SCM Lifescience

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	[Website] http://www.scmlifescience.com

[Industry]
Biotechnology
[Business Domain]
Stem Cell Therapeutics
Research & Manufacturing
Contract Manufacturing
Cosmeceutical
Employees: 45

COMPANY PROFILE

SCM Lifescience is a research-based biopharmaceutical company focused on developing next-generation stem cell therapeutics for severe inflammatory immune diseases. It has a robust pipeline in clinical and pre-clinical stages based on its proprietary platform technologies in isolation and manufacturing. Through over 10 years of R&D, SCM Lifescience has obtained intellectual property protection for its high-purity stem cell isolation technology, subfractionation culturing method, in major markets including Korea, US, Japan, China and EU. Our globally patented technology serves to provide patients with high-homogeneity, high-efficacy, and low-cost stem cell therapies.

SCM-CGH is a clonal mesenchymal stem cell therapy for steroid refractory, chronic graft-versus-host disease (GvHD). Other products in clinical trials include SCM-AGH for acute graft-versus-host disease, SCM-AD for atopic dermatitis and SCM-AP for acute pancreatitis. Currently, SCM Lifescience is running four clinical trials from IIT to Phase II with two additional trials scheduled to initiate by 2019.

Additionally, our research focuses on the field of regenerative medicine for technological breakthroughs including the regeneration of hair, skin, cartilage, bone and other various tissues.

SCM Lifescience aims to build commercialization capabilities in global markets. It has strategic partnerships with Hitachi PCT and Merck in acquiring large-scale production capability using 3D bioreactor culture system. In addition to the existing area of stem cell therapeutic business, we are investing our efforts to develop cosmeceuticals for atopic dermatitis and alopecia patients.

BUSINESS AREAS

Our areas of businesses stretch from stem cell therapy to other related areas such as high-purity stem cell storage, contract manufacturing, contract research and consulting, and cosmeceuticals.

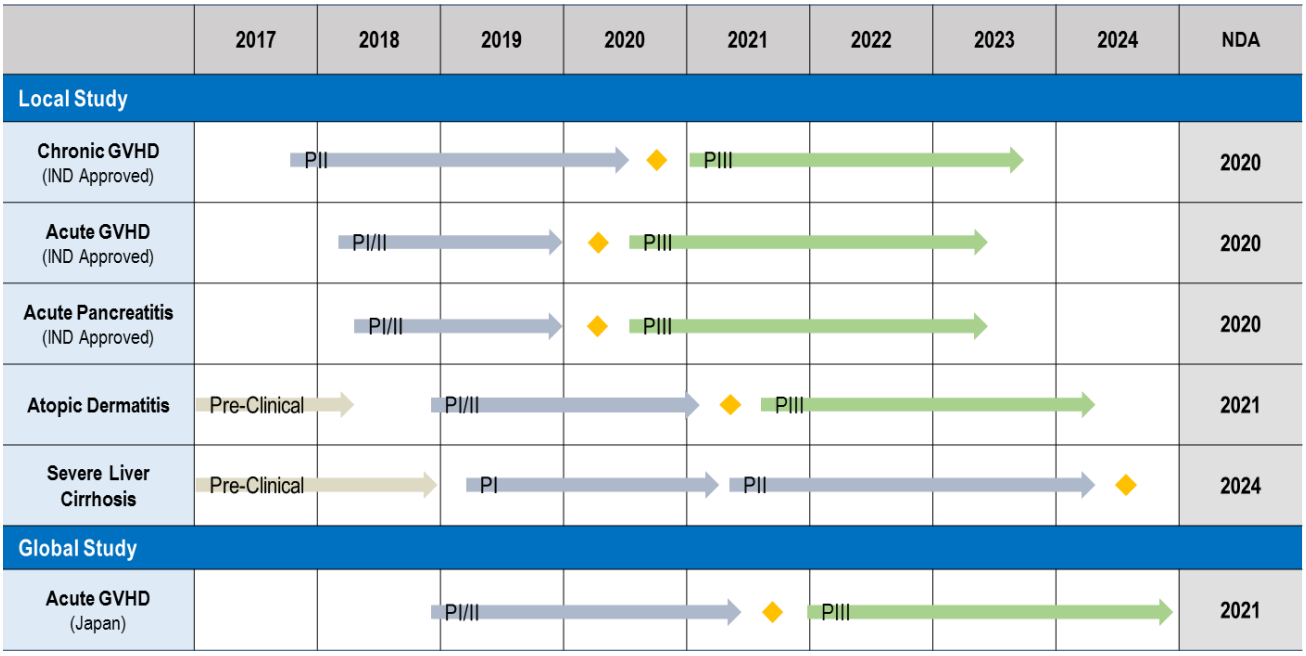
MANAGEMENT

- BG Rhee, Ph.D. CEO
  Chairman of CARM (Council for Advanced Regenerative Medicine), Korea
  Former Chairman of Korea BIO
  Former Vice Chairman of CKD Pharm
  Former President of Green Cross Corp
- Sun U. Song, Ph.D. Founder and CSO
  Professor at Inha University Medical College
  Director, Translational Research Center, Inha University

PRODUCT INTRODUCTION

SCM Lifescience has both fresh and frozen formulation products to meet the needs of patients; fresh cMSC product for chronic patients and frozen cMSC product for acute patients. All of our products utilize clonal MSCs isolated by subfractionation culturing method.

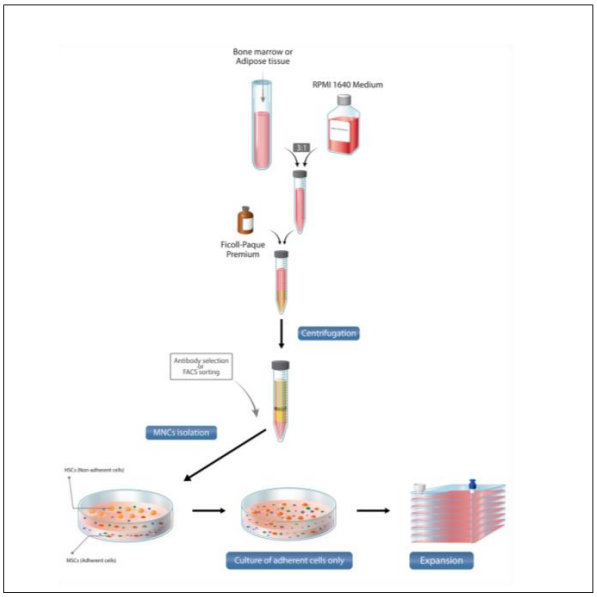
Our pipeline focuses on inflammatory immune diseases from chronic and acute GVHDs, acute pancreatitis, atopic dermatitis to liver cirrhosis.



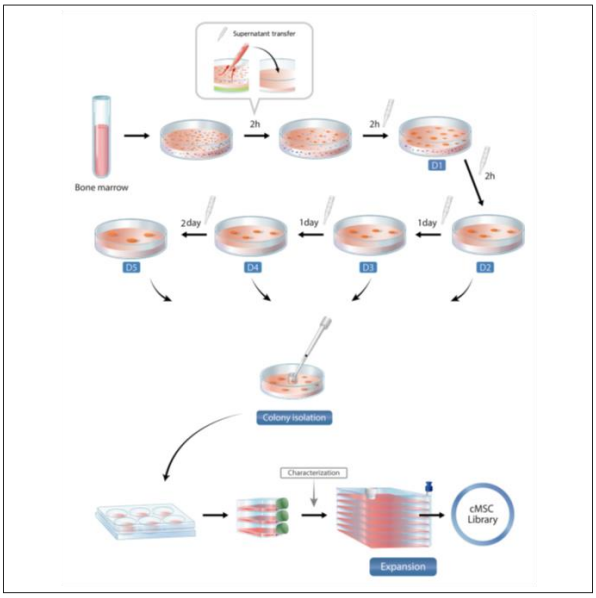
TECHNICAL HIGHLIGHTED SUMMARY

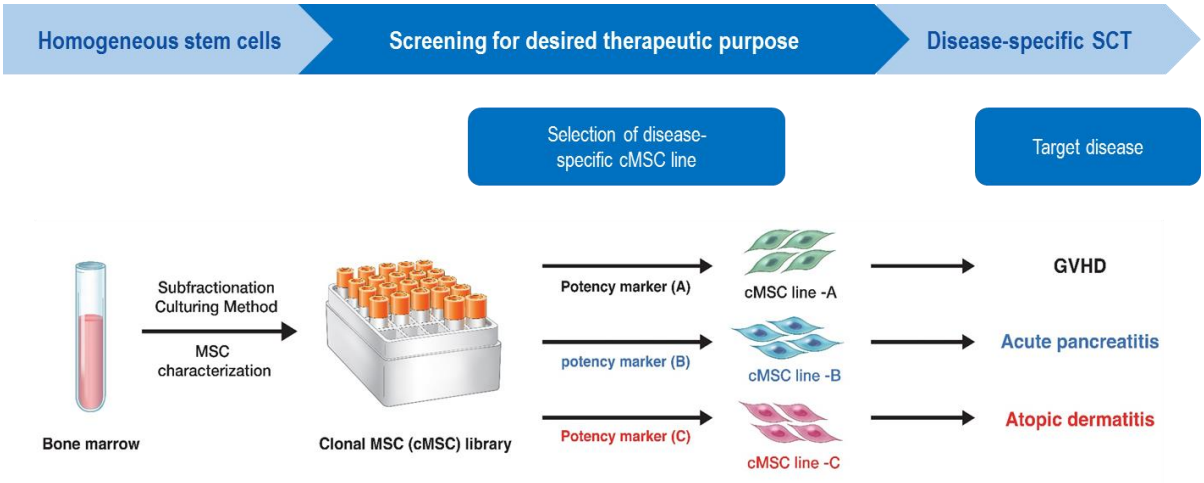
Conventional isolation method for mesenchymal stem cells is density-gradient centrifugation method (GCM) developed by Osiris Therapeutics. However, due to its concern for heterogeneity (non-stem cells mixed with MSCs), isolated MSCs have proven to be inevitably less efficacious in clinical settings. However, SCM Lifescience's proprietary, subfractionation culturing method, ensures production of highly homogenous population of MSCs by isolating and culturing **single cell-derived clonal mesenchymal stem cells**.

GCM (Existing Method)



SCM





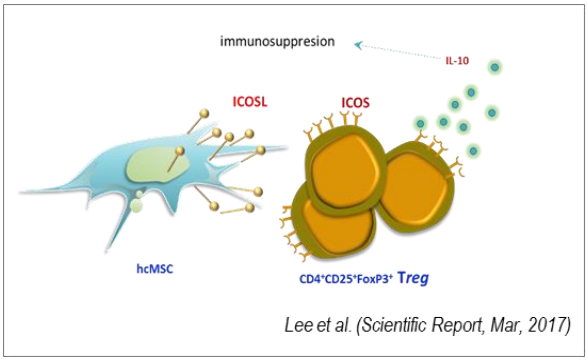
Some of key advantages of subfractionation culturing method are:

- Ability to screen and select healthy, homogenous clonal stem cells prior to manufacturing of drug products to enhance treatment efficacy.
- Possible selection of clonal stem cell line specific to target disease indication through potency marker development: cell surface marker expression and T cell suppressive assays.
- Fraction of raw material required for SCM method (1mL of BM for more than 50 patients) compared to the conventional isolation method (minimum 20mL of BM for single patient).
- Reduced treatment dosage regimen and number of administration for treatment cost reduction.

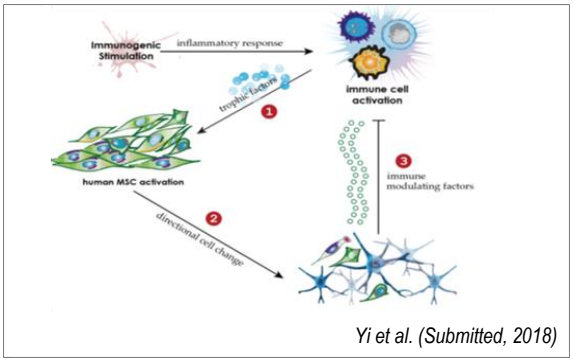
MECHANISM OF ACTION

Therapeutic immunomodulatory mechanisms elicited by MSCs during inflammation has been discovered, providing the insight knowledge for treating immune diseases using MSCs.

- Increased ICOSL expression on MSCs in inflammatory condition enhances induction of Treg cells and their IL-10 release through interaction with its counterpart ICOS on Treg cells. (Lee et al., Scientific Report, 2017)
- Immune cell activation causes MSCs to manifest cholinergic neuron-like properties and induce release of acetylcholine. Binding of acetylcholine to immune cell leads to inhibition of lymphocyte proliferation and pro-inflammatory cytokine production. (Yi et al., Submitted, 2018)



Lee et al. (Scientific Report, Mar, 2017)



Yi et al. (Submitted, 2018)

TECHNICAL ADVANTAGES

Our Technology	Existing Problems	Advantages
Subfractionation culturing method (facilitates isolation of single colony MSCs to produce clonal MSC products)		
Homogeneity/Purity	• Heterogenous stromal cells	• Homogeneous clonal MSC • Enhanced treatment efficacy
Cell line selection	• High variability	• Selection of appropriate disease-specific cell line through potency marker expressions • Low variability
Dosage regimen	• High dosage ($2x10^6$ cells/kg) Temcell approve in Japan for Acute GvHD	• Low dosage ($1x10^6$ cells/kg) SCM Clinical trial in Japan for Acute GvHD
Administration	• 8 times (twice weekly for 4 weeks) Temcell approved in Japan for Acute GvHD	• 4 times (once weekly for 4 weeks) SCM clinical trial in Japan for Acute GvHD
Cost	• High treatment cost	• 2~4 fold reduction in cost
Manufacturing technology		
Limited treatment for acute patients	• Fresh MSC formulation (autologous)	• Fresh MSC formulation (allogenic) • Frozen MSC formulation (acute, allogenic)

Intellectual Property

SCM Lifescience has over 30 patents registered/filed globally, covering from isolation and manufacturing to treatment of pipeline diseases. Some key patents are listed as below:

- The method for isolation of mesenchymal stem cells from bone marrow using subfractionation culture method (KR10-0802011)
- Isolation of Multi-Lineage Stem Cells (US07781211, JP05155855, CN101198691B, EU01917348)
- Treatment of graft-versus-host disease (JP05683264, EP2160100B1, US09439929)
- Manufacturing process for fresh and frozen stem cells (US08796020)
- Markers for detecting senescence in adult stem cells and its uses (KR10-1541958)
- Pharmaceutical compositions for atopic dermatitis comprising clonal mesenchymal stem cells (KR10-1655780)
- Pharmaceutical composition for preventing or treating hair loss comprising CXCL1 protein (KR10-1657082)
- Pharmaceutical composition for preventing or treating hair loss comprising TYMP protein (KR10-1671361)