Cell Engineering For Origin

A Leading Company in Cell Therapy Products for Fundamental Treatment

CEFO Co., Ltd.

CEFO

History

2025
(Jan.) CF-M801 has been designated as a orphan medicinal product by EU (ODD number : EU/3/24/3022)
(Aug.) Application for Phase IIa clinical trial for hip fragility fractures(CF-M801)

2024
(Jul.) CF-M801 Selected for the 'Bio Challenger' program by the Ministry of Food and Drug Safety (MFDS)
(Sep.) Approved for Phase II clinical trial for osteonecrosis of the femoral head(CF-M801) by the MFDS

2023
(May.) Obtaining permission for human cell management business from the MFDS
(Jun.) CF-M801 Phase I clinical trial completed
(Oct.) Obtaining Permission for IVD Manufacturing Business from the MFDS and ISO13485 certification

2022
(Mar.) Selected as the final choice to carry out the business by Korea fund for Regenerative Medicine
(Jul.) The treatment of osteonecrosis of the femoral head(CF-M801) has been designated as a rare drug by the MFDS

2021
(Jul.) Approved for Phase I clinical trial for osteonecrosis of femoral head(CF-M801) by the MFDS
(Aug.) Obtaining permission for manufacturing Advanced biological products business from the MFDS
(Oct.) Introduction of CAR-NK cell and NKT cell manufacturing method technology from KRIBB

2020
(Jan.) Completion of efficacy test of CF-M801 in a goat model of femoral shaft cortical bone defect
(Apr.) Introduction of Natural Killer(NK) cell manufacturing method technology from KRIBB
(Jun.) Phase III Manufacturing site Validation Completed in Good Manufacturing Practice (GMP)

2019
(Apr.) Animal testing begins as a strategic shift toward osteoblast-based therapeutics
(Nov.) Establishment of GMP Center for Cell Therapy Production in Gwangmyeong City

2018
(Feb.) Selected as an Engineering Service Provider (ESP) by the Ministry of SMEs and Startups
(Jun.) Obtained ISO9001 certification for enzyme and stem cell culture solution

2017
(May.) Raising 10 billion(KRW) in Series B funding from institutional investors

2016
(Sep.) Signed a memorandum of understanding(MOU) & Confidential Disclosure Agreement(CDA) with the Kyungpook National University College of Medicine for clinical research on bone cell therapeutics

2015
(Sep.) Selected as an operator for a technology commercialization project of the Ministry of Agriculture, Food and Rural Affairs(MAFRA)

2014
Applied for major patents such as stem cell cryopreservation, 3D cells culture system, and cell culture method using this system

2013
Development and patent application of key ingredients of CEFOgro™(cell culture medium) and STeMiN®(cosmetic raw material based on stem cell culture extract)

2012
(Sep.) Selected as an international joint research project operator of the Korea Institute for Advancement of Technology (KIAT) for the Development of Stem Cell Culture Technology Using bio-gel
(Nov.) Signed an international joint research agreement with the University of Strathclyde, UK

2011
(Sep.) Established the CEFO Co., Ltd

Greetings

Healthy cells make Healthy people

CEO Hyun Sook, Park

Hello, I am Hyun-Sook Park, CEO of CEFO Co., Ltd.

CEFO was founded in September 2011 with the goal of researching, developing, and commercializing stem cell therapies. As a venture company, we have faced numerous challenges and trials, but thanks to the unwavering dedication of our employees in securing large-scale stem cell cultivation and differentiation technologies, we are now on the verge of achieving significant milestones.

Our core proprietary technology lies in three-dimensional (3D) stem cell culture and differentiation. In particular, we have developed a bio-gel for differentiation induction by integrating optimized stem cell culture media technology with bio-gel synthesis and hardness control technology. This advanced culture and differentiation technology was recognized in 2023 when it was certified as a New Excellent Technology (NET) by the Ministry of Health and Welfare.

Currently, CEFO is focused on developing stem cell therapies for bone defects, with our first new drug targeting osteonecrosis of the femoral head(ONFH). In July 2021, we received Phase 1 clinical trial approval from the Ministry of Food and Drug Safety, produced clinical trial drugs in our own GMP facility, and conducted trials at Kyungpook National University Hospital. Based on the safety and exploratory efficacy data obtained in Phase 1, we secured approval for Phase 2 clinical trials in September 2024, marking a significant step forward.

As a biopharmaceutical development company, CEFO embraces Open Innovation as a key strategy. Recognizing the limitations of a small to mid-sized venture, we actively seek strategic partnerships for role allocation at each clinical stage and technology transfers to specific regions, including the United States, Japan, and China.

As CEFO continues to grow as a leading company in stem cell therapy, we appreciate your continued interest and support. Thank you.

CEO Profile

BS/MS in Biology, Korea University
Ph.D in Cell Pathology, Imperial College School of Medicine, University of London
Senior Researcher, Korea Institute of Radiological & Medical Sciences
Director, MizMedi Hospital Medical Science Research Center
Vice Direct, Bio Solution-Affiliated Research Institute

- Pubilshed Paper: Ph.D - Crypt fission in the spread of mutated clones in the intestinal epithelium (Supervisor : Nicholas A Wright, M.D., Ph.D., DSc., FRCPath.)
- Patents (registered) : Method of inhibiting differentiation of pluripotent stem cell - Korea 10-0632851
- Book : Tissue Engineering and Regenerative Medicine, 2nd, Ji Yoo, Chapter 31 Bioartificial Skin 2002,9.16. Koonja Publishing

Next generation
Cell therapy for regeneration

With the global aging trend, the number of patients suffering from musculoskeletal diseases is rapidly increasing. However, current treatment options are limited to artificial implants or chemical drugs, with no fully developed regenerative solutions.
CEFO Co., Ltd. has successfully achieved large-scale cultivation of osteoblasts differentiated from allogeneic stem cells, enabling the regeneration of a patient's own bone.
Osteonecrosis fundamentally occurs due to the death of osteocytes, which is caused by various factors that obstruct blood supply. Effective bone regeneration requires not only osteoinduction, osteogenesis, and osteoconduction but also vascular formation, which plays a crucial environmental role.
The CF-M801 consists of early-stage osteoblasts that secrete both angiogenic and osteogenic regulators. This means that these cells have the unique ability to promote blood vessel formation while simultaneously secreting bone matrix to facilitate bone regeneration.

Osteonecrosis of the femoral head(ONFH)
ONFH is a condition where disrupted blood supply to the femoral head leads to bone cell death, causing joint pain and potential collapse of the hip joint.

Indications

Osteonecrosis of the Femoral Head
A disease wherein the blood flow is blocked at the upper end of the femur(femoral head), causing the death of the bone tissue

Causes : Excessive alcohol consumption, use of steroid medicines (for COVID-19, SARS, etc.)

Market size

• United States: An estimated 20,000 to 30,000 new cases are diagnosed ONFH annually. This disease accounts for approximately 10% of patients treated with joint replacement surgery. (Source : DR Steinberg et al., Diagnosis and Management of Hip Disease 2015)
• China: Primarily occurs in individuals aged 30–50, with an average annual prevalence of 100,000 to 200,000 cases (73.91% male). The total number of patients is estimated at around 8.2 million, the highest in the world. (Source: J Orthop Translat 2020 & Othop Surg 2021)

ONFH develops during a period of high social activity. Since there is no early treatment, joint replacement surgery remains the final option.

Osteoporotic Fracture
A fracture caused by weakened bone strength due to osteoporosis

Causes: Decrease in female hormones, smoking, calcium deficiency, etc.

Market Size

• The incidence of osteoporotic fractures in adults over 50 in Korea is approximately 3% (Source: National Health Insurance Service claim data, 2008–2016)
• Limitations of Bone Graft Materials: When recovery ability is weakened, as commonly seen in osteoporotic fractures, the surrounding bone is prone to refracture due to the higher strength of injectable bone cement compared to natural bone.

Research on osteoporotic fractures is needed to develop fusion products that combine stem cells and biomaterials, providing both structural support for fractured vertebrae and promoting their regeneration.

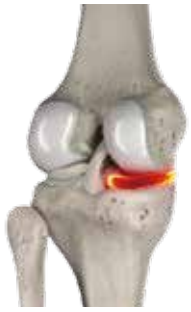
Spinal Fusion (Spinal implant)
A complementary method to spinal fusion, the most widely used surgical procedure to treat diverse spinal diseases

Spinal fusion is the primary treatment for disc herniation, spinal deformity correction, prevention of deformity progression, and spinal instability. However, nonunion—where the bones fail to fuse properly—occurs in approximately 56% of cases.

Market Size

• The spinal implant market in Korea was approximately $132 million in 2021. (Source: L&K BIOMED)

Successful bone fusion, including in the spine, requires new bone formation and vascular induction. In this context, osteoblast transplantation may enhance spinal fusion.



Osteoarthritis
a degenerative disease caused by the wear and tear of joint cartilage, primarily affecting the knee and hip joints.

Causes: Traumatic injury, aging, obesity, genetic factors, etc.

Market Size

• The number of osteoarthritis patients in Korea exceeds 4 million (4,042,159 patients). (Source : 2019 Health Insurance Review & Assessment Service)
• Major Degenerative Disease in the Elderly: Among individuals aged 65 and older, osteoarthritis occurs in approximately 66% of the spine, 60% of hand joints, 38% of knee joints, 5% of shoulder joints, and 2% of hip joints. (Source: Korean Orthopedic Association, Orthopedic Textbook, 2022)

There is currently no complete cure for osteoarthritis. Surgical treatment, such as joint replacement surgery, does not provide a fundamental cure or promote tissue regeneration.

Off-the-shelf Drug as Cell Therapy

The limitations of first-generation cell therapies stemmed from their reliance on culturing a patient's own cells, often resulting in undifferentiated therapies with unclear mechanisms. These treatments had low or unpredictable yields, making quality control difficult. As a result, they functioned more like procedures, with high costs and inconsistent efficacy.
CEFO addresses these challenges by mass-culturing allogenic stem cells from umbilical cords, and differentiating them into early-stage osteoblasts while demonstrating therapeutic efficacy. Ultra-low temperature cryopreservation also eliminates constraints on shelf life and production capacity.

Biomimetic 3D cell differentiation platform technology

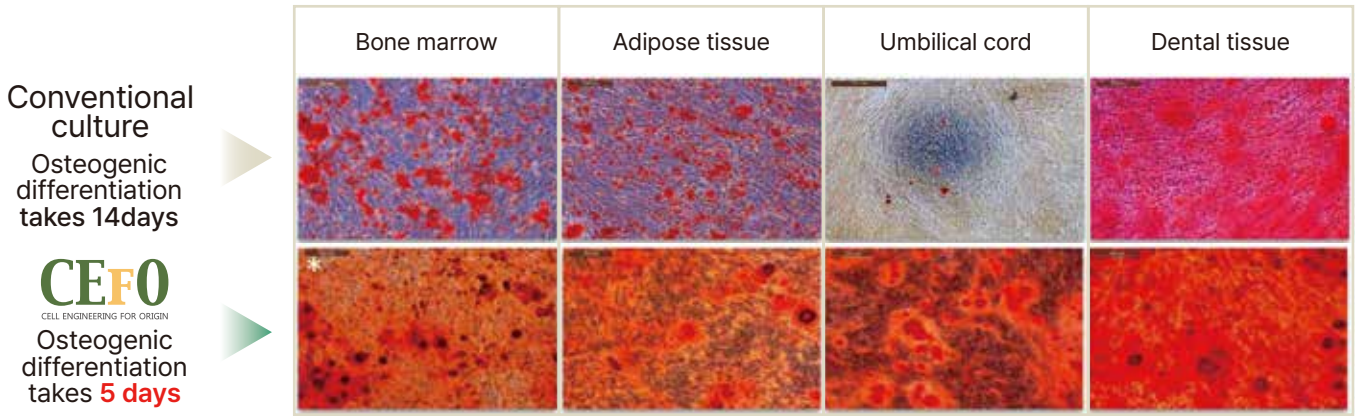
Using a biomimetic Hydro Bio-gel culture method, which replicates the physical environment in addition to chemical signaling, we have reduced the differentiation period from over 14 days to just 5 days.
Our culture platform technology ensures high purity and cost efficiency in cell therapy production.

1) Cross-linking of synthetic gels
2) Cell inoculation and cultivation
3) Induction of osteogenic differentiation

High efficiency,Rapidity, High reproducibility

Patents KR 10-1860301, US10,494,601, JP6475323, CN ZL201580050101.2, EP (in pending)

2023 New Excellent Technology (Pharmaceuticals)



> Alizarin Red staining : Red colors indicate calcium deposition and osteocyte differentiation.

CF-M801, an allogenic pre-osteoblast

What Sets CF-M801 Apart

Hydrogel-based stem cell osteogenic differentiation

The world's only differentiation technology
(patented domestically and internationally)
Dramatic reduction in differentiation time

Osteogenic capacity + Angiogenic capacity

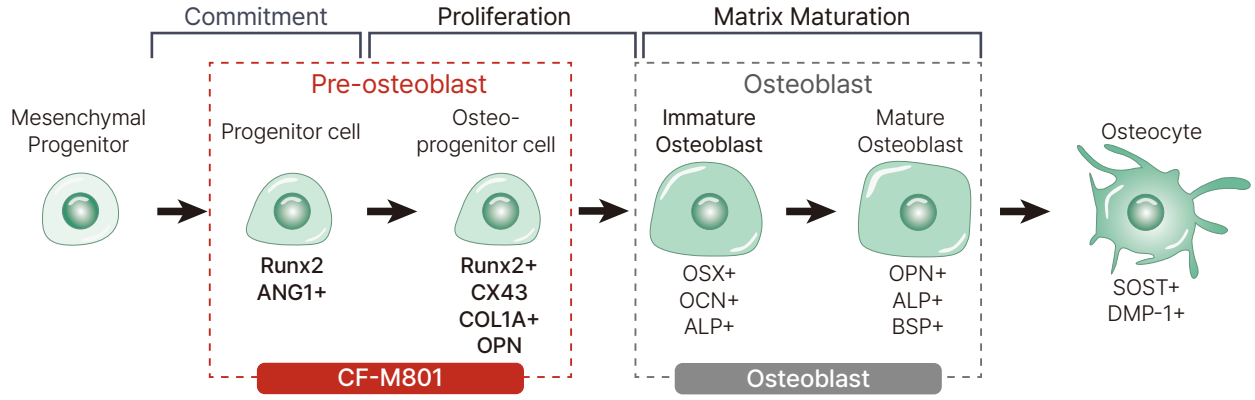
Improved bone tissue regeneration efficiency
→ Reduced bone formation time (50–60%)

Allogenic umbilical cord-derived stem cells

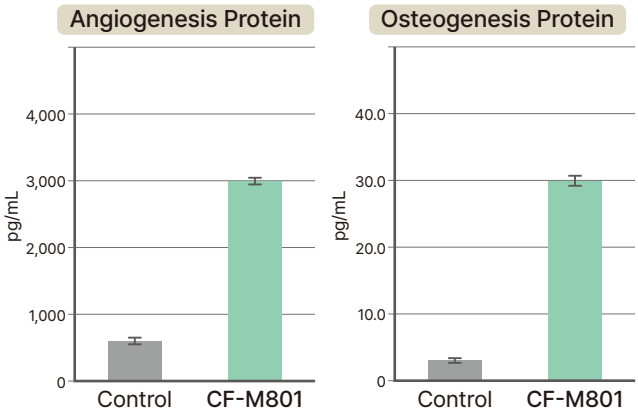
Enabling yield control & master banking
Cryopreserved final product
→ Suitable for mass production
Easy transport and clinical use

Key feature of CF-M801

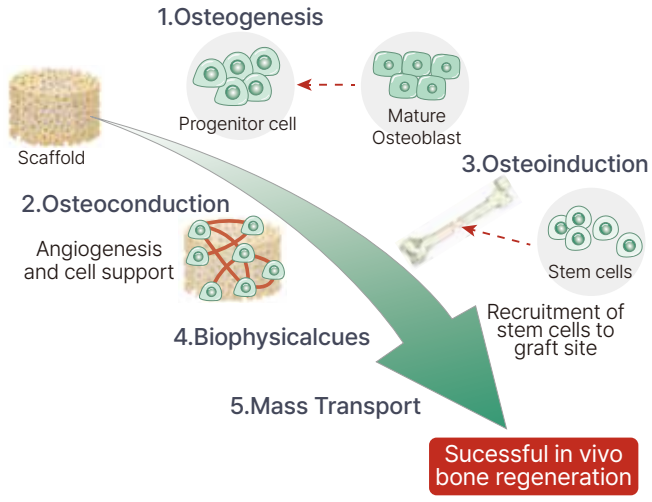
• Pre-Osteoblast : Runx2, AP+, COL1+, OPN+



Mode-of-Action of CF-M801



Bone Regeneration ability of CF-M801

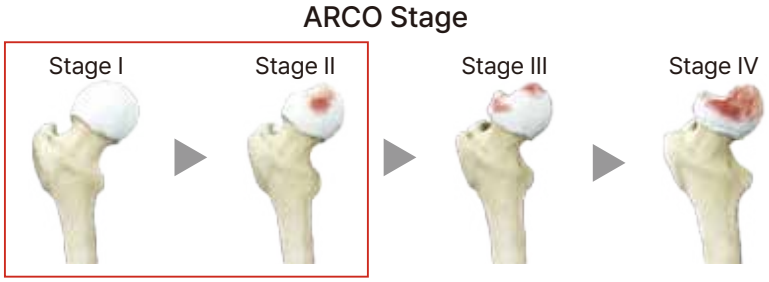


Efficacy and Safety of CF-M801

Results of Phase 1 Clinical trial

CEFO's first clinical application targets Osteonecrosis of the femoral head (ONFH), a condition caused by impaired blood flow to the femoral head, leading to bone tissue necrosis. CF-M801, a pre-osteoblast, is administered to necrotic bone tissue, promoting bone induction, formation, and conduction for regeneration. Additionally, it stimulates new blood vessel formation in the treated area. In July 2021, CF-M801 received Phase 1 clinical trial approval from the MFDS. The trial was completed in 2023, confirming its safety and efficacy.

Clinical application of CF-M801 for ONFH

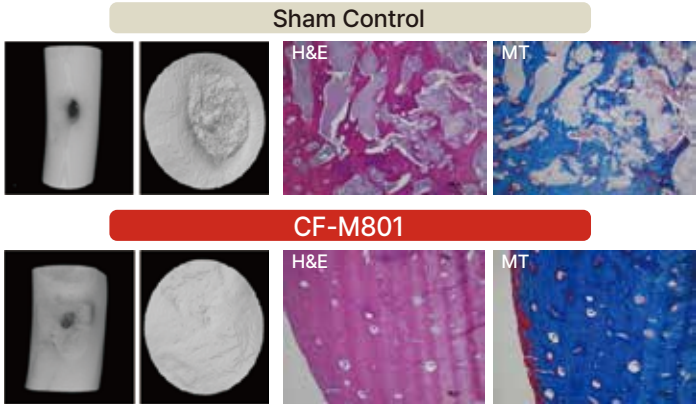


ARCO Stage I & II +
Avascular Necrosis of femoral head

Pre-clinical Study

- CF-M801 Efficacy: Rat Radius Defect model

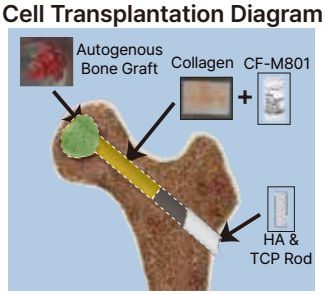
- CF-M801 Efficacy : Goat Femur Defect model



Clinical results

Phase 1 Clinical trial Summary

Cell Transplantation Diagram



Division	Phase 1	Safety / Efficacy
Target patient	ARCO Stage I & II with Avascular Necrosis of femoral head	
Region	Republic of Korea (Kyungbook National University)	
Subjects	9 subjects	
Safety endpoint	Adverse event, laboratory test, vital signs, physical examination, electrocardiogram test, PRA panel (immune reaction)	No adverse event No immune reaction (No allo-antibody production, PRA panel) Under 5-year monitoring
Dosage	Low Dose 3 patients, Medium Dose 3 patients, High Dose in 3 patients	The impact of CF-M801 on pain relief, radiographic findings, and WOMAC/HHS scores was dose-dependent
Exploratory efficacy endpoint (implemented in addition to the phase 1 trial)	Changes in necrotic lesion size (X-ray, MRI) Changes in ARCO stage : Size of osteonecrosis site Changes in JIC stage Changes in pain VAS (1-10): Degree of pain Changes in Harris Hip score (100, daily life possible) Changes in WOMAC score (96, joint function)	Reduction in Pain: 9/9 cases (VAS score) Improved Physical Function : 8/9 (WOMAC score) 9/9 (HHS) X-ray/MRI imaging: Decrease in Necrotic Angle: 9/9 cases Improvement in JIC stage: 3/9 cases : C2 →C1/B No disease progression in ARCO stage

Published paper: S.-H. et al, Pharmaceuticals 2024, 17(10), 1366

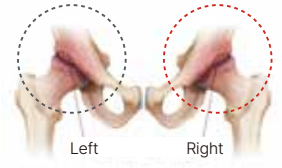
- CF-M801 clinical trial result: case of bilateral ONHF patient

w/o Cell Transplantation

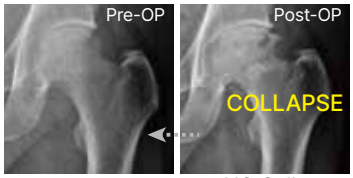
1Year
→ Collapse

w/ CF-M801 Transplantation

1Year
→ NO Collapse

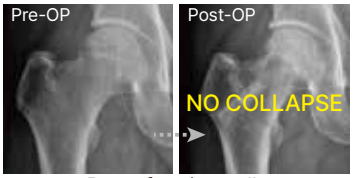


w/o Cell transplantation : Collapse



NO Cells

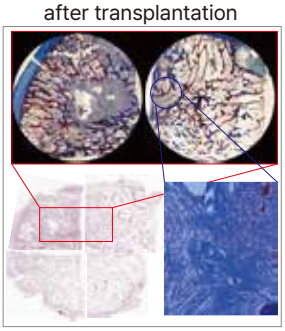
w/ Cell transplantation : Halts collapse



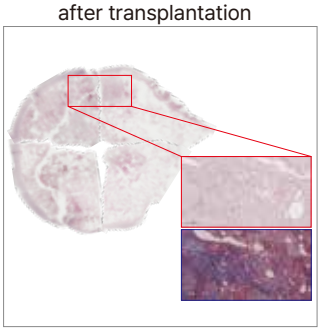
Bone-forming cells

- Bone regeneration confirmed at the CF-M801 implantation site

R001: THA at 9 months after transplantation



R009: THA at 18 months after transplantation



Both of the have no collapse.
Neo-collagen synthesis ↑

Phase 2 clinical trial of CF-M801 in progress

	Phase 2 Pivotal clinical trial - Randomized, Double-blind, Placebo-Controlled, Multi-Site	
Indications	**Osteonecrosis of the Femoral Head (ONFH)**	**Hip Fragility Fracture**
Target patient	ARCO Stage I & II with JIC stage C1 & C2, modified Kerboul Angle (over 200 degrees)	Hip Fragility Fracture
Subjects	80 subjects (Placebo 40, IP 40) Parallel Arm, Fixed Dose	36 subjects (Placebo 18, IP 18) Parallel Arm, Fixed Dose
IP	CF-M801	CF-M801
BLA	Conditional Approval at Phase 2	Conditional Approval at Phase 2a
Safety endpoint	Adverse/Serious Adverse Events, Allogeneic Immune Reaction, Clinical Laboratory Test, Vital Signs, Physical Exam, Electrocardiogram Test	Adverse/Serious Adverse Events, Allogeneic Immune Reaction, Clinical Laboratory Test, Vital Signs, Physical Exam, Electrocardiogram Test
Efficacy endpoint	ARCO Stage 3b (Radiographic: Collapse) JIC Classification (Radiographic: Necrotic Region) Modified Kerboul Angle (X-ray, MRI, CT: Lesion Size) Harris Hip score (Clinical endpoint) Quality Of Life (measured by EQ-5D) Biomarker Analysis	RUSH score Modified Harris Hip Score (mHHS) Koval Index Bone resorption marker (CTx) and bone formation markers (P1NP, B-ALP, Osteocalcin) Fracture rate in the proximal part of the application site

CF-M801:
Expandable to various bone-related indications

CEFO is expanding its pipeline for various musculoskeletal disorders, led by CF-M801, a cell therapy derived from umbilical cord–sourced allogeneic stem cells and differentiated into early osteoblasts. Designed for large-scale production and cryopreservation, CF-M801 and related therapies can be applied to a wide range of diseases.

Products	Indications		Target	Discovery
CF-M801	Bone Repair	Necrosis	ONFH* (ODD in Korea, EU)	
		Fracture	Hip Fragility Fracture	
			Spinal Fracture	
			Hairline Fracture	
		Delayed	Spinal Fusion via OLIF**	
		Osteoporosis	Osteoblast Transplantation	
CF-M802	Cartilage Repair	Arthritis	Knee/Ankle	
		Disc	Low Back Pain	
CF-M803	Muscle	Muscle	Sarcopenia	

*ONFH: Osteonecrosis of the Femoral Head
**OLIF: Oblique Lateral Interbody Fusion

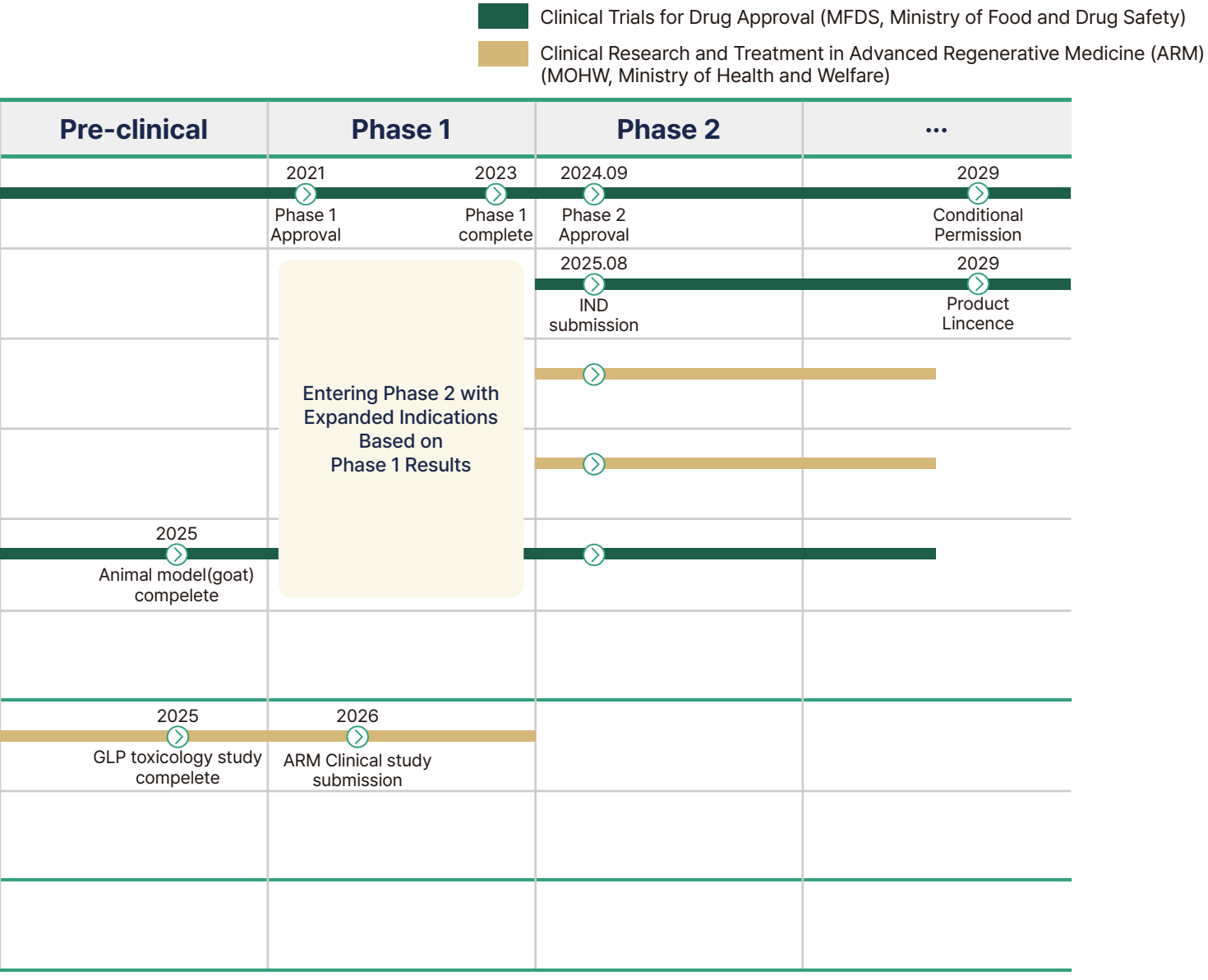
Pipeline

Key Milestones of CF-M801

- Designated as an Orphan Drug by the MFDS (2022.07)
- Phase 1 Clinical Trial for Osteonecrosis of the Femoral Head (ONFH): Approval(2021.07) and Completion (2023.06)
- Phase 2 Clinical Trial for ONFH: Approval (2024.09)

Indication Expansion and Global Market Entry

- Expansion of CF-M801 indication to hip fragility fractures
  - Phase 1 waiver, Phase 2 IND submission(2025.08)
- CF-M801 designated as an Orphan Drug by the European EMA (2025.01)

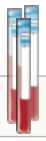


From Culture to Cure:
Our Proprietary System

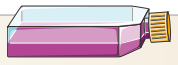
Based on extensive research and development in cell biology, CEFO has independently developed and manufactures all essential components for cell therapy, including culture media, enzymes, cryo-preservation solutions, and freezing systems. Our lead therapy, CF-M801, is also produced using CEFO's proprietary technologies. With our unique culture techniques and systems, we ensure stable and reproducible production of advanced cell therapies.

CF-M801 Manufacturing Process

Donor's Umbilical Cord

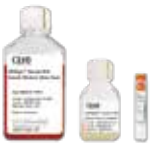


Donor compatibility test



Stem cell isolation & culture

UCMSC Master Cell Bank (MCB)



CEFOgro™ Human MSC Growth Medium (Xeno-free)

CEFO™ CRYOTUBE KIT

Adicol™ Freeze-dried Sterile Collagenese

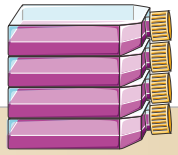
CEFO™ TExpress Recombinant Trypsin

Proprietary

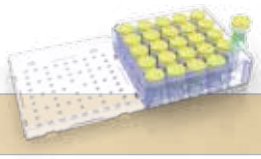
Certified Manufacturing & Quality System

- ISO 13485/9001 certified for culture media and related components
- MFDS-approved for GMP biopharmaceutical manufacturing, cell processing, and human cell management
- CEFO™ CRYOTUBE KIT licensed and registered as an in vitro diagnostic device

CEFOcryo™ Cryogenic Storage Box(5x5)

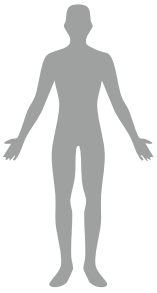


3D differentiation to pre-osteblast



Cell harvest & Cryopreservation

CF-M801 stored at -180°C



Administer CF-M801 to patient

CEFOdif™ Human MSC Differentiation Medium

Bone regeneration Cell Therapy Agent **CF-M801**

Off-the-shelf Ready-to-use

From Cell to System - Our Product & Service

CEFO has developed and manufactured cell culture components based on its proprietary research and technologies. We also bring extensive experience in GMP-compliant cell therapy manufacturing and quality control. Here, we present our portfolio of products and services, built on CEFO's know-how and technological expertise.

Stem Cells

▶ Human Tissue-derived Mesenchymal Stem Cells

Catalog #	Product	Unit	Composition
CEFO-ADMSC	CEFO™ Human Adipose tissue-derived MSC	vial	1 vial (P2, ≥ 5x10^5 cells)
CEFO-BMMSC	CEFO™ Human Bone Marrow-derived MSC	vial	1 vial (P2, ≥ 5x10^5 cells)
CEFO-UCMSC	CEFO™ Human Umbilical Cord-derived MSC	vial	1 vial (P2, ≥ 5x10^5 cells)

CEFO™ Human Adipose tissue-derived MSC
CEFO-ADMSC

· Surface Markers
CD31(-), CD73(+), CD105(+)

CEFO™ Human Bone Marrow-derived MSC
CEFO-BMMSC

· Surface Markers
CD31(-), CD73(+), CD105(+)

CEFO™ Human Umbilical Cord-derived MSC
CEFO-UCMSC

· Surface Markers
CD31(-), CD73(+), CD105(+)

Cells & Media kit

◆ Cell + Growth Medium Kit available at a discounted price compared to individual purchases.

Catalog #	Composition
CEFO-ADMSC-kit	1 vial/500 mL GM
CEFO-BMMSC-kit	1 vial/500 mL GM
CEFO-UCMSC-kit	1 vial/500 mL GM
CEFO-HDP-kit	1 vial/500 mL GM
CEFO-HUVEC-kit	1 vial/500 mL GM
CEFO-HF-kit	1 vial/500 mL GM

· 1Kit

Primary & Stem cell

+

Growth Medium

Product Catalog

Primary Cells

▶ Human Tissue-derived Cells

Catalog #	Product	Unit	Composition
CEFO-HDP	CEFO™ Human Hair Follicle Dermal Papilla cells	vial	1 vial (P2, ≥ 5x10^5 cells)
CEFO-HUVEC	CEFO™ Human Umbilical Vein Endothelial cells	vial	1 vial (P2, ≥ 5x10^5 cells)
CEFO-HF	CEFO™ Human Dermal Fibroblast cells	vial	1 vial (P1, ≥ 5x10^5 cells)
CEFO-PDL	CEFO™ Human Periodontal Ligament cells	vial	1 vial (P2, ≥ 5x10^5 cells)

CEFO™ Human Hair Follicle Dermal Papilla cells
CEFO-HDP

· Surface Markers
CD29(+), CD90(+)

CEFO™ Human Umbilical Vein Endothelial cells
CEFO-HUVEC

· Surface Markers
CD31(+)

CEFO™ Human Dermal Fibroblast cells
CEFO-HF

· Surface Markers
CD29(+), CD90(+)

CEFO™ Human Periodontal Ligament cells
CEFO-PDL

· Surface Markers
CD146(+)

Cell Growth Medium

Catalog #	Product	Unit	Composition
CEFOgro-MSC	CEFOgro™ Human MSC Growth Medium · Cell Type ADMSC, BMMSC, UCMSC, HF	500 mL	- Basal Medium - Supplements - P/S
CEFOgro-MSC-XF	CEFOgro™ Human MSC Growth Medium (Xeno-free) · Cell Type ADMSC, BMMSC, UCMSC	500 mL	- Basal Medium - Supplements - P/S
CEFOgro-HDP	CEFOgro™ Human Dermal Pailla Growth Medium · Cell Type HDP	500 mL	- Basal Medium - Supplements - P/S
CEFOgro-HUVEC	CEFOgro™ Human Umbilical Vein Endothelial Growth Medium · Cell Type HUVEC	500 mL	- Basal Medium - Supplements - P/S
CEFOdif-Osteo	CEFOdif™ Human MSC Differentiation Medium (Osteogenesis) · Cell Type Osteblast	500 mL	- Basal Medium - Supplements - P/S

Product Catalog

Enzyme

Catalog #	Product	Unit	Composition
CEFO-ENZ-COL	AdiCol™ Freeze-dried Sterile Collagenase	set	1 set (25 mL x 2)
CEFO-ENZ-TE	CEFO™ TExpress Recombinant Trypsin	bottle	100 mL

AdiCol™ Freeze-dried Sterile Collagenase
CEFO-ENZ-COL
Store at 2°C to 8°C

· Product Type
Collagenase Type 1

CEFO™ TExpress Recombinant Trypsin
CEFO-ENZ-TE
Store at 15°C to 30°C

· Applications
MSCs, HUVEC, HK, MRC-5
VERO, MDCK, BHK-21 etc.

Plasticware

Catalog #	Product	Unit	Composition
CEFO-CRYO25	CEFOcryo™ Cryogenic Storage Box (5x5)	box	1 box (24 ea)
CEFO-CRYO81	CEFOcryo™ Cryogenic Storage Box (9x9)	box	1 box (24 ea)
CEFO-CRYOKIT	CEFO™ CRYOTUBE KIT	kit	1 kit (1 bottle & 25 ea/pk)
CEFO-CRYOTUBE	CEFO™ CRYOTUBE	pk	1 pk (25 ea/pk)

CEFOcryo™ Cryogenic Storage Box (5x5)
CEFO-CRYO25

· Applications
5x5 Array for 2mL
like AT-Closed Vial®, CRYOTUBE

CEFOcryo™ Cryogenic Storage Box (9x9)
CEFO-CRYO81

· Applications
9x9 Array, 81 Holes
for Cryogenic tube & vial

CEFO™ CRYOTUBE KIT
CEFO-CRYOKIT

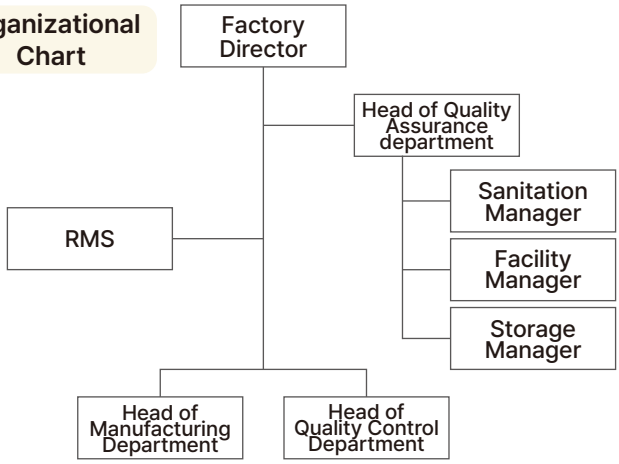
· Applications
Cryopreservation for
cells and tissues

Service

GMP

A-B107, 108 B1F, SK Techno Park, 60, Haan-ro, Gwangmyeong-si, Gyeonggi-do, Republic of Korea
- Registered the center as a factory on Oct. 8, 2020
- Total Area(578.09m²)

Organizational Chart



- Obtaining permission for manufacturing Advanced biological products business from the MFDS
- Obtaining permission for human cell management business from the MFDS
- ISO9001, ISO13485 certifications

CMO/CDMO Service

· Leveraging CEFO's expertise in advanced biopharmaceuticals, we offer reliable contract manufacturing services.

▪ Cell banking	▪ GMP production	▪ QC test	▪ RA support
▪ Process development	▪ GMP grade Media produciton	▪ Stability test	▪ Storage & shipping validation

Key Service Case

Company A	Master Cell Bank (MCB) - Established for stem cell cosmetic raw materials
Company B	Clinical Trial Material Manufacturing & Testing - Manufacturing, aseptic processing, and quality testing
Company C	Custom Media Production for Cell Therapy - Based on client-provided SOPs
Company D	Establishment of Master Cell Banks (MCB) - From animal muscle–derived stem cells

Company E	Exosome Production from Stem Cells
Company F	Stability Testing Services for Cell Therapies
Company G	Establishment of Master Cell Banks (MCB) - From client-provided stem cells
Company H	Clinical Trial Material Manufacturing - For autologous stem cells with quality testing

CMO/CDMO Service Process

STEP.01 Client Request ▶ STEP.02 NDA Agreement ▶ STEP.03 Project Discussion & Scope Alignment ▶ STEP.04 Cost Estimation

STEP.05 Contract Execution ▶ STEP.06 Pilot Production ▶ STEP.07 Contract Manufacturing ▶ STEP.08 Product Release

Service

Analytical Research Services

· Backed by R&D expertise, proven know-how, and advanced infrastructure, we deliver rapid and reliable analytical research services.

Key Service Items

- MLR(Mixed Lymphocyte Reaction)
- HLA Typing
- Cytotoxicity Analysis
- NK cell Lysis Assay
- Anti-inflammatory Assay
- Tumorigenicity Testing (in vitro)
- ELISA Analysis
- FACS Analysis
- Cell Culture Services
- Differentiation Assays (Osteogenic / Chondrogenic / Adipogenic)
- Custom Services

Key Service Case

Company a	MLR Analysis & HLA Typing - For allogeneic cell therapies
Company b	Anti-inflammatory Assay - Evaluation of inflammatory responses to animal-derived materials
Company c	MLR Analysis & HLA Typing - For exosomes and source cells
Company d	MLR Analysis - For mitochondria and source cells

Company e	Cytotoxicity & In Vitro Tumorigenicity Testing
Company f	Client SOP Validation Testing
Company g	NK cell Lysis Assay
Company h	Customized Cell Culture Services - For human tissue–derived cells

Analytic Research Service Process

STEP.01 Analytical Research Request Form ▶ STEP.02 Project Discussion & Scope Alignment ▶ STEP.03 Cost Estimation

STEP.04 Contract Execution ▶ STEP.05 Analytical Research Implementation ▶ STEP.06 Submission of Final Report

Information, Q&A

- COA is available upon request (purchase date and Lot# required).
- Storage conditions are specified in the enclosed documents and on the product description page of our website.
- For CMO/CDMO and analytical research service requests, a CPR (Customer Project Request) form is required (available on our website).

- For product quotations, orders, or service inquiries, please contact us via:
  Product webpage : www.cefobio.biz
  Email : order@cefobio.com

Product Orders & Service Inquiries

Patents

Cell cultivation and differentiation (19 patents)

3D Method for Osteogenic Differentiation Using Hydrogel	- KR, US, JP, CN, EP, ES, IE, PCT
A composition for preserving cells comprising plant-derived recombination human serum albumin and plant peptide	- KR, US, JP, EP, PCT
3D Cell Culture System and Cell Culture Method Using the Same	- KR, US, JP, CN, EP, ES, IE, PCT

Immune cell therapy products (3 patents)

Method for producing natural killer cell and use thereof	- KR, US, JP, EP, PCT
Method For Producing Immune cells and Use Thereof	- KR, US, JP, EP, PCT
Method For Producing Car Gene-Introduced Nk Cells and Use Thereof	- KR, US, JP, EP, PCT

Technology commercialization (10 patents)

Automated Cell Culturing Method	- KR, PCT
Device for cryopreservation of cells	- KR, US, JP, EP, IN, PCT
Culture Device of Inserting Type For Three-Dimensional Cell Culture, Kit And Co-Culture Method Of Three Dimensional Cell Using The Same	- KR, US, PCT

Brain disease (2 patents)

A composition for preventing or treating Neurological disorders comprising mesencephalic, astrocyte-derived neurotrophic factor	- KR, US, JP, CN, EP, PCT
A Composition for preventing or treating Neurological disorders comprising placental growth factor	- KR, US, JP, CN, EP, PCT

Papers

"Comparison of temperature equilibrium rate and cell growth/viability under air circulation in cryogenic storage container" - J. Medical Devices 2022
"Directly reprogrammed nature killer cells for cancer immunotherapy" – Nature Biomedical Engineering 5:1360-1376 2021
"Medroxyprogesterone reverses tolerable dose metformin-induced inhibition of invasion via matrix metallopeptidase-9 and transforming growth factor-β1 in KLE endometrial cancer cells – J Clin Med 9(11):3585 2022
"Differentiation of equine induced pluripotent stem cells into mesenchymal lineage for therapeutic use. – Cell Cycle 18(21) 2954-2971 2019
"Establishment of stably expandable induced myogenic stem cells by four transcription factors" – Cell Death an Disease 9(11) 1092 2018
"Functional nanosome for enhanced mitochondria-targeted gene delivery and expression" – Mitochondrion 37:27-40 2017
"Recurrent variations in DNA methylation in human pluripotent stem cells and their differentiated derivatives." – Cell Stem Cell 10(5):620-34 2012
"Comparison of mesenchymal-like stem/progenitor cells derived from supernumerary teeth with stem cells from human exfoliated deciduous teeth." – Regenerative Medicine 6(6):689-99 2011
"The effects of the physical properties of the culture surface on the growth and differentiation of human embryonic stem cells." – Biomaterials 32:8816-29 2011
"Dynamic changes in the copy number of pluripotency and cell proliferation genes in human ES and iPS cells during reprogramming and time in culture" – Cell Stem Cell 8(1)106-18 2011
"Restricted ethnic diversity in human embryonic stem cell lines" – Nature Methods 7(1):6-7 2010
"Adipogenic differentiation of feeder cells by human embryonic stem cells" – Tissue Engineering and Regenerative Medicine 7(1):82-86 2010
"Consensus guidance for banking and supply of human embryonic stem cell lines for research purpose." – Stem Cell Rev and Rep 5(4):301-14 2009
"Comparative phenotypic analysis of mesenchymal stem cells derived from bone marrow, skin, adipose tissue and umbilical cord" – Tissue Engineering and Regenerative Medicine 6(1):179-185 2009

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