

2018 KSBB International Academia-Industry Joint Meeting
2018 한국생물공학회 추계국제학술대회 및 산학협력심포지엄

Corporate Special Sessions

기업 특별 세션

2018년 10월 10일 ~ 11일 서울 세종대학교 컨벤션센터



한국생물공학회
THE KOREAN SOCIETY FOR
BIOTECHNOLOGY AND BIOENGINEERING

Corporate Special Session

| 휴먼 마이크로바이옴 |

2018.10.10 16:35-18:20



| 화장품 |

2018.10.11 09:15-11:00



| 바이오의약 |

2018.10.11 14:00-15:45



| 생물 공정 |

2018.10.11 16:00-17:45



Innovations and Global Business of Biopharmaceuticals

October 11(Thursday), 2018 14:00-15:45

Organized by KSBB Enzyme and Protein Engineering Division

Sponsored by Biomedical Manufacturing Technology Center

Biopharmaceuticals became the core of the pharmaceutical industry with the fastest growth rate. Biopharmaceuticals are among the most sophisticated and elegant achievements of biotechnology. With four outstanding companies, we will witness how the innovations in biotechnology could be transformed into global business.

| 14:00-14:30 |

Competitiveness of Samsung Bioepis in the biosimilar business area

Vice President, Yongkook Kim

Samsung Bioepis 삼성바이오에피스



| 14:30-14:55 |

Process development for large-scale ex-vivo expansion of allogeneic natural killer cells in stirred-tank bioreactor

Head of Process Unit, Sang Hoon Paik

GC LabCell Cell Therapy Research Center Process Unit GC녹십자랩셀 세포치료연구소



| 14:55-15:20 |

INVOSSA[®]-K: Innovative Cell and Gene Therapy for Osteoarthritis

Director, Heonsik Choi

Kolon Life Science / Bioinnovation Center 코오롱 생명과학(주) 바이오신약 연구소



| 15:20-15:45 |

Development of Beta-Glucan Production Technology by Fermentation and Pharmaceuticals

CEO, Jongdae Lee

Quegen Biotech 큐젠바이오텍



■ Chair : Prof. Dae-Hyuk Kweon (Sungkyunkwan University)

Competitiveness of Samsung Bioepis in the biosimilar business area



Yongkook KIM

DP team, Samsung Bioepis

Biosimilars are biologic medicines that have been tested and determined to be highly similar to a reference biologic, in that there are no clinically meaningful differences related to safety, purity and potency notwithstanding minor differences in clinically inactive components. Since its establishment in February 2012, Samsung Bioepis has been committed to increasing patient access to high-quality medicines through the development of biosimilars. From cell line generation through clinical development, Samsung Bioepis has implemented high quality standards at every step. This means Samsung Bioepis employs the latest analytical techniques for physicochemical and functional analyses, while using comprehensive control strategies and real-time monitoring to ensure consistency throughout the manufacturing process. By doing so, Samsung Bioepis is able to develop biosimilars that target a broad spectrum of diseases. Biogen and Merck, which is known as MSD outside of the United States and Canada, are responsible for commercializing Samsung Bioepis' products in designated territories worldwide following approval. Samsung Bioepis is advancing an extensive pipeline of biosimilar candidates that cover unmet patient need. The initial six biosimilar candidates are focused on immunology, oncology and metabolic diseases. In this session, it will be presented for competitiveness of Samsung Bioepis in the biosimilar business area.

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Process development for large-scale ex-vivo expansion of allogeneic natural killer cells in bioreactor



Sang Hoon Paik

Cell Therapy Research Center, GC LabCell

GC LabCell (GCLC) is a biotechnology company newly established in July 2011 based on cord blood and stem cell banking, clinical laboratory services, and cell therapy business that GC Pharma (Green Cross Corporation) strategically focuses its energies on. We will continue to concentrate our effort on these core business areas to become a global leader of cell therapy for the healthier life of mankind.

GCLC matured Natural Killer (NK) cell-based platform so that Phase I clinical trial was completed in 2012 in Korea while its manufacturing facility is fully compliant with GMP guideline. Current MG4101, ex vivo-expanded allogenic NK cell, are on the way of Phase II trials for the patients in Korea. GCLC is committed to pioneering NK cell-based next generation adoptive cellular immunotherapy for the treatment of cancers.

NK cell has been considered an attractive candidate for cancer therapy. Peripheral blood shows the low frequency of NK cells, so ex vivo expansion method is important to obtain sufficient NK cells for therapeutic use. Current NK cell culture protocol using static bags or tissue culture flasks is labor intensive process and is hard to scaled-up because a lot of bags or flasks for mass production are required. Stirred-tank bioreactor could be considered as optimal alternative system for large-scale NK cell expansion compared with other ones because it is automated, less labor intensive, scalable, well-controlled and cost-effective. For that reason, we have developed bioreactor processes using flasks, mini-scale bioreactors and small-scale bioreactors with statistical design and further developed to manufacturing-scale.

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INVOSSA[®]-K: Innovative Cell and Gene Therapy for Osteoarthritis



Heonsik Choi

Kolon Life Science / Bioinnovation Center

INVOSSA[®]-K is a novel cell and gene therapy for OA, administered by an intra-articular injection. It consists of a mixture of human allogeneic chondrocytes and genetically modified chondrocytes expressing TGF- β 1 in a ratio 3:1. Clinical trials demonstrated that INVOSSA[®]-K improved pain and function, and possibly the cartilage structure in OA patients. However, underlying mechanisms have not been investigated. Using a MIA model, we explored whether INVOSSA[®]-K influenced the symptoms and inflammatory profile of OA knee joints.

Pain relief was noted on Day 7 and maintained until the end of the observation period after treatment. In addition, structure improvement was also observed. Cytokine expression profiles showed that the level of IL-10, an anti-inflammatory cytokine, was increased in synovial fluid after 4 days of treatment. Furthermore, INVOSSA[®]-K increased the expression of arginase 1, a marker of M2 and decreased the CD86, a marker of M1.

These results suggest that INVOSSA[®]-K induces a M2 dominant environment which may be the underlying mechanisms for the improvement of pain and potential structure improvement noted in OA patients in clinical trials.