PERSPECTIVES FROM ISCT

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Cellicon Valley ‘21

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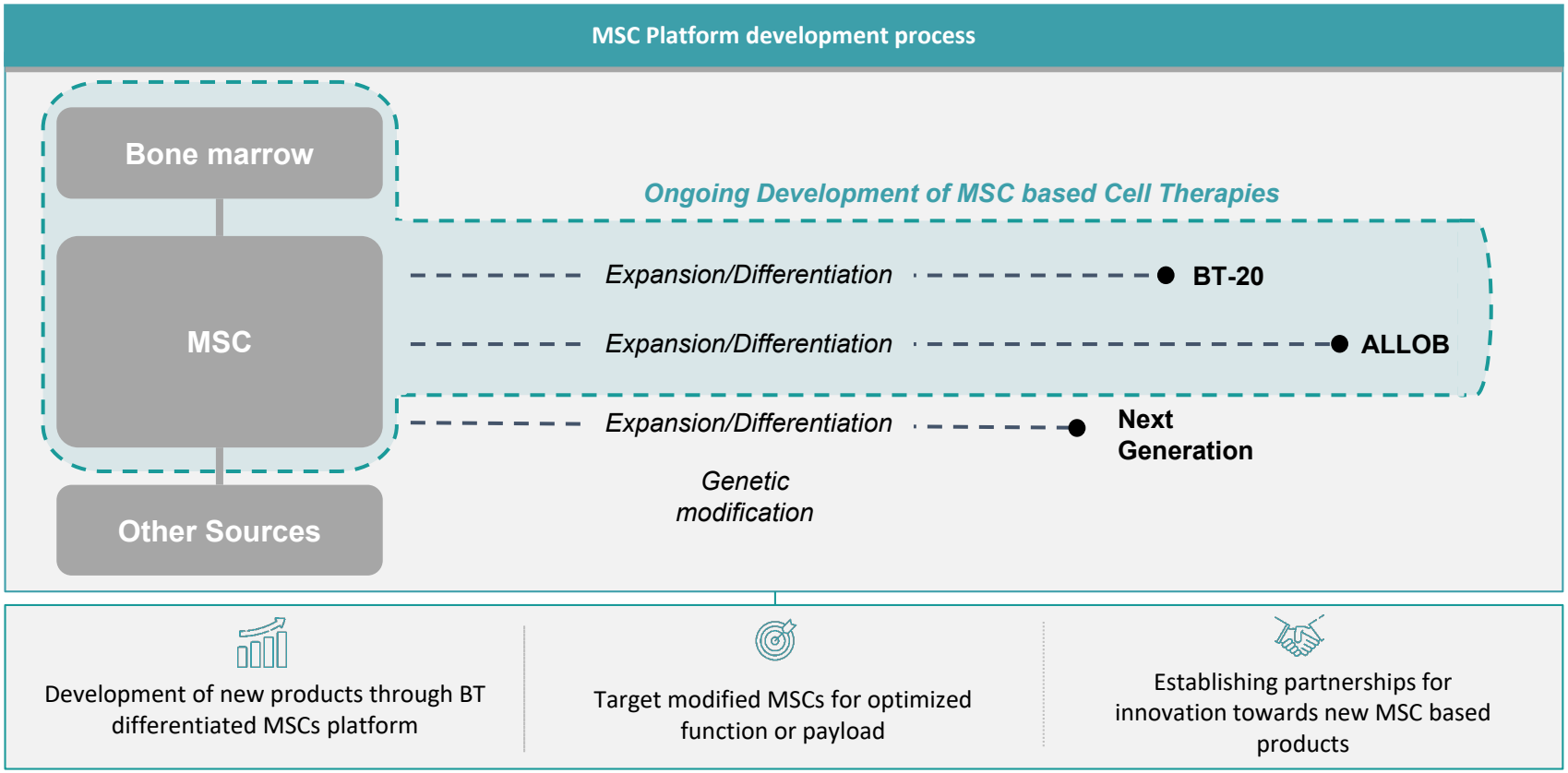
Leveraging MSC Platform Technology

Our vision is to become the preeminent cell therapy company by taking MSC therapies to the next level



Recent Partnerships

	LICENSING	MANUFACTURING	PROCESS DEVELOPMENT	RESEARCH
Partner	HG 领晟医疗 LINK HEALTH GROUP PREGENE	Catalent	RIGENERAND Steps Ahead In Cell Technology	3D-SIDE, BioWin, CERHUM, IREC UCLouvain, mSkill Liège
Deal	• **Exclusive license** to ALLOB and related IP and knowhow • **China**, Hong Kong, Macau, Taiwan, Singapore, **Thailand, South Korea**	• Catalent acquired Bone Therapeutics' cell therapy **manufacturing facilities** • Catalent will manufacture and supply **ALLOB**	• Collaboration focusing on **product and process development** for Bone Therapeutics' cell therapy products as they advance towards patients	• **Research Collaboration** for the development of patient-specific **scaffolds for use in combination with ALLOB**
Financials	• **€55 million in total** upfront and milestone payments plus tiered **double-digit royalties** on net sales	• **€12 million** in total payments to Bone Therapeutics		• **€3 million** in total grant funding from BioWin, the health cluster of the Wallonia Region (Belgium)
Notes	• **Link Health** and **Pregene** will conduct and finance development in Asia	• **Catalent** is a leading global CDMO for drugs, biologics, **gene therapies**, and consumer health products	• Potential for Bone Therapeutics to broaden its therapeutic targets and **explore new mechanisms of action with potential gene modifications** for its therapeutic portfolio	• The new **biocompatible scaffolds** will be modelled with state-of-the-art software and **3D printed**

These transactions reposition Bone Therapeutics around its focus on product and platform development

International Society
ISCT
Cell & Gene Therapy®

INTERNATIONAL SOCIETY FOR CELL & GENE THERAPY

Established in 1992, ISCT is the global society fostering cell and gene therapy translation to the clinic. The society is comprised of over 2,400 cell therapy experts across five geographic regions and from over 60 countries. ISCT members are part of a global community of peers, thought leaders and organizations invested in cell therapy translation.

ISCT leads the field in the translational aspects of developing cell-based therapeutics, advancing scientific research into innovative treatments for patients. ISCT has built a unique collaborative environment that advances three key areas of clinical translation: Academia, Regulatory and Commercialization. This has been achieved through long-term strategic relationships with global regulatory agencies, academic institutions, and industry partners internationally.

MORE INFO: WWW.ISCTGLOBAL.ORG

ISCT has co-founded two accreditation bodies:

Foundation for the Accreditation of Cellular Therapy (FACT), in partnership with the American Society for Transplantation and Cellular Therapy

FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

Joint Accreditation Committee – ISCT & EBMT (JACIE), in partnership with the European Society for Blood and Marrow Transplantation

JACIE Joint Accreditation Committee ISCT | EBMT

MISSION:

To improve lives through safe and effective cell and gene therapies.

VISION:

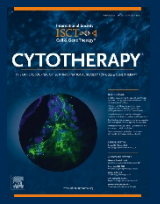
To drive clinical translation of cell and gene therapies worldwide.

VALUES:

- **Promote innovation in translational research**
- **Strive for excellence in everything we do**
- **Respect and support diversity and inclusivity**
- **Uphold the highest ethical standards**
- **Serve our members and advocate for our society**

ISCT Membership continues to maintain a consistent upwards trajectory across the globe

Cytotherapy, the official journal of ISCT, is a leading publication in the Cell and Gene Therapy sector, with a growing impact factor at 4.218



ISCT Global Initiatives

REGULATORY HARMONIZATION AND ADVOCACY

WORKING WITH THE WHO - INTERNATIONAL NONPROPRIETARY NOMENCLATURE

PUBLIC HEARING INQUIRY - AUSTRALIAN HOUSE OF REPRESENTATIVES

ISCT ANNUAL AND REGIONAL MEETINGS

Regulatory Consultation and Support

With the goal of building consensus within the cell and gene therapy sector, ISCT has developed several programs that help to build bilateral communications between regulatory bodies and industry/community stakeholders, and continues to provide consultation and support to regulatory bodies seeking advocacy from the field around the globe.

ISCT provides consultation and support to regulatory bodies seeking advocacy from the field around the globe, including:

- **United States Food & Drug Administration (FDA)**
- **Health Canada**
- **Australian Therapeutic Goods Administration (TGA)**
- **European Medicines Agency (EMA)**
- **World Health Organization (WHO)**
- **International Organization for Standardization (ISO)**

FDA Cell Therapy Liaison Meeting (CTLM)

Since 2004, ISCT has been the host coordinating up to 17 global stakeholder organizations in the annual FDA Cell Therapy Liaison Meeting (CTLM).

World Health Organization (WHO)

ISCT, has been chosen by the World Health Organization to publish a **landmark document on international nonproprietary nomenclature (INN)** in the Official Journal of the Society, *Cytotherapy ®*.

International Organization for Standardization (ISO)

ISCT is a **Category A Liaison** to the International Organization for Standardization and participates actively in ongoing CGT standards development.

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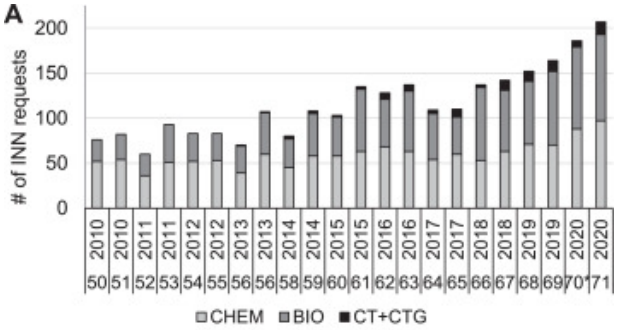
ISCT ANNUAL AND REGIONAL MEETINGS

Working with the World Health Organization

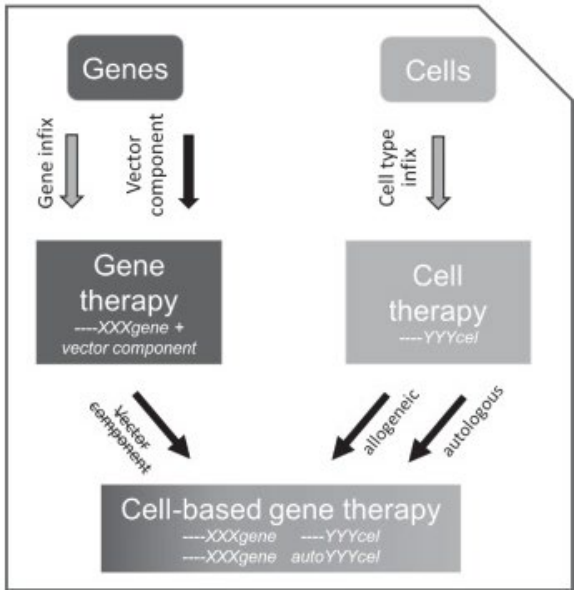
ISCT, as the leading global organization in cell and gene therapy translation, has been chosen by the World Health Organization to publish a **landmark document on international nonproprietary nomenclature (INN)** in the Official Journal of the Society, *Cytotherapy ®*.

This publication establishes the standard for harmonized naming standards, leading to more precise communication, especially for clinical and research settings, and fewer prescribing errors.

This development also provides a means for increased vigilance around pharmacovigilance, by establishing a recognizable standard for names in products that have passed official regulatory approvals.



Between 2010 and 2020, INN requests have steadily increased in the CGT space



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ISCT ANNUAL AND REGIONAL MEETINGS

Working with the Australian House of Representatives

ISCT is regularly called upon to work with regulatory agencies and policymakers to develop informed guidelines and standards in harmony with a global perspective.

Recently, the ISCT Australia and New Zealand Legal and Regulatory Affairs Committee was invited to attend an upcoming public hearing to be held by the Australian House of Representatives, as part of an inquiry into the Approval Processes for New Drugs and Novel Medical Technologies in Australia.

Within this capacity, ISCT will offer expert analysis and recommendations supporting the development of measures that can make Australia a more attractive location for clinical trials for new drugs and novel medical technologies, while simultaneously encouraging harmonization with global regulatory frameworks in relation to GMOs and Clinical Trials.

By working directly with policymakers on a global scale, ISCT works to ensure coordinated standards are maintained in the field, and to facilitate the safe and effective translation of novel cell and gene therapies.

Australian Government
Department of Health

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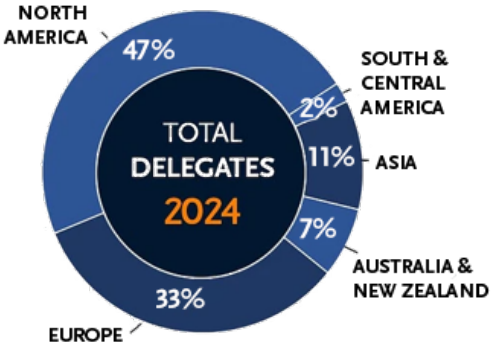
ISCT ANNUAL AND REGIONAL MEETINGS

ISCT2021 NEW ORLEANS MAY 26-28 VIRTUAL

Orchestrating Global CGT Translation: Building Consensus for the Path Forward

Jaap Jan Boelens, *MD, PhD*
Co-Chair
ISCT 2021 New Orleans Virtual
MSKCC

"As we begin the "new wave" of cell and gene therapies, initially these will be available to treat a limited number of rare conditions. By harmonizing eligibility criteria, endpoints, and monitoring standards, we will fast track successful CGT development."



The ISCT Annual Meeting is a key forum to build consensus for the path forward. The purpose of seeking consensus is not necessarily to endorse one approach as a field. In this context, seeking consensus is a decision to collaborate across the field to promote continued impactful research in light of rapid developments in all areas of CGT.

ISCT2021 NEW ORLEANS MAY 26-28 VIRTUAL

MAY 28-29 ISCT 2020 Paris VIRTUAL

2019 ISCT melbourne MAY 29–JUNE 1

ISCT 2018 Montréal · Canada · May 2-5

ISCT 2017 Annual Meeting | MAY 3 TO 6 | London, UK

isct2021.com