MEDIPOST

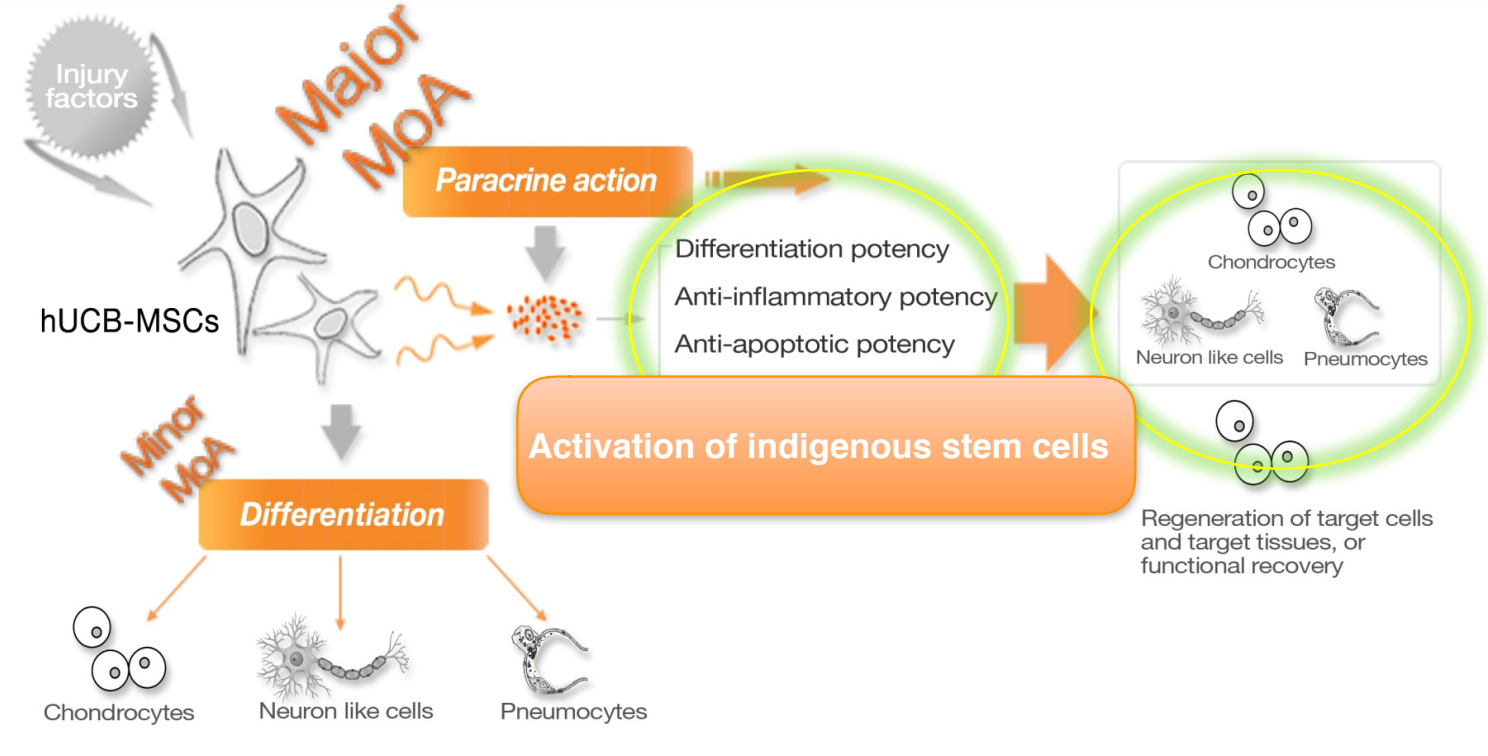
Regenerative Skincare

(New Product Pipeline for Alopecia: NGF-574H)

(www.medipost-dermocare.co.kr)

Paracrine action of MSC

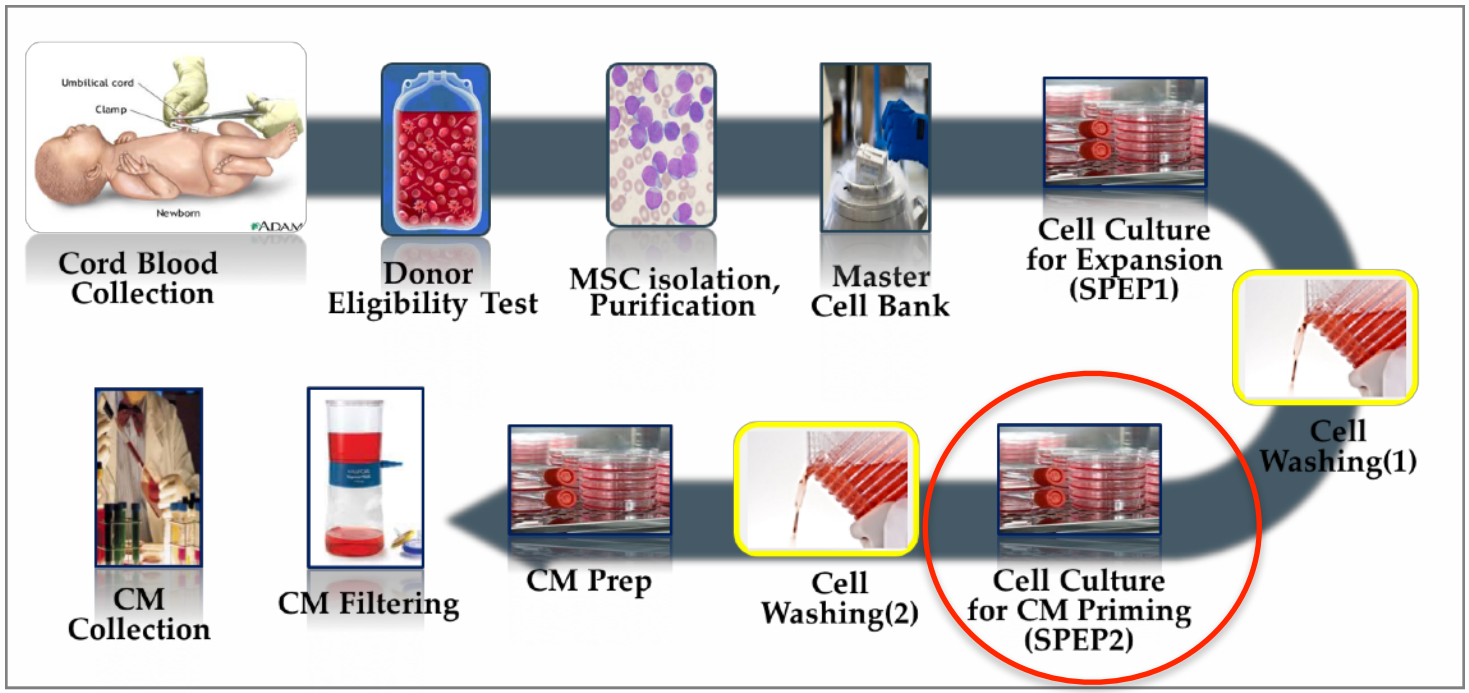
- Paracrine action of MSC is a part of adaptation mechanism of MSC for its own survival and protection in a new environment
- Environmental conditions around the MSC impacts on the paracrine action of MSC by changing the composition of trophic factors secreted by MSC



Pretreatment of MSC: primed conditioned media

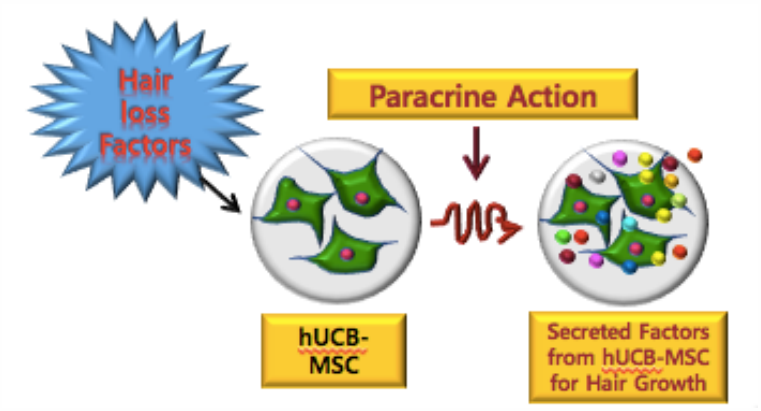
(Hypothesis)

- If conditioned media are to be used for specific indication of desire, the composition of the conditioned media may be optimized for the certain indication by exposing MSC to the specific environment artificially mimicking disease area in the body.



Optimum priming factors for alopecia

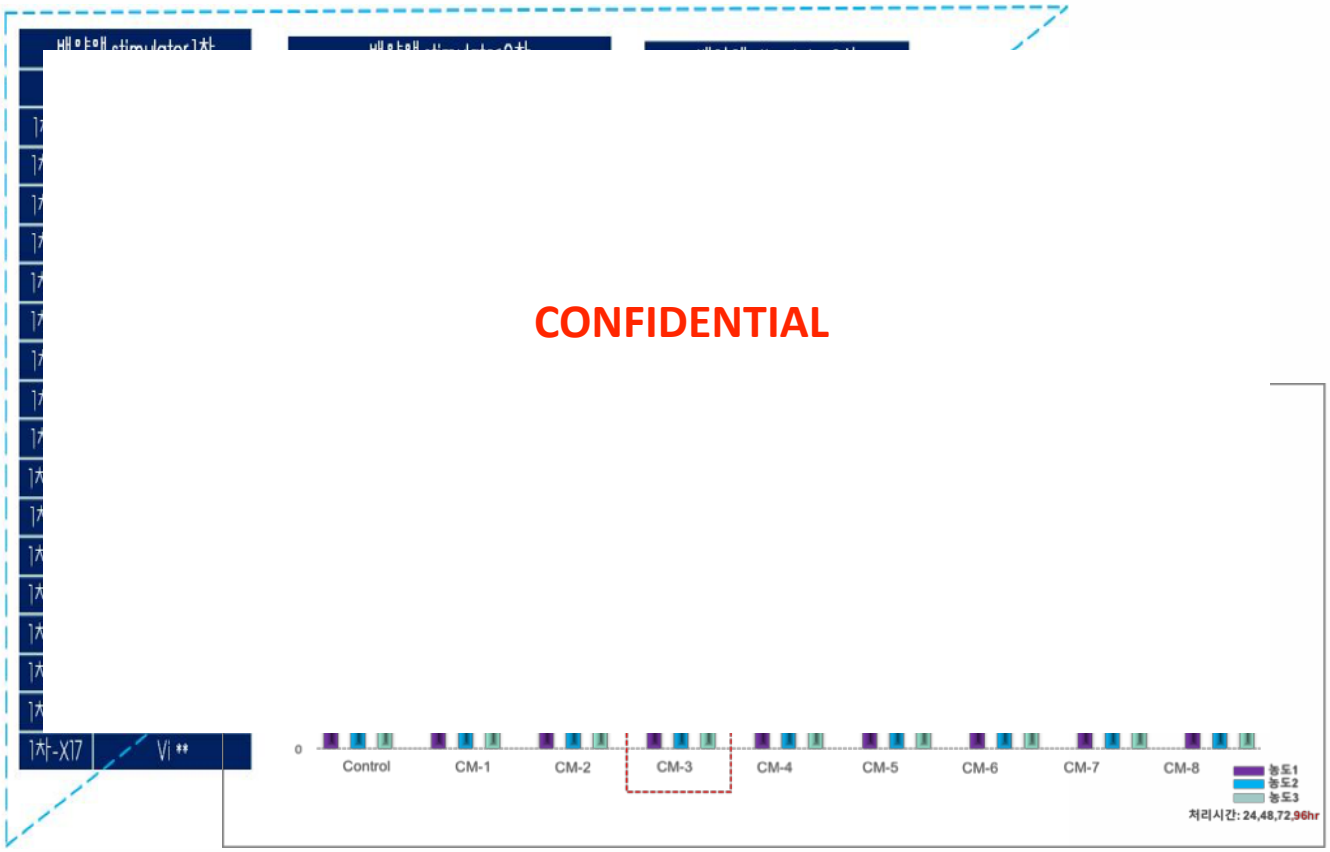
- Literature survey to find specific molecule(s) overly expressed in alopecia patients in order to artificially design alopecia state in vitro for priming MSC.



접근 기전	주요 탈모방지 및 발모 전략		비 고; 미세환경 모사 방안
모발주기 조절	▪ 휴지기 → 성장기 유도	➢ 혈행촉진 (Vasodilation)	✓ Minoxidil etc
		➢ Nutrition Therapy	✓ Vitamines, Minerals etc
	▪ 성장기 → 퇴행기 (휴지기) 방지	➢ Androgen Receptor Blocker	✓ Cyproterone acetate, Flutamide etc
		➢ 5α-Reductase Inhibition	✓ Finasteride, Dutasteride
		➢ Estrogen therapy	✓ Flavonoids
		➢ TGF-beta Signaling	✓ DHT, TGF-beta analog
		➢ STAT / MAPK pathway	✓ Interleukins , JAK inhibitor and LPS
모낭줄기 세포조절	▪ HF Epithelial Stem Cell	➢ Wnt pathway	✓ Chemicals, Synthetic signal peptide
	▪ HF Mesenchymal Stem Cell	➢ Hedgehog pathway	✓ Stemoxide
	▪ HF Stem Cell Niche	➢ BMP pathway	✓ Cell Adhesion Molecules
	▪ Follicular Morphogenesis	➢ Immune Privilege	✓ Corticosteroids, NSAIDs

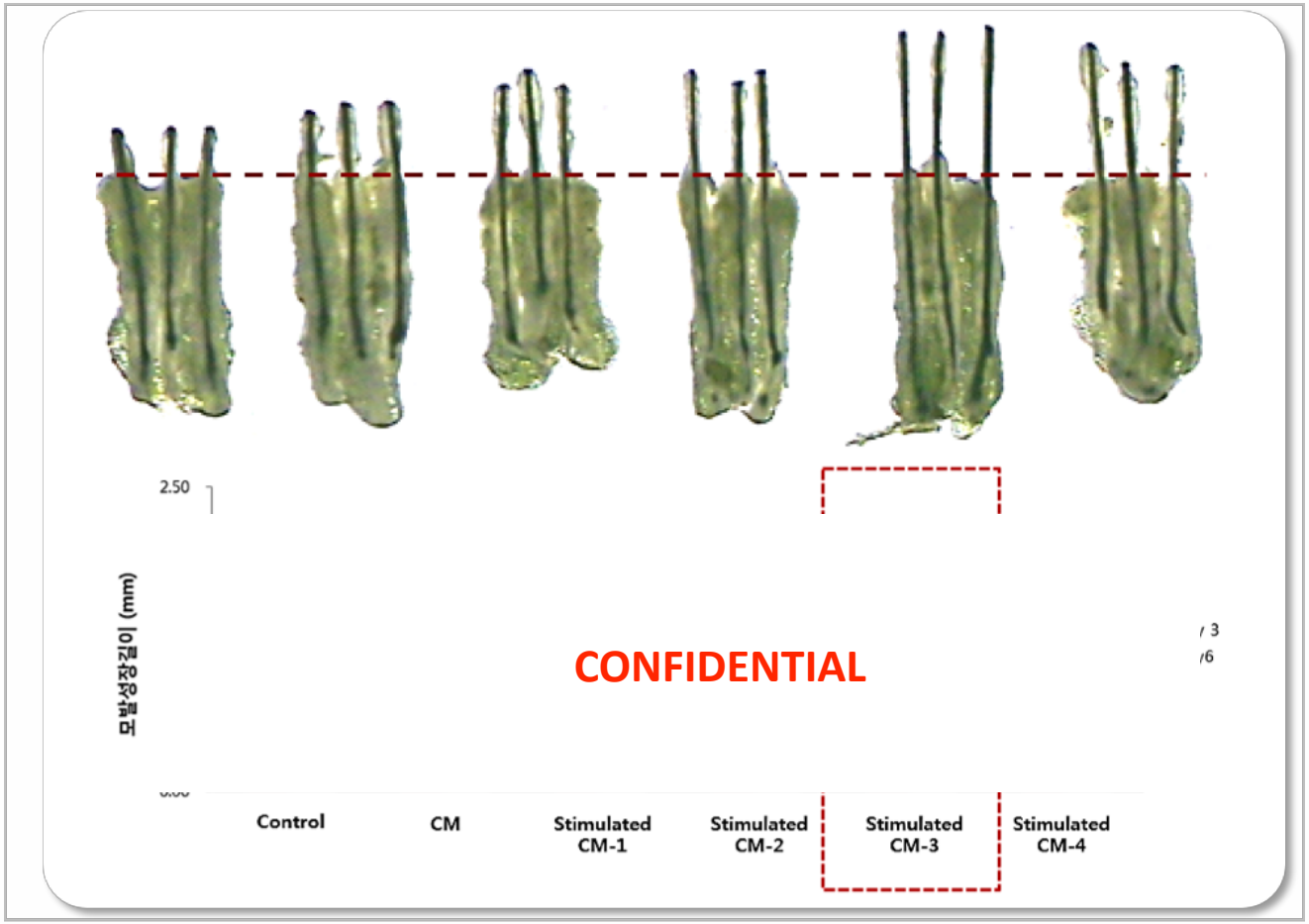
Optimum priming factors for alopecia

- 17 molecules selected by the literature survey results in 147 combination for experiment.
- Optimum priming condition was found and CM-3 was selected for conditioned media for alopecia based on the DP cell proliferation assay.



Proof of concept (1) : ex vivo experiment

- CM-3 results in 51% increase compared with control in hair length in ex vivo experiment with human hair follicles.



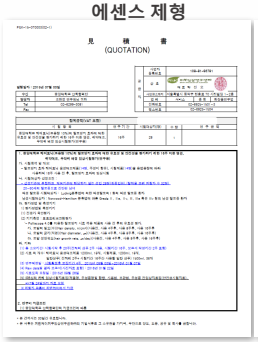
POC clinical trial : Synopsis

- A complete toxicity study was completed based on the MFDS (KFDA) guideline
- Pilot formulation was developed with 5% of CM-3 for POC clinical trial
- A POC clinical trial was designed in total 16 weeks use once daily by topical administration.
- Total 30 subjects (alopecia patients) were tested in a placebo controlled double blind trial.

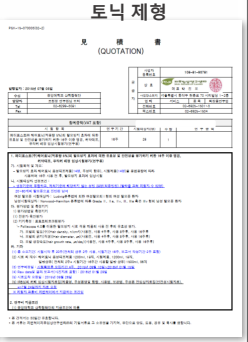
시제품 제작

IRB 원료 안전성 자료 확보	IRB 진행 및 완료	시험자 모집 및 시험 선정기준 확인	시험계획 확인	인체시험 진행 총 16주 관찰	유효성평가 변수확인 및	결과자료 및 보고서 작성

에센스 제형



토닉 제형



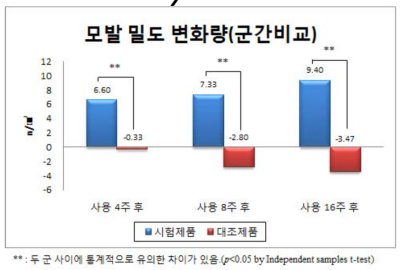
방문일 / 확인/평가항목	방문 1 2주 전	방문 2 3일 전	방문 3 0주 후	방문 4 4주 3일 전	방문 5 4주 후	방문 6 8주 3일 전	방문 7 8주 후	방문 8 16주 3일 전	방문 9 16주 후
시험대상자 동의서	◎								
인구학적 조사	◎								
선정/제외기준 검토	◎								
시험대상자 번호 배정	◎								
병력 조사	◎								
병용 약물	◎								
활력징후 조사	◎								
시험대상자 선정	◎								
삭모/타부/측정		◎		◎		◎		◎	
모발 밀도측정(모발)			◎		◎		◎		◎
모발 굵기 측정(모발)			◎		◎		◎		◎
모발성장속도 측정(모발)			◎		◎		◎		◎
탈모육안평가(모발)	◎		◎		◎		◎		◎
시험대상자 설문평가			◎						◎
Folliscope 사진촬영	◎		◎		◎		◎		◎
이상반응(안전성평가)			◎		◎		◎		◎
전처리 일반샴푸 배포	◎								
시험용 헤어토닉/음성대조용 헤어토닉 배포			◎						
순응도 평가		◎	◎	◎	◎	◎	◎	◎	◎
기호도조사									◎
시험제품 회수									◎

POC clinical trial: Top-line results

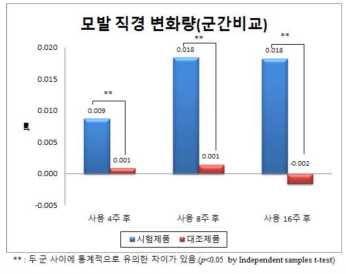
- Cosmetic formulation containing 5% MSC-CM showed statistically significant superiority in total hair count, hair diameter and hair growth rate compared with placebo control (treated with vehicle formulation only) after 16 weeks of use.

Clinical trial

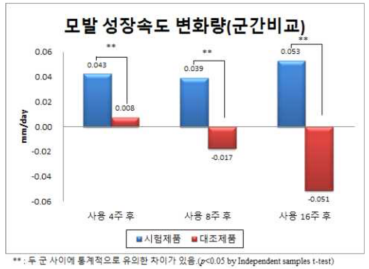
hair density

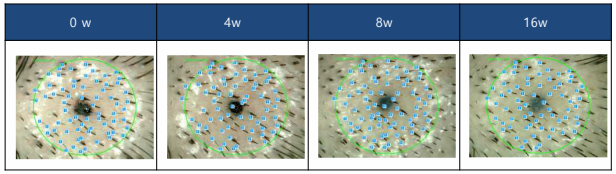


hair diameter

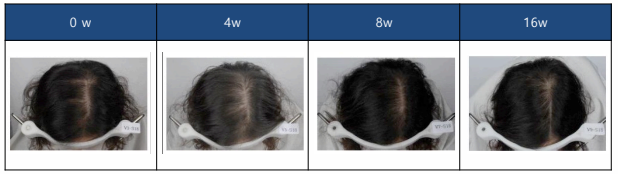


hair growth rate





Phototrichogram for hair density



PGA for investigator assessment

Efficacy comparison

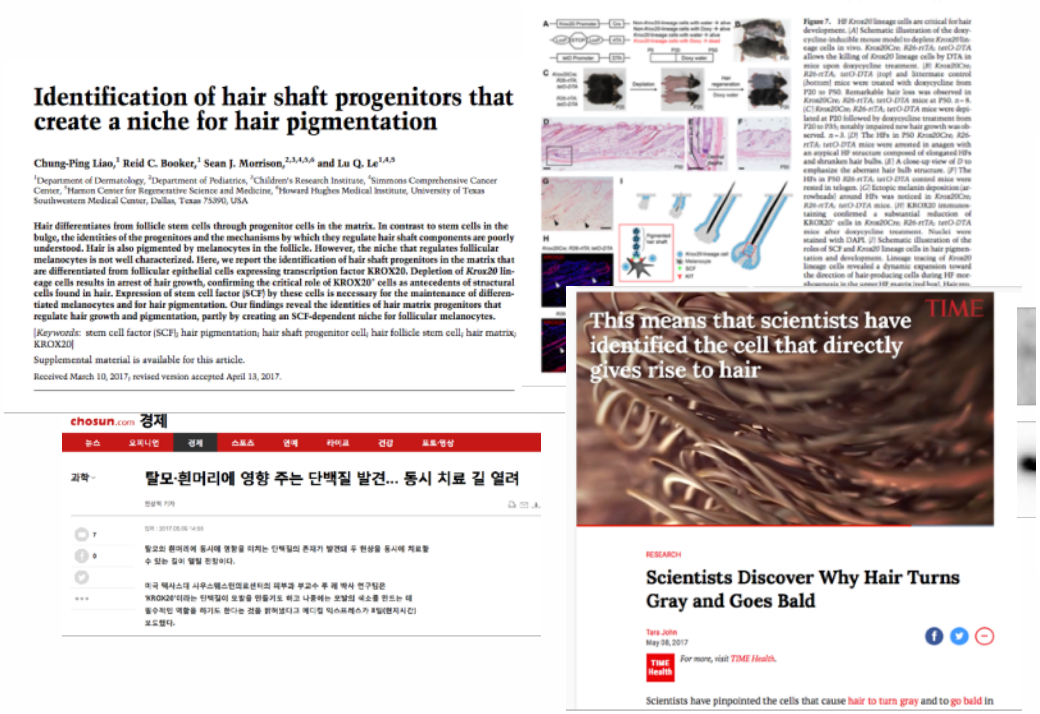
- Despite shorter length of treatment period (16w vs.48 w), the MSC-CM's efficacy is at least comparable to Minoxidil (Rogaine®) available in the market for alopecia as an OTC drug.

Active Ingredient	Number of patient	Time of evaluation	Method of assessment	Protocol	Total Hair Count (change from the baseline in number/cm^2)	Total Hair Count (% change from the baseline)	p-value between groups	Investigation Area
CM3	30	**16w**	phototrichogram	MSC-CM 5% solution, 1x/day, topical	13.3	**14.2%**	<0.001	Vertex
Minoxidil*	393	**48w**	phototrichogram	Minoxidil2%, 2x/day, topical	12.7	**8.8%**	<0.001	Vertex

*https://www.sciencedirect.com/science/article/pii/S019096220200124X

MOA (1): KROX-20

- KROX-20 is reported to play a key role in development of hair follicle in human and animal model*
- NGF-574H (CM-3) significantly increases expression of KROX-20 gene by western blot
- KROX-20 is likely involved in the hair growth efficacy of CM-3



Identification of hair shaft progenitors that create a niche for hair pigmentation

Chung-Ping Liao,[1] Reid C. Booker,[1] Sean J. Morrison,[2,3,4,5,6] and Lu Q. Le[1,4,5]

[1]Department of Dermatology, [2]Department of Pediatrics, [3]Children's Research Institute, [4]Simmons Comprehensive Cancer Center, [5]Harmon Center for Regenerative Science and Medicine, [6]Howard Hughes Medical Institute, University of Texas Southwestern Medical Center, Dallas, Texas 75390, USA

Hair differentiates from follicle stem cells through progenitor cells in the matrix. In contrast to stem cells in the bulge, the identities of the progenitors and the mechanisms by which they regulate hair shaft components are poorly understood. Hair is also pigmented by melanocytes in the follicle. However, the niche that regulates follicular melanocytes is not well characterized. Here, we report the identification of hair shaft progenitors in the matrix that are differentiated from follicular epithelial cells expressing transcription factor KROX20. Depletion of *Krox20* lineage cells results in arrest of hair growth, confirming the critical role of KROX20$^+$ cells as antecedents of structural cells found in hair. Expression of stem cell factor (SCF) by these cells is necessary for the maintenance of differentiated melanocytes and for hair pigmentation. Our findings reveal the identities of hair matrix progenitors that regulate hair growth and pigmentation, partly by creating an SCF-dependent niche for follicular melanocytes.

[*Keywords*: stem cell factor (SCF); hair pigmentation; hair shaft progenitor cell; hair follicle stem cell; hair matrix; KROX20]

Supplemental material is available for this article.

Received March 10, 2017; revised version accepted April 13, 2017.

chosun.com 경제

뉴스 오피니언 경제 스포츠 연예 라이프 건강 포토·영상

과학

탈모·흰머리에 영향 주는 단백질 발견... 동시 치료 길 열려

TIME

This means that scientists have identified the cell that directly gives rise to hair

RESEARCH

Scientists Discover Why Hair Turns Gray and Goes Bald

Tara John

May 08, 2017

TIME Health For more, visit TIME Health.

Scientists have pinpointed the cells that cause hair to turn gray and to go bald in

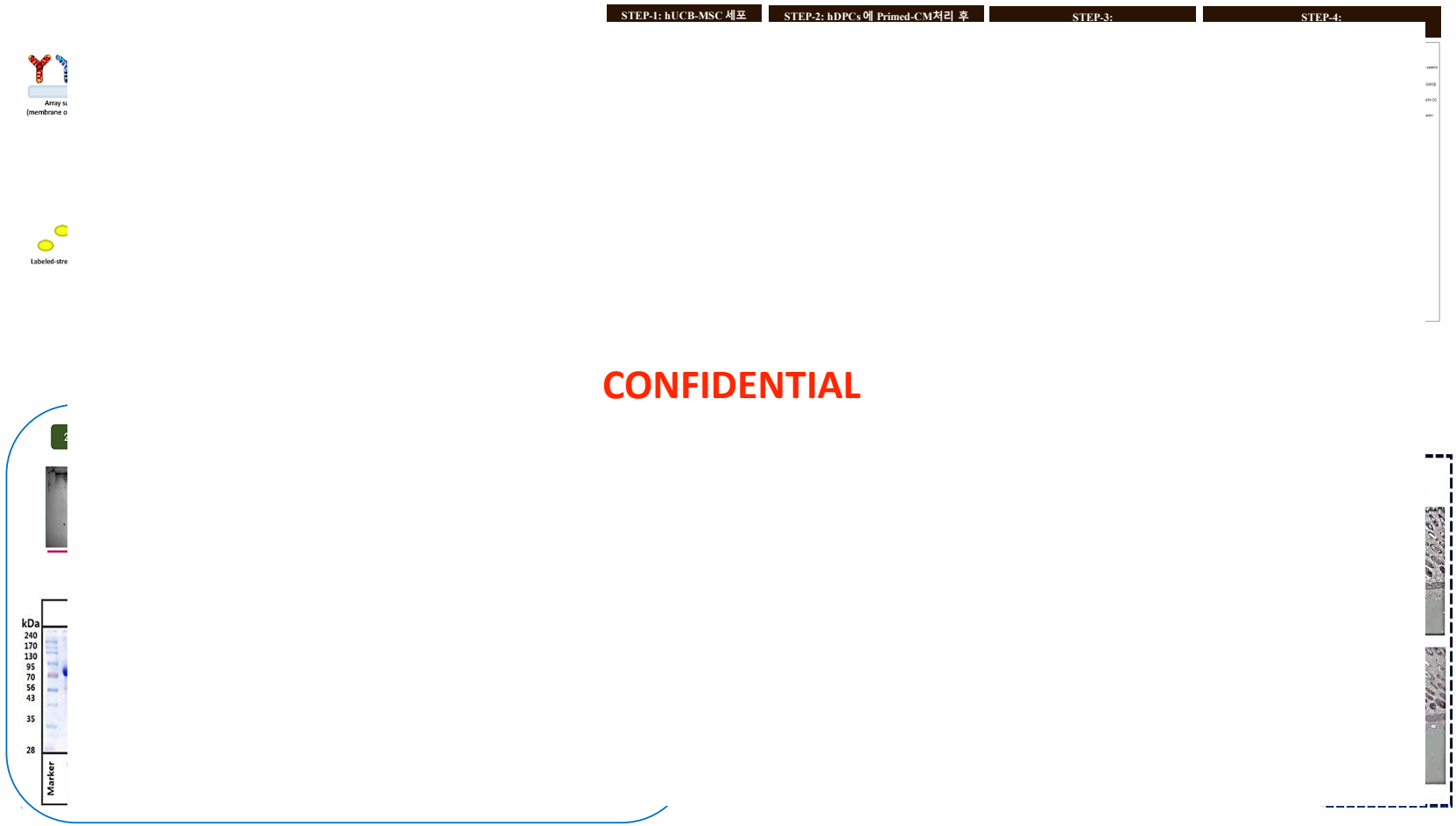
CONFIDENTIAL

)X-20

PDH

http://genesdev.cshlp.org/content/early/2017/05/02/gad.298703.117.short

MOA (2): potentially enhanced vasodilation by angiogenesis



Current Status

- 24 week clinical trial was completed for registration as a functional cosmetics for hair loss prevention in Korea: dose response was clearly confirmed at 0.5, 1, 5% concentrations
- Active ingredient register to ICID with a trade name of NGF-574H
- Awarded New Excellent Technology by Ministry of Health and Welfare Korea.
- Bigger scale 24 week POC clinical trial for 24 weeks will initiate in Nov 2018
- Market launch is due in 1Q 2019 first for professional use, followed by consumer use


기업

메디포스트, 탈모 방지 줄기세포기술 보건신기술 획득

기사입력 : 2017-12-12 14:01 | 수정 : 2017-12-12 14:01

바이오스펙터이터 천승현 기자

복지부 선정..내년말께 탈모 관련 제품 발매 계획

메디포스트는 '탈모 방지 효능 향상을 위한 인체 제대혈 유래 줄기세포 배양액 제조 기술'이 보건
부 보건신기술(NET, New Excellent Technology) 인증을 획득했다고 12일 밝혔다.

보건복지부와 한국보건산업진흥원이 주관하는 보건신기술 인증은 국내 기업 및 연구기관, 대학
서 개발한 신기술을 조기 발굴하고 우수성을 인증, 신기술의 상용화와 기술 거래를 촉진하기 위
도다.


NIH U.S. National Library of Medicine

ClinicalTrials.gov

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Brief Summary:
The purpose of this study is to assess whether cosmetic investigational product containing NGF-574H is safe and effective in the treatment of an

Condition or disease	Intervention/treatment
Androgenic Alopecia	Other: conditioned media of umbilical cord blood-derived stem cells Other: Placebo

Detailed Description:
NGF-574H is a obtained by collection of paracrine factors secreted by human umbilical cord blood-derived mesenchymal stem cell that was exp
environment mimicking alopecia state in hair follicles to prime the composition of the paracrine factors optimized for hair growth. This study is to
and effective in the treatment of androgenic alopecia in asian adults.

Study Design

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	90 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Product group / Control(placebo) group
Masking:	Double (Participant, Investigator)
Primary Purpose:	Supportive Care