Programme: the Korean ISCBI Symposium and Workshop, 24th – 25th September, 2019.

Local organiser in Seoul/Pangyo: Professor Jihwan Song (CHA University)

Local organisers in Osong: Dr Lydia Koo and Dr Jung-Hyun Kim (KNIH)

Please note the 2019 ISSCR/KSSCR International Symposium KSSCR/ISSCR meeting is 26-27th Sept (from 8am 26th, ending on 27th at 6pm followed by a reception), to be held at the Grand Hilton Hotel Seoul. For registration, please visit www.ksscr.org .

The 2nd ISCBI Symposium in Korea on *Pluripotent Stem Cell Quality Control and Banking for Clinical and Research Applications*

CHA Bio Complex, Pangyo/Seoul, 24th September, 2019

ISCBI Workshop on *Management of Stem Cell Data, Genetic Testing of hPSC Lines and Cost of Goods Considerations for hPSC Banking.*

KNIH and Korean Biobank Campus, Osong, 25th September, 2019

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For detailed programmes see pages 2-3 or go to www.iscbi.org

The 2nd ISCBI Symposium in Korea on *Pluripotent Stem Cell Quality Control and Banking for Clinical and Research Applications*

Co-organized by ISCBI, GAiT Korea and CHA University

24th Sept, 13.30-18.00h, CHA Bio Complex, Pangyo/Seoul.

13.00-13.50 Registration on site at CHA Bio Complex, Pangyo

13.50-14.00 Welcome and introduction. Jihwan Song, Professor, CHA University, Korea –

14.00-14.25 The KNIH programme for clinical use of hPSCs. Jung-Hyun Kim, National Center for Stem Cell and Regenerative Medicine, K-NIH, Osong, Korea.

14.25-14.50 Development of iPSCs in Japan, Yuji Arakawa, CiRA, Kyoto, Japan.

14.50-15.15, Stem cell standardization, Tong-Biaou Zhao, Institute of Zoology, Chinese Academy of Sciences, Beijing, China.

15.15-15.40 EBiSC European biobank of iPSCs for disease modelling. Heiko Zimmerman, EBiSC coordinator, Fraunhofer-IBMT, Sulzbach, Germany.

15.40-16.00 Coffee break

16.00-16.25 GAiT programme for haplobanked iPSCs. Stephen Sullivan, GAiT International Liaison Officer, Edinburgh, UK.

16.25-16.50 *Title to be confirmed.* Uma Lakmishpathy, Thermo Fisher Scientific.

16.50-17.15 *Title to be confirmed*. Shin Kawamata, Foundation for Biomedical Research and Innovation (FBRI), Kobe, Japan.

17:15-17: 35 *Title to be confirmed* Chang Pyo Hong, Theragen Etex Bio Institute, Korea (20 min)

17.35-18.00 hPSCs for treatment of Age-related Macular Degeneration. Kapil Bharti, NIH, Washington DC, USA.

18.00-18.10 Concluding remarks and outline for day 2 workshop, Glyn Stacey, International Stem Cell Banking Initiative, Cambridge, UK.

18.30- Networking reception

For Day 2 Workshop Programme in Osong, see page 3-4 below (or go to www.iscbi.org) .

ISCBI Workshop on *Management of Stem Cell Data, Genetic Testing of hPSC Lines and Cost of Goods Considerations for hPSC Banking.*

25th Sept ISCBI Workshop, KNIH and Korean Biobank Campus, Osong

08.00 Departure from Seoul and Pangyo by separate buses: One from Seoul centre and one from Pangyo (Courtyard Marriot hotel) both by KNIH organised bus - Travel time expected to be around 1h20min (details of departure points/times to be confirmed).

10.00am Delegates gather at KNIH (**Please note**: photographs will be taken of delegates and speakers may be recorded during the meeting. Please let us know if you would prefer not to have your photograph appear on the ISCBI website and newsletter)

10.00-10.10, Welcome from KNIH Director Dr Lydia Koo, and coffee

10.10-10.30 Introduction to the Korean Biobank and tour of biomaterials processing and storage facilities, hosted by Dr.S-J Chou, Director Korean National Biobank, KNIH.

10.30-10.50 Introduction to the National Center for Stem Cell and Regenerative Medicine and the Korean National Stem Cell Bank and tour of facilities, hosted by Dr Jung-Hyun Kim (Deputy Director Korean National Stem Cell Bank, KNIH).

10.50-17.00 ISCBI Workshop, KNIH lecture theatre.

10.50-11.00 "Tour de table" of delegates and summary of ISCBI Virtual Updates Session (circulated by email). Glyn Stacey, ISCBI, UK.

11.00- 12.45 Session I: Research participant (donor) data.

Chairs Rosario Isasi, University of Miami, USA and Andreas Kurtz, Charite Universitatsmedizin Berlin, Germany.

Purpose of session: considerations for stem cell banks in the management of donor and cell line data including genetic data.

11.00-12.15 Introductory speakers (10min each) from different jurisdictions: Detailed questions will be recorded and deferred to the discussion period.

- Korean regulation on consent and genetic data. So Young Yoo, Asan Medical Center, Seoul, Korea.
- US requirements regarding cell donor data. Rosario Isasi, University of Miami, Miami, USA.
- EU GDPR and best practice in donor data management: models for best practice and impact of GDPR on hPSC collaborations with the EU. Rosario Isasi, University of Miami, USA.
- Japanese requirements for donor consent and data management, Mika Suzuki, CiRA, Kyoto, Japan.
- Experience at the Chinese Academy of Sciences with Chinese regulation of donor data. Yao-Jin Peng, Institute of Zoology, Chinese Academy of Sciences, Beijing, China.
- Experiences in hPSCreg in stem cell data management, Andreas Kurtz, Berlin-Brandenburg Center for Regenerative Therapies, Charité- Universitätsmedizin Berlin, Berlin, Germany.
- Japanese stem cell registry (SKIP) and international activities on integration (ICSCB) and QC (ICTAC) of cell data with MIACARM guidelines. Wataru Fujibuchi, CiRA, Kyoto University, Japan.

12.15-12.45 Open discussion on key areas of consenting procedures for hPSC applications in different countries and operation of stem cell banks under donor data protection regulations. Presentations and discussion will focus on the questions:

- What regulations apply to obtaining donor consent, donor personal data and the use of pluripotent stem cell lines?
- What kinds of donor data would be considered private and should be protected?
- What key requirements are applied for obtaining consent from donors of cells/tissues to be used in the derivation of stem cell lines?
- What requirements if any, apply to the collection, handling and sharing/dissemination of data from pluripotent stem cell lines and donor specific data including genetic data?

Other questions which may be addressed:

- What are the main approaches used for reconsenting in different countries?
- Feasibility of open consent?
- What types of donor data are considered to be sensitive and what are the key procedures to protect such data and avoid reidentification?
- Who owns genetic data and what are impacts for scientific publication?
- What common structures/systems are needed by stem cell banks to manage sensitive donor data, what guidance is available and how should it be used?
- Can we standardise donor genetic data: from donor identifiers to next generation sequencing?

12.45-13.15 Lunch and informal discussion

13.15-14.45 – Session II: Reagents and testing services for stem cell banks for manufacture of cell therapies.

Chairs Shin Kawamata, Kobe Medical Centre, Kobe, Japan and Glyn Stacey, ISCBI, UK and Beijing Stem Cell Bank, IOZ-CAS, Beijing, China.

Purpose of session: further development of perspectives on qualification of raw materials for hPSCs for cell therapy manufacture and new discussion on qualification of testing services

13.15-13.20 Summary from LA ISCBI workshop on qualification of reagents and methods for clinical stem cell lines. Glyn Stacey, ISCBI, UK.

13.20-13,40 Key note: Korean regulation of cell therapy and analytical methods. Dr Ho-Sang Jung, MFDS, Osong, Korea.

13.40-13.50 Assuring the quality of karyological testing, Koji Tajino, Chromocenter, Japan.

13.50-14.30 Open discussion on suitability of testing services for stem cell therapies including consideration of the following questions:

- What are the considerations for sensitivity, specificity, reproducibility of genetic testing techniques e.g., karyology, WGS, adventitious agents detection?
- What standards are applicable or needed for testing?
- What criteria should hPSC banks use for selection of external service providers?

- Other questions from workshop participants…?

14.30-14.45 – Coffee break

14.45 – 15.45. Session III: Cost of Goods considerations for production of hPSC for clinical use, Chair Jung-Hyun Kim, KNIH, Osong, Korea and Steve Oh BTI A*Star

Purpose of session: to consider the full costs of preparing hPSC banks for clinical development and additional costs to take them into clinical trials

14.45-14.55 Introduction to COGs evaluation for cellular therapies. Ohad Karnielli, ATVIO Biotech Ltd., Israel.

14.55-15.05 Presentation of results from COGs analysis in hPSC cell banks. Dr Jung-Hyun Kim, KNIH, Korea.

15.05-15.45 Open discussion: COGs for hPSC banking to address overall costs for each cell line to include consideration of:

- Sourcing cell lines or donor tissue
- Facility: construction/rent, validation, requalification, environmental monitoring and maintenance (cleaning, servicing etc.), staff time.
- Production of cell lines (staff, materials, equipment)
- Banking of cell lines (materials and disposables, local characterisation, QA and safety testing (include any expansion of cells in materials and staff), outsourced testing.
- Annual costs of storage (staffing/services, liquid nitrogen/electricity, tanks (cost/20 years), rental, outsourcing for back up storage)
- Cost development moving into NDA and clinical trials.

15.45-16.00 Conclusions and discussion on future plans for ISCBI conferences, Glyn Stacey, ISCBI.

16.00 Departure: Gather for KNIH organised bus to Pangyo and Seoul (KNIH Bus – travel time expected 1h.20mins to Pangyo Tollgate and drop-off in Seoul)

END