kim YK, Gho YS. *ACS Nano*. 2013;7(9):7698-710

7. Gram-positive bacteria produce membrane vesicles: proteomics-based characterization of Staphylococcus aureus-derived membrane vesicles. Lee EY, Choi DY, Kim DK, Kim JW, Park JO, Kim S, Kim SH, Desiderio DM, Kim YK, Kim KP, Gho YS. *Proteomics*. 2009;9(24):5425-36

8. Extracellular membrane vesicles from tumor cells promote angiogenesis via sphingomyelin. Kim CW, Lee HM, Lee TH, Kang C, Kleinman HK, Gho YS. *Cancer Research*. 2002;62(21):6312-7.

Scalable mass production of Gram-negative bacterial outer membrane vesicles for the next-generation cancer immunotherapeutic agents

Jaemin Lee¹, Changjin Lee¹, Solchan Won³, Sunghyun Song¹, Seoyoon Bae², Jaewook Lee¹,
Tae Ryong Lee¹, Dong-Sup Lee³, Yong Song Gho^{1,2}

¹Rosetta Exosome Co. Ltd., Seongnam, Republic of Korea,

²Department of Life Sciences, POSTECH, Pohang, Republic of Korea,

³Department of Biomedical Sciences, Seoul National University College of Medicine,
Seoul, Republic of Korea

For intercellular and interkingdom communication, both Gram-negative and Gram-positive bacteria actively released extracellular vesicles (EVs) into extracellular milieu. Recently, our group discovered that Gram-negative and Gram-positive bacterial EVs have potent anti-tumor activities by inducing a sustainable anti-tumor immune response in several mouse tumor models (Kim et al. 2017). However, it is difficult to produce large quantities of bacterial EVs for pre-clinical studies and clinical trials. This study aims to develop manufacturing processes for scalable mass production of *Escherichia coli* EVs, known as outer membrane vesicles (OMVs) and to investigate the in vivo anti-tumor activities of *E. coli* OMVs in mouse tumor model. *E. coli* was grown in bioreactors and OMVs were isolated by the combination of tangential flow filtration and size exclusion chromatography. Purified *E. coli* OMVs were characterized by protein amount, number, size, morphology, and outer membrane protein A (Omp A). For in vivo anti-tumor activities, *E. coli* OMVs were injected twice a week in tumor-bearing mice for 2 weeks, and tumor volume was measured every 3-4 days. To evaluate adverse effects, *E. coli* OMVs were injected and monitored the body weight and survival rate. Using a 200-liter scale bioreactor, we isolate large quantities of *E. coli* OMVs with high purity: 2.2 mg in total protein amounts and 2.5×10^{12} particles of OMVs were isolated from one liter of the conditioned media. The purified OMVs were spherical morphology limited by lipid bilayer, 20 nm in a diameter, and enriched with Omp A (a well-known OMV marker protein). Furthermore, the purified *E. coli* OMVs showed a dose-dependent anti-tumor activities in mouse bladder cancer model. Treatment of 0.5 μ g *E. coli* OMVs/head caused not only complete regression of tumor growth but also completely block the tumor growth of re-challenged bladder cancer cells by inducing long-term anti-tumor memory effects. We also observed that no mice were dead after administration of 10 μ g and 30 μ g of *E. coli* OMVs: the mice administered with OMVs showed temporal loss of body weights, but they gradually gained body weights from a week after OMV treatment. This study shows that Gram-negative bacterial OMVs can be produced in a large amount with high purity, and have potent anti-tumor activities with a wide therapeutic window, suggesting that Gram-negative bacterial OMVs are novel candidates for the development of next-generation cancer immunotherapeutic agents.



Yoon-Keun Kim

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Educational
Background &
Professional
Experience

2014-Present	MD Healthcare Inc	CEO
2014-2015	Ewha University Hospital	Professor
2006-2014	POSTECH	Professor
1999-2014	SNU College of Medicine	Professor
1995-1997	SNU College of Medicine	PhD
1993-1995	SNU College of Medicine	MS
1983-1987	SNU College of Medicine	MD

Research
Interests

- Pathogenesis of intractable diseases
- Microbial EV therapy
- Precision medicine using microbiome data

List of Major Publications

1. Jinho Yang, Tae-Seop Shin, Jong Seong Kim, Young-Koo Jee, Yoon-Keun Kim. A new horizon of precision medicine: combination of the microbiome and extracellular vesicles. *Exp Mol Med*. 2022 Apr;54(4):466-482

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Microbial EV therapy
for the treatment of CNS disorders

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Over several decades, the disease pattern of intractable disease has changed from acute infection to chronic disease accompanied by immune and metabolic dysfunction. In addition, scientific evidence has shown that humans are holobionts; of the DNA in humans, 1% is derived from the human genome, and 99% is derived from microbial genomes (the microbiome). Extracellular vesicles (EVs) are lipid bilayer-delimited nanoparticles and key messengers in cell-to-cell communication. Many publications indicate that microbial EVs are both positively and negatively involved in the pathogenesis of various intractable diseases, including neurological diseases. Microbial EV therapies are a smart drug that can easily penetrate the gut mucosal barrier, readily interact with gut immune cells, and distribute to brain, giving them great therapeutic potential for the treatment of intractable CNS disorders, such as autism spectrum disorder (ASD), Alzheimer’s disease (AD), and Parkinson’s disease (PD).



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Educational Background & Professional Experience

2021-Present	SOL Bio Corporation	Founder, President, CEO
1994-2020	Korea University	Professor
2006-2007	The Korean Biochip Society	Founder, President
1992-1994	Biotech Research Institute, LG Chem	Research Scientist
1986-1991	The University of Michigan, Ann Arbor	Ph.D. in Bioengineering

Research Interests

- Isolation of exosome in subpopulations
- Exosome-based liquid biopsy for early diagnosis of cancer
- Point-of-care immuno-diagnostic kits and devices
- Bioconjugation and protein immobilization

List of Major Publications

1. Da-Yeon Choi, Ji-Na Park, Sung-Ho Paek, Seung-Cheol Choi, Se-Hwan Paek. (2022) Detecting early-stage malignant melanoma using a calcium switch-enriched exosome subpopulation containing tumor markers as a sample. *Biosensors and Bioelectronics* 198, 113828.
2. Jin-Ha Choi, Joungpyo Lim, Minkyu Shin, Se-Hwan Paek, Jeong-Woo Choi. (2021) CRISPR-Cas12a based nucleic acid amplification-free DNA biosensor via Au nanoparticle-assisted metal-enhanced fluorescence and colorimetric analysis. , 693-699.
3. Se-Hwan Paek. (2020) Real-time Monitoring of Biomarkers: Current Status and Future Perspectives. *Biochip J.* 14, 1-1.
4. Dong-Hyung Kim, Il-Hoon Cho, Ji-Na Park, Sung-Ho Paek, Hyun-Mo Cho, Se-Hwan Paek. (2017) Semi-continuous, real-time monitoring of protein biomarker using a recyclable surface plasmon resonance sensor. *Biosensors and Bioelectronics* 88, 232-239.

The Art of Exosome-based Liquid Biopsy

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Exosomes have received attention as biomarkers for liquid biopsy. Exosomes are released in the form of microvesicles from human cells and reflect the characteristics of the original cells. In practice, different analytical products targeting components (e.g., proteins and RNAs) present in exosomes as biomarkers have been developed or are currently being developed for early diagnosis and companion diagnostics of cancer. However, since exosomes derived from all cells exist in a mixed state in body fluids, there is a limitation in accurately diagnosing specific diseases such as cancer using a bulk population of exosome samples separated from body fluids. Moreover, the concentration of exosomes derived from specific disease-associated cells in body fluids is relatively very low particularly in the early stage of disease onset. Isolation and enrichment of target exosomes from body fluids are, therefore, prerequisites for early diagnosis. Although many techniques for exosome isolation are known, we have developed a technology in an effort to solve problems that are inherent in currently available isolation products. One aspect of the development is to provide a technique for sequential immunoaffinity isolation under mild conditions. Here, a subpopulation, a sub-subpopulation or a subset thereof containing exosomes associated with the specific disease in a body fluid is separated and recovered intact in high yield and is used as a liquid biopsy sample. The technique can also provide a sample containing target exosomes to discover biomarkers such as specific disease-associated proteins and nucleic acids present in the target exosomes. In this presentation, we introduce a novel technology using a reversible linker that enables an exosome recovery without damage after isolation and demonstrate its practical applications to early diagnosis of cancers as an example.

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