FOL005

Non-confidential presentation

May2023

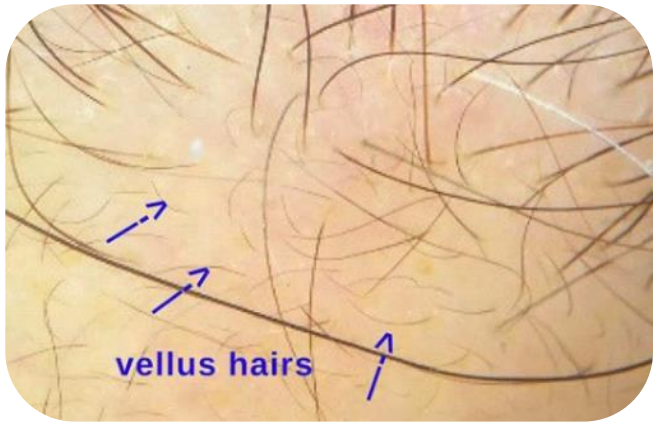
- A portfolio company of Coegin Pharma AB

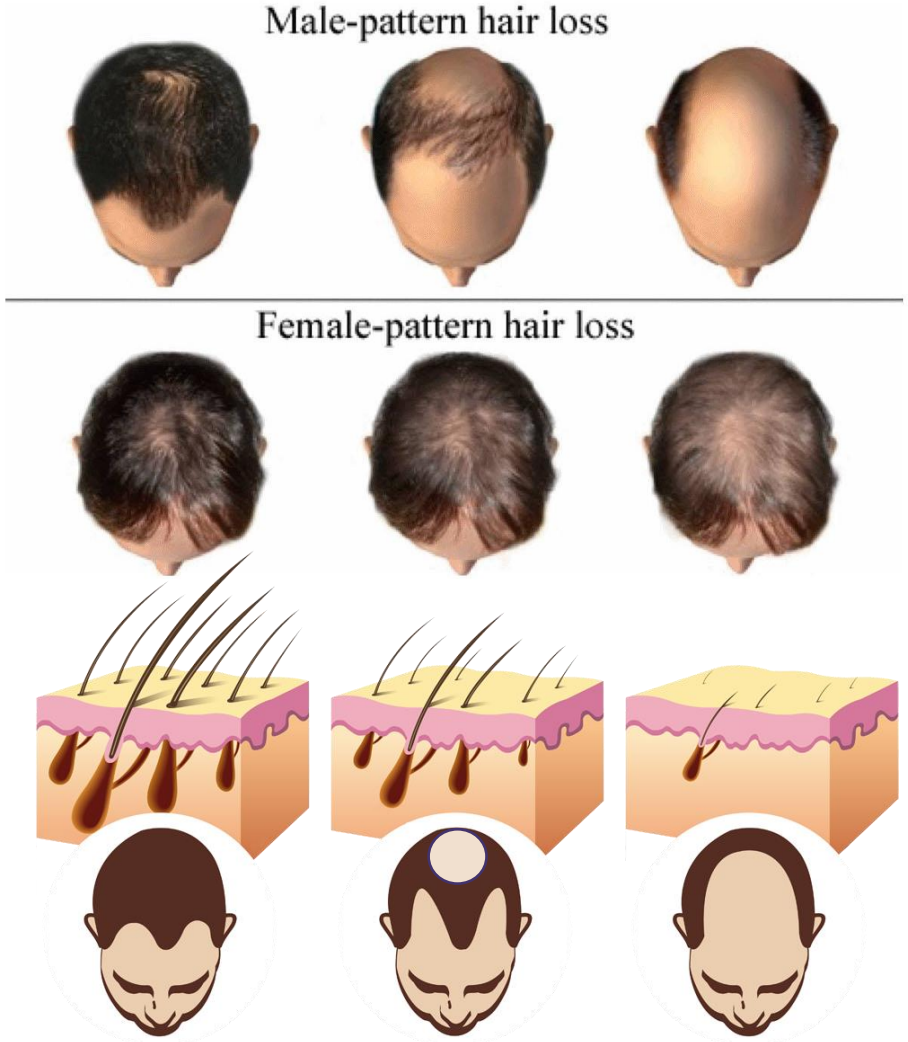
Pattern baldness or hair loss
Androgenetic Alopecia – understand the disease

Androgenetic alopecia accounts for >95% of hair loss in men with 50–60 million men and 30–35 million women affected in the US

Androgenic changed to andro-**genetic** alopecia as heritance also plays a key role for the disease

Androgenetic alopecia is characterized by the gradual conversion of terminal hairs into indeterminate, and finally into vellus, hairs.





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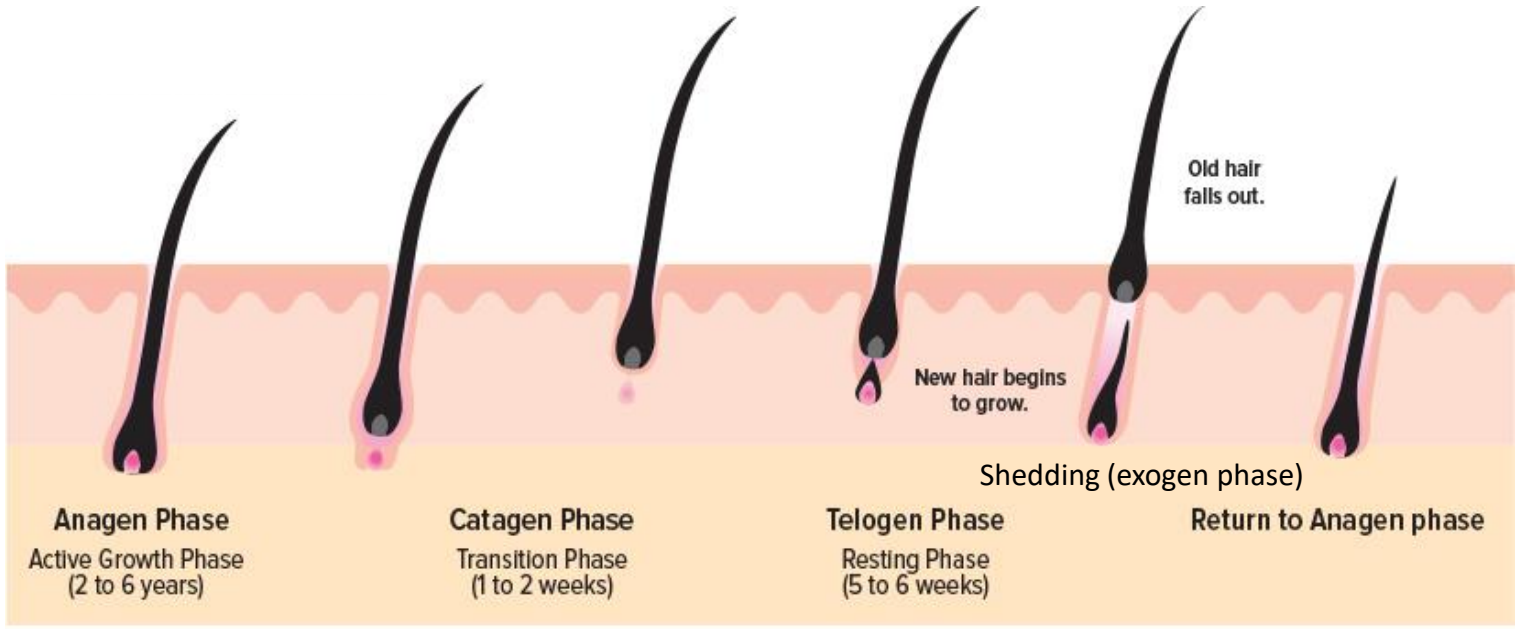
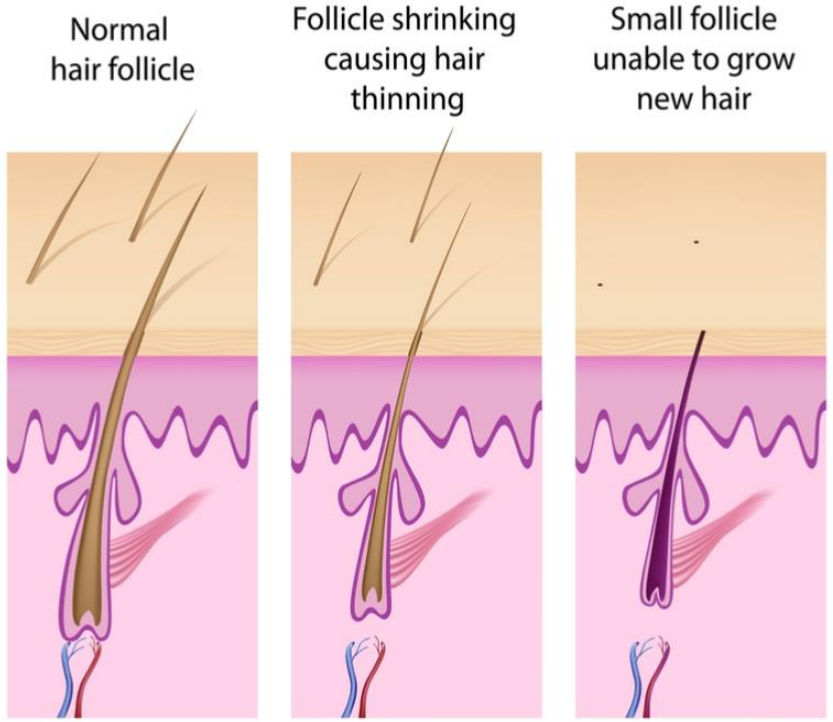
Reference:
Fitzpatrick's Dermatology, American Hair Loss Association, www.aaaesthetic.com & www.pngkey.com

The Hair Growth Cycle and Hair Loss

Key feature of androgenetic alopecia is abundance of telogen-stage follicles which, with time, decreases in size and eventually atrophy



The growth phase of new hairs takes around 4-6 months



The growth phase of new hairs in androgenetic alopecia is often impaired and caused by increased hormone levels and poor formation of blood vessels around hair follicles

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Reference:
Fitzpatrick's Dermatology

Existing Medical Treatments

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Existing treatments has few responders – representing a market with a high unmet need for new treatments

Finasteride
Oral anti-androgen (male sex hormones) drug taken once daily

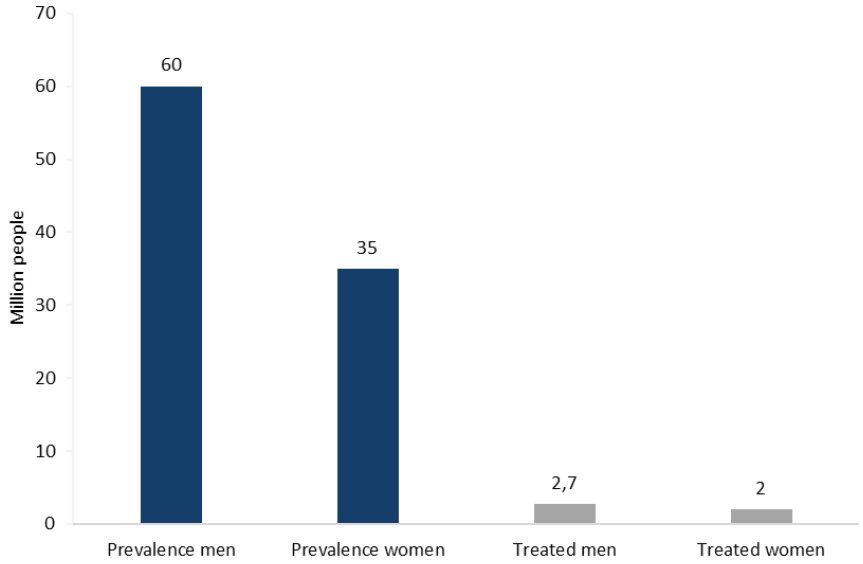
Clinical response typically observed after 4-9 months. Less than 40% of patients will regrow 7.0-13.5 hairs/cm2 ($p < 0.0001$) hair after 4-6 months

Minoxidil
Topical blood vessel stimulating solution applied to the scalp daily

Clinical response typically observed after 3-6 months. Around 40% of patients will regrow 4-18.6 hairs/cm2 ($p=0.074$, $p< 0.0001$) at 12 months

The market
Only two pharmaceutical treatments available with limited effect and with side effects

High unmet medical need with a large potential to expand the existing market in 2024:
- Finasteride estimated 3.2 bUSD
- Minoxidil estimated 1.9 bUSD



Gap between prevalent and treated population in USA

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Reference: EDF Guidelines and consensus statement for Androgenetic Alopecia & Dermatol Ther. Jan-Feb 2015;28(1):13-6; EDF Guidelines and consensus statement for Androgenetic Alopecia & Plast Aesthet Res 2017;4:161-73; American Hair Loss Association, Grand View Research, GlobeNewswire, Global Market Insights

FOL005 is strongly differentiated against competitors

	Compounds	Ease of use	Dosing	Efficacy	Safety	Gender	Responders	Patent
Marketed	Minoxidil	X	Topical twice daily	✓	X	M+F	~40%	off patent
Marketed	Finasteride	✓	Oral once daily	✓	X	M	~30%	off patent
Pipeline	Breezula	X	Topical twice daily	✓	✓	M	?	2023/2030
Pipeline	KSX-826	✓	Oral twice daily	✓	✓	M+F	?	?
Pipeline	FOL-005	✓	Topical once daily	✓	✓	M+F	~60%	2040

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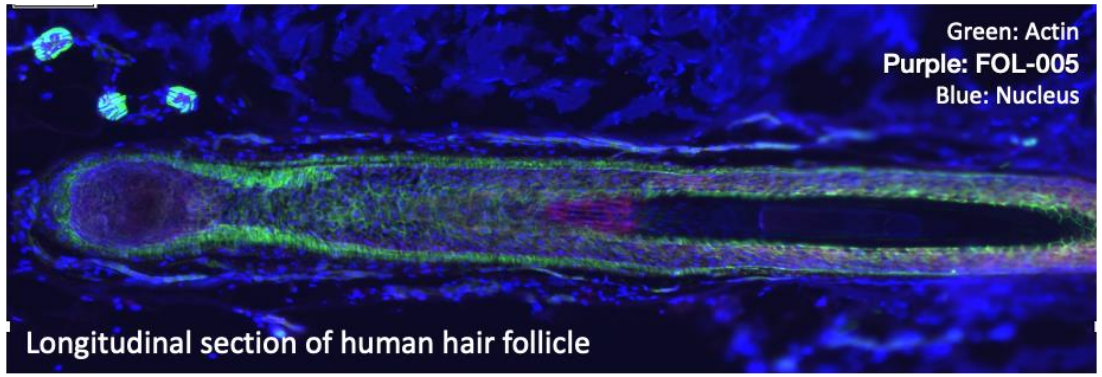
First in class NRP1 agonist with unique dual mode of action of FOL005 in androgenic alopecia

- FOL-005 is a synthetic peptide derivate of osteopontin and comprised of 15 amino acids with a free N and C- terminal
- Molecular weight is 1.672 kDa
- FOL-005 accumulates in the outer root sheath cell layer along the hair shaft
- FOL-005 binds specifically to Neuropillin-1 where it as a co-factor activates both stem cells and endothelial cells
- This results in stimulation of 1) hair growth and 2) increased vascularization of the hair follicle
- Three studies, phase I and II, in a sub-cutaneous or topical formulation has been conducted with positive outcomes



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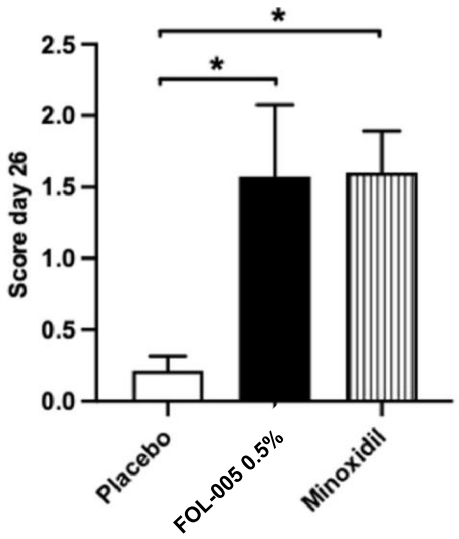
FOL-005 topical administered once daily showed a similar hair growth stimulation potential as topical minoxidil when administered twice daily

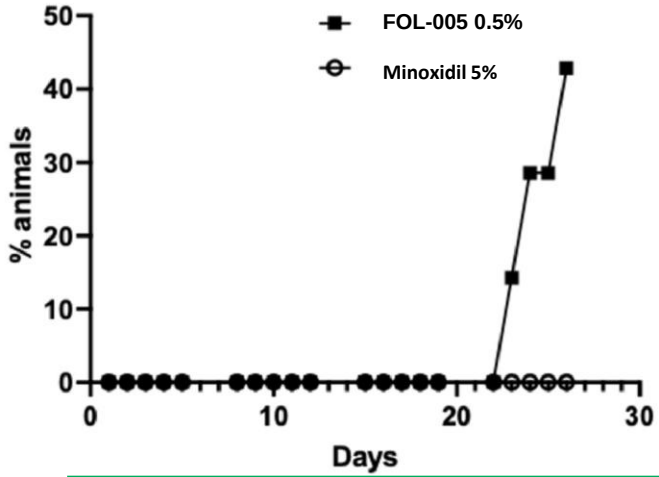
No animals in the Minoxidil group showed a dense normal coat at the end of the treatment period, whereas 43% of the animals in the 0.5% FOL-005 group reached a normal coat at day 26

Hairgrowth at end of treatment



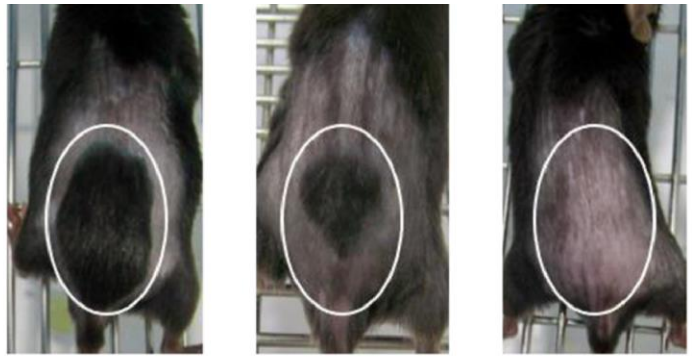
For medium dose (0,05%), and low dose (0,005%) FOL-005 an modest effect was observed after D23, data not shown.

Fraction of animals reaching full hair growth score (3.0)



Observation	Score
No hair growth, pink skin	0
Skin colour changes from pink to grey without visible hair growth	0.5
Skin colour changes from pink to grey or black without visible hair growth, indicating the onset of anagen	1.0
Sparse hair growth	1.5
Sparse or diffuse short hair growth	2.0
Moderate hair growth	2.5
Dense, normal coat hair	3.0

Representative animals from each group
(C57Bl/6 mouse, 6-9 weeks of age, at this age, all dorsal hair follicles are in stable telogen (resting) phase)



FOL-005 0.5% q.d. **Minoxidil 5% b.i.d.** **Placebo q.d.**

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Reference: Runnsjö A, Liljedahl S, Sagna D, Ekblad M, Alenfall J. A Novel Microparticle Based Formulation for Topical Delivery of FOL-005, a Small Peptide. J Pharm Sci. 2022 May;111(5):1309-1317. doi: 10.1016/j.xphs.2022.01.009. Epub 2022 Jan 31. PMID: 35093338.

Trial design for FCS003 – FOL005

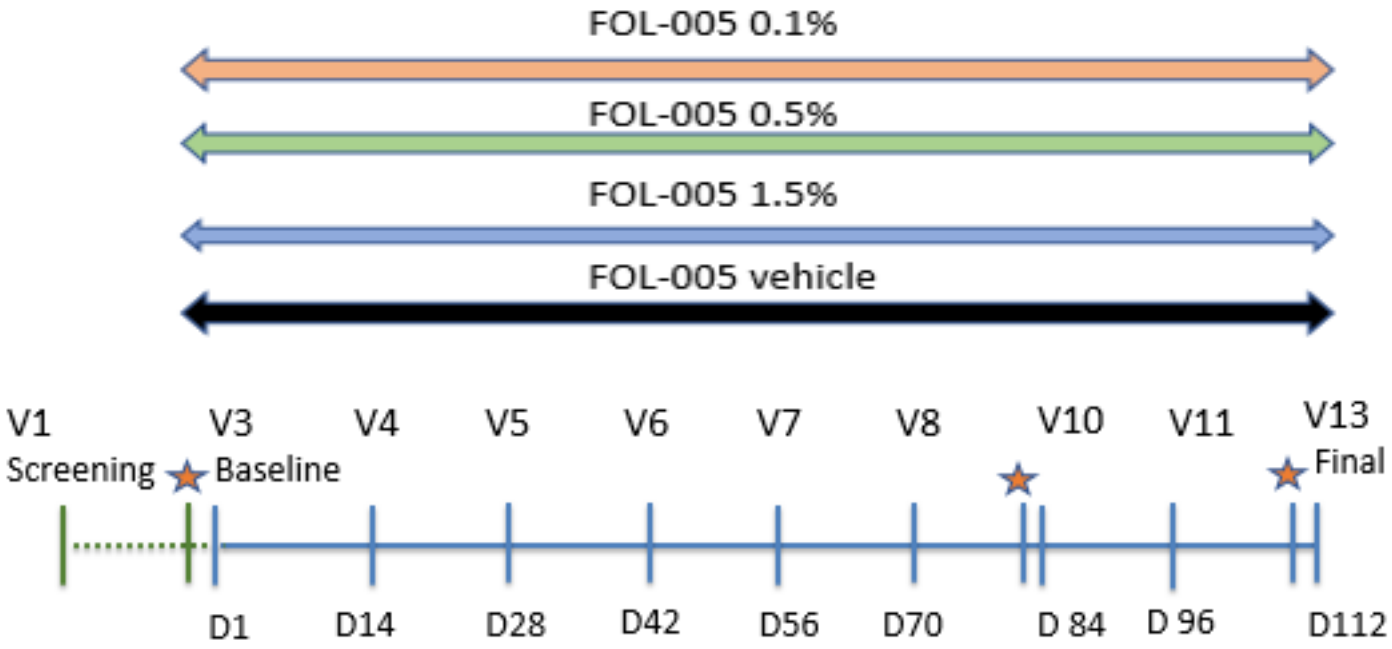
Phase 2a topical formulation

Safety, tolerability, and efficacy of FOL005 topical formulation

Three strengths of FOL005 0.1%, 0.5% and 1.5%, and vehicle

Administered once daily for 4 months (112 days)

In 210 male subjects with androgenetic alopecia



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Reference:
NCT04774874

FOL-005 has a statistically significant and dose dependent effect in treating androgenic alopecia in patients with <255 hairs/cm²

Normal hair growth is generally considered for hair density above 250 hairs/cm²*.

In the FCS003 study, patients with hair density below 255 hairs/cm² were identified as optimal treatment group based on analysis of baseline value

The following efficacy results presents data from this subgroup of patients with <255 hairs/cm² at baseline, representing 83 out of 199 patients

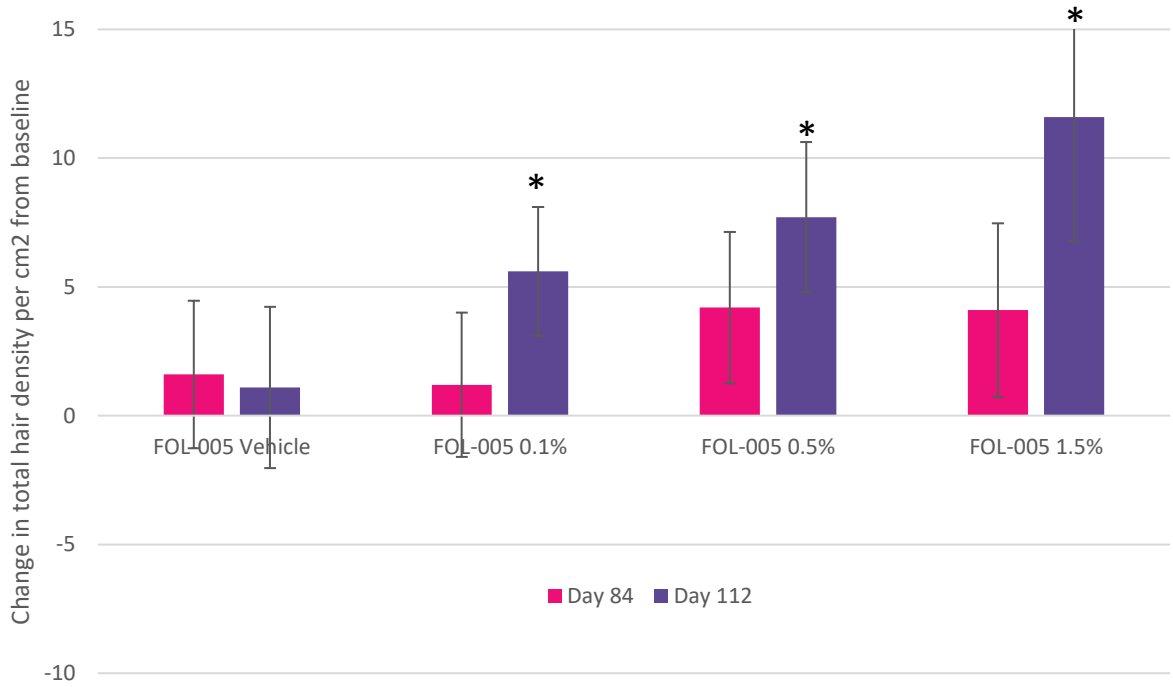


Figure 5-1, Total hair density, subset of subjects with a total hair density lower than 255 at baseline, +/-SEM (* p<0.05), per protocol poluation

*Barman JM, Astore I, Pecoraro V. The Normal Trichogram of the Adult. J Invest Dermatol. 1965;44:233-6.

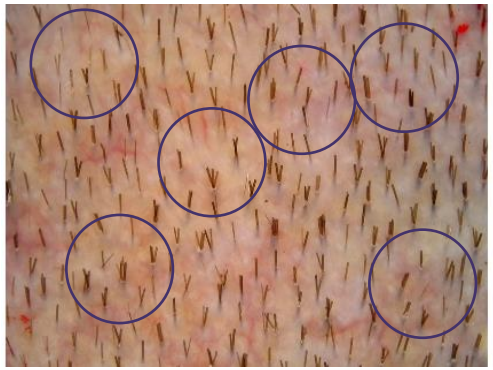
Reference:
Coegin Pharma AB data on file, explorative analysis of 2019-004305-26

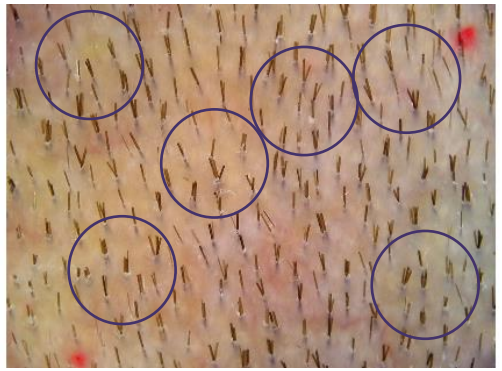
Representative TrichoScan images – phase IIa study

Day 1 (Baseline) **Day 112 (End of Treatment)**

FOL-005 1.5%

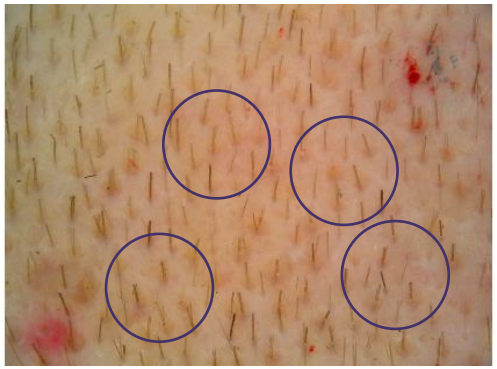
Difference in total hair counts 12 hairs/cm2
and non-vellus hair counts 12 hairs/cm2
Baseline counts 200 hairs/cm2 and
Day 112 212 hairs/cm2

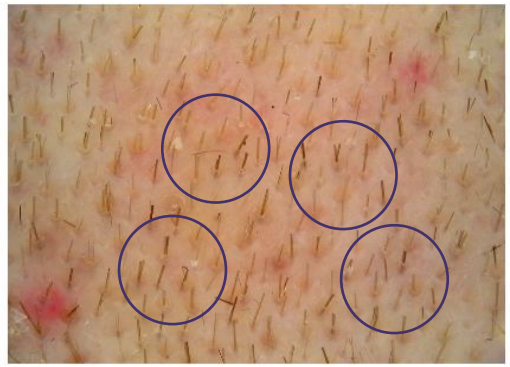




FOL-005 0.5%

Difference in total hair counts 7 hairs/cm2
and non-vellus hair counts 12 hairs/cm2
Baseline counts 252 hairs/cm2 and
Day 112 259 hairs/cm2





Circles indicate change in number of hairs from Baseline to End of Treatment

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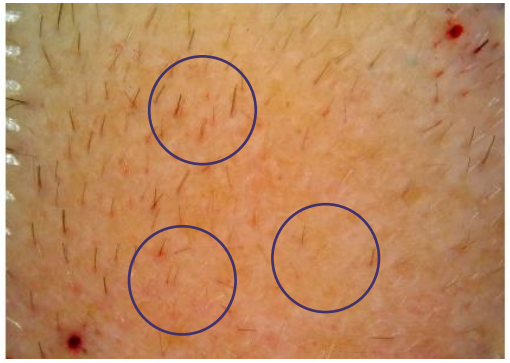
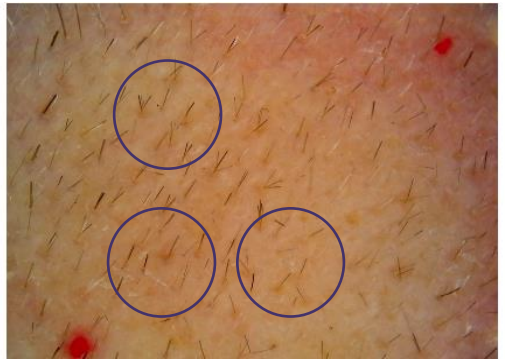
Representative TrichoScan images – Phase IIa study

Day 1 (Baseline) **Day 112 (End of Treatment)**

FOL-005 0.1%

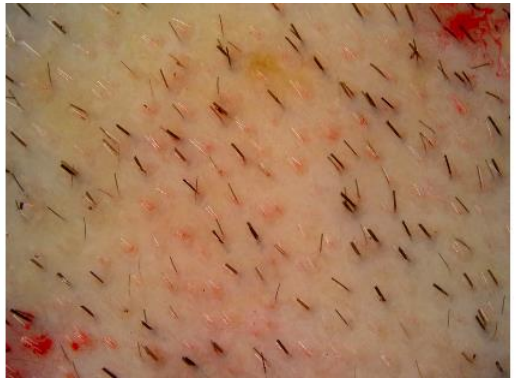
Difference in total hair counts 5 hairs/cm2
and non-vellus hair counts 13 hairs/cm2
Baseline counts 245 hairs/cm2 and
Day 112 251 hairs/cm2

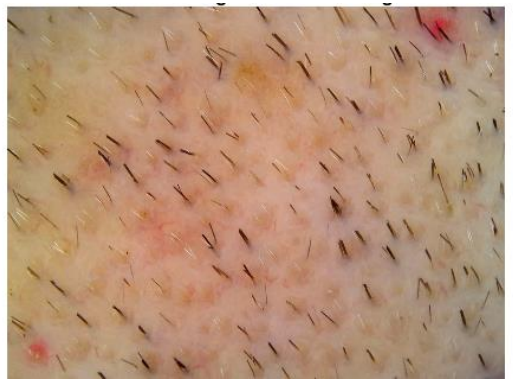




FOL-005-Vehicle

Difference in total hair counts 0 hairs/cm2
and non-vellus hair counts -9 hairs/cm2
Baseline counts 223 hairs/cm2 and
Day 112 223 hairs/cm2





Circles indicate change in number of hairs from Baseline to End of Treatment

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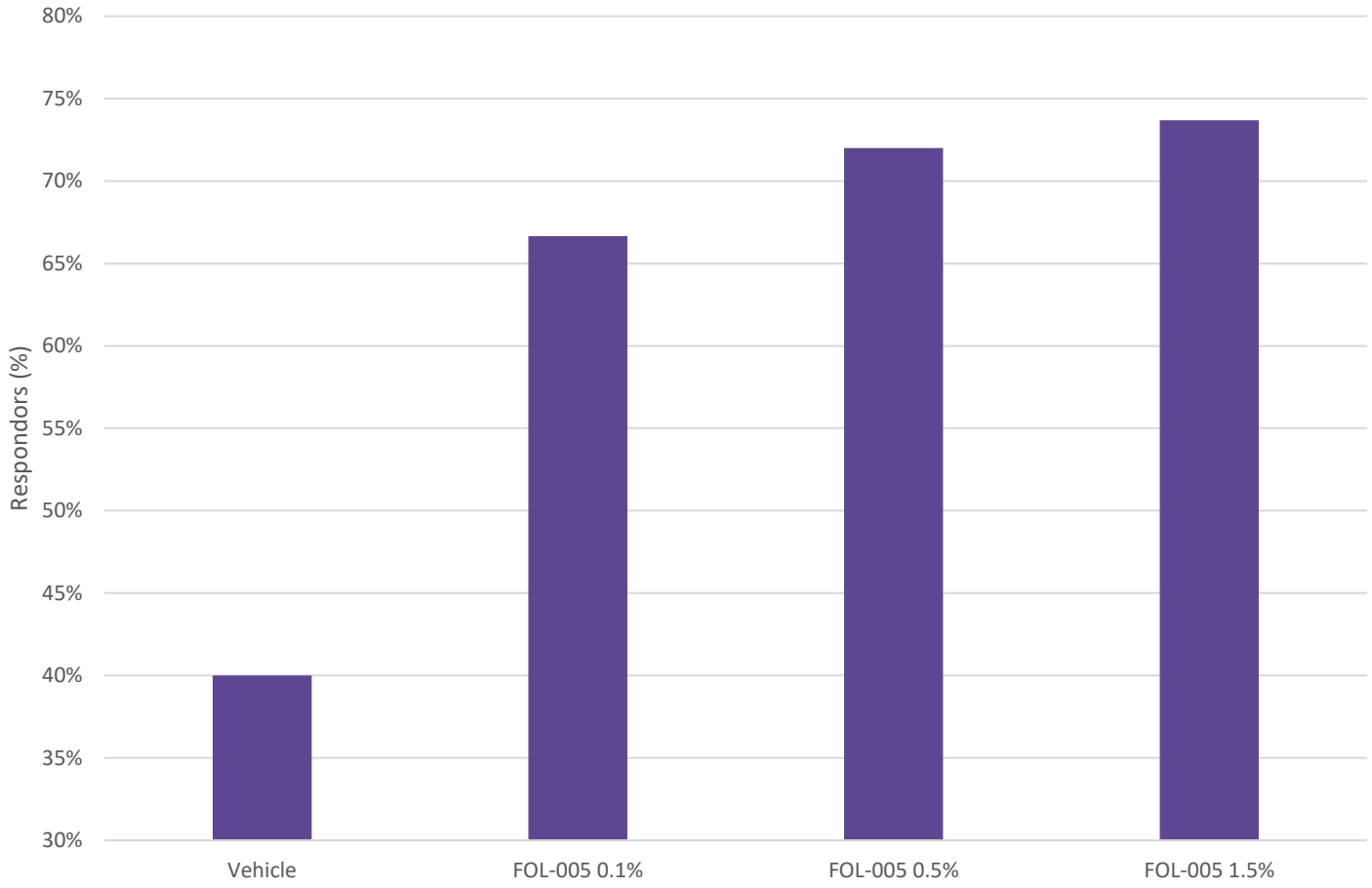
High degree of responders in the sub-group after 4 months

In patients with a total hair density lower than 255 at baseline, the responders were more than 60% at day 112 for all FOL005 treatment groups



In comparison the response rate for finasteride and minoxidil is 30 - 40%

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Reference: EDF Guidelines and consensus statement for Androgenetic Alopecia & Dermatol Ther. Jan-Feb 2015;28(1):13-6; EDF Guidelines and consensus statement for Androgenetic Alopecia & Plast Aesthet Res 2017;4:161-73;

Summary of Clinical Safety Data

313 males have been exposed to FOL-005 either in a topical (top.) or subcutaneous (s.c.) formulation

In three clinical trials FSC-001/2/3 in total 4 SAEs *unlikely* related to FOL-005 has been reported

In trial FCS-002, 2 subjects (both treated with placebo and the second highest dose 0.050 µg) were withdrawn due to AEs of mild severity.

In FSC-003, a total of 229 AEs in 112 (53.3 %) patients, *unlikely* related to FOL-005, with the majority of AEs being of "mild" severity. The most frequently reported AEs were headache (25.8 %) and nasopharyngitis (11.8 %).

In FSC-003 the investigational products were generally well tolerated, as erythema, scaling or pruritus were evident in less than 14 %, burning sensation in leass than 10 %, and induration in less than 2 % of of the patients

Overall safety and tolerability of FOL-005 topical formulation (0.1%, 0.5% and 1.5% strength) was considered as good when applied for the duration of 4 months

- First in Man trial FSC-001, 10 male subjects completed the Single Ascending s.c. Dose, 33 male subjects completed the Multiple s.c. Dose part, 12 weeks treatment
- Phase II trial FSC-002, 60 males diagnosed with androgenetic alopecia, 53 completed 12 weeks treatment
- Phase II trial FSC-003, 210 males diagnosed with androgenetic alopecia, 199 completed 12 weeks of top. treatment, no AE was reason for non-completion

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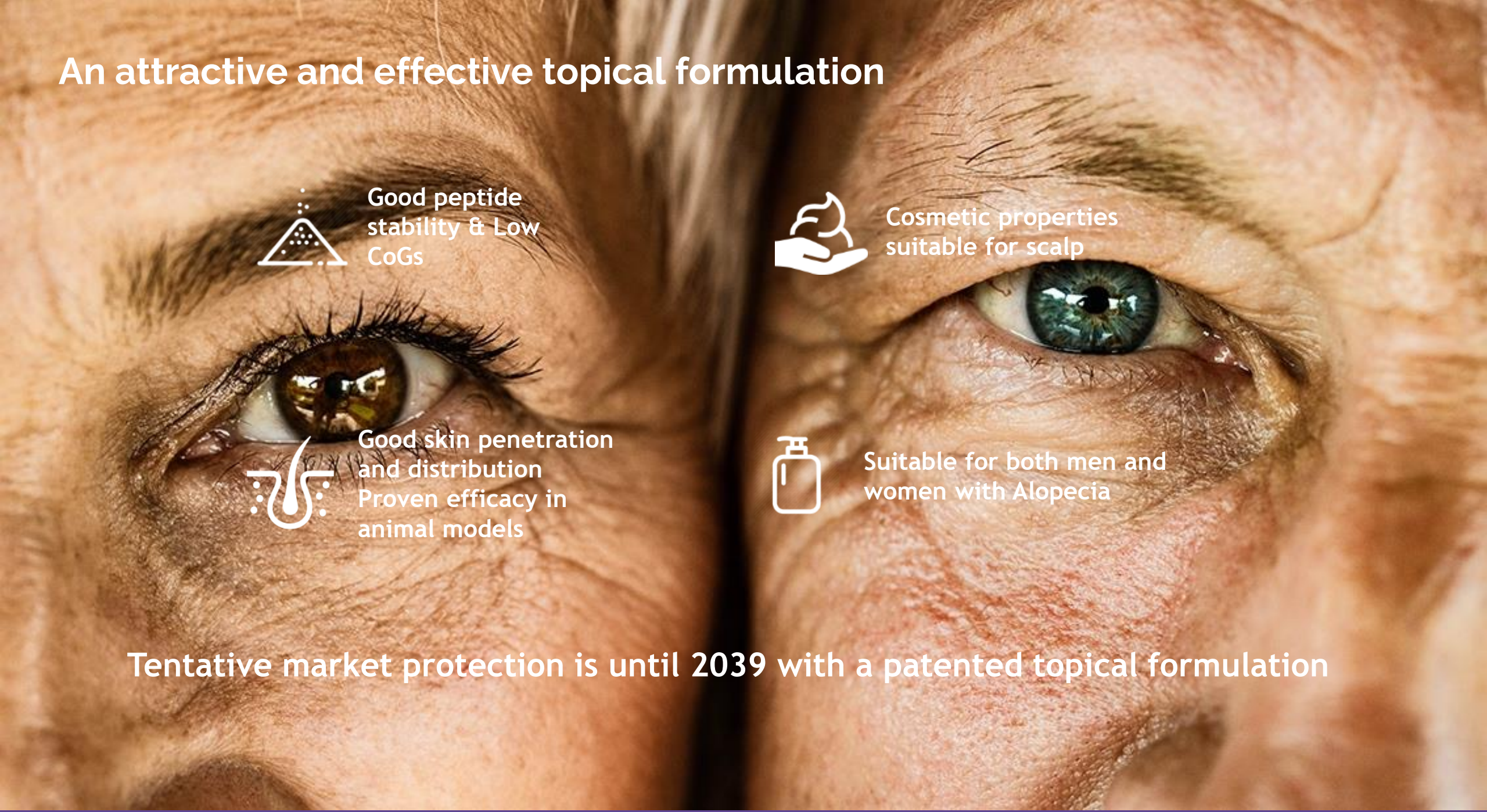
Reference: Coegin Pharma AB data on file, CTR FSC-001, FSC-002, and FSC-003

The cut-off date of clinical safety data is 05 JUN 2022

An attractive and effective topical formulation



Good peptide stability & Low CoGs

Cosmetic properties suitable for scalp

Good skin penetration and distribution
Proven efficacy in animal models

Suitable for both men and women with Alopecia

Tentative market protection is until 2039 with a patented topical formulation

Clinical trials FCS-001, FCS-002, FCS-003 successfully completed

		FCS-001*	FCS-002**	FCS-003***	FCS-004	FCS-005-7
Study	Phase I	Phase IIa	Phase IIa	Phase IIa	Phase IIb	Phase III, Three geographies (EU, USA, JP)
Purpose	Safety	Safety Efficacy – hair density	Safety Efficacy – hair density	Safety Efficacy – hair density	Efficacy – hair density Safety Biomarker (NRP-1)	Efficacy – hair density Safety
Area	Thighs	Thighs	Scalp	Scalp	Scalp	Scalp
Treatment	Injections Single ascending 4 doses	S.c. Injections Single ascending up to 3 times/week 3 months 4 doses (5, 25, 125, 250 ng, vehicle)	S.c. Injections 3 times/week 3 months 4 doses	Topical Daily/weekly 4 months 3 doses (0.1%, 0.5%, 1.5% + vehicle)	Topical Daily Up to 6 months 2 doses (0.5%, 1.5%, and vehicle)	Topical Daily 6-12 months 1 dose (TBD, and vehicle)
Subjects	10 Males	30 Males	Androgenetic Alopecia 60 Males	Androgenetic Alopecia 210 Males****	Androgenetic Alopecia Estimated >210 male and female in a sub-population	Androgenetic Alopecia Est. 700 males and females
Year	2016	2017	2018	2019-2023*****	2024	2025	2026	2027

* FCS-001: **A randomised, double-blind, placebo-controlled phase I/IIa trial of FOL-005 to investigate clinical safety and effect on hair growth in healthy volunteers**

** FCS-002: **A randomised, double-blind, placebo-controlled phase IIa trial of FOL-005 to investigate efficacy on hair growth on scalp skin in alopecia subjects**

*** FCS-003: **A randomized, double-blind, vehicle-controlled, dose-finding, multi-center, phase IIa trial of FOL-005 topical formulations to investigate hair growth potential and safety in healthy male volunteers**

**** In total 199 patients were treated per protocol, of which 89 patients (45%) had a hair density below 255 hairs/cm^2

***** Timeline impact due to COVID-19 pandemic

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FOL-005 - Potential First-in-class drug candidate

- Stable peptide
- **Low production cost**

- Optimised topical formulation
- **Strong IP until 2039**

- **Proven safety and efficacy**
- Efficient skin penetration and distribution

- **Suitable for both men and women**
- **Enhanced once daily ease-of-use**

FOL-005 has the potential to address a very high unmet medical need and a very large market opportunity replacing and complementing existing old products and expanding the market

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Executive Management

- A seasoned team with profound international hands-on R&D, commercialization and business development experience from both large and midsize pharma companies, world renown institutions and key disease areas

Tore Duvold
Chief Executive Officer

- Former CEO Aker Biopharma AS, SVP LEO Pharma A/S (part of Exec. Man)., and **CEO Innovation Fund DK.**
- M.Sc. in Organic Chemistry, and Ph.d. in Bioorganic Chemistry.
- Vast experience in **dermatology, drug research, pharma & biotech partnerships** incl. **licensing and exits.**

Lars Bukhave Rasmussen
Chief Financial Officer

- Former Head of US Marketing and other VP roles in LEO Pharma A/S, and CFO & COO Pila Pharma AB.
- Executive MBA, Graduate Diploma in Accounting, and Doctor of Veterinary Medicine.
- Vast experience in **dermatology**, financing, project management, **organizational design**, commercialization, and **business development** incl. **biotech/pharma partnerships.**

Berit Johansson
Chief Scientific Officer

- **Professor Norwegian University of Science and Technology (NTNU).**
- Ph.d. in Molecular Genetics.
- Vast experience in molecular biology, **inflammation** and **cancer** research.

Kristian Lykke Fick
Chief Commercial Officer

- Former **Head of Corporate Business Development** and other VP roles in LEO Pharma A/S incl. **President & CEO LEO Pharma Canada**.
- B.Sc. Business Administration, and M.Sc. Agricultural Economics.
- Vast experience in commercialization, and **business development** incl. **biotech/pharma partnerships**.

John Zibert
Chief Medical Officer

- Former **CEO at Studies&Me,** Chief Medical Officer at LEO Innovation Lab, Head of Medical Affairs EU+ LEO Pharma A/S.
- Ph.D. immunology and medicine, M.Sc. Molecular Oncology and Cancer Biology.
- Vast experience in **clinical study design and execution**, **dermatology**, **oncology**, research and development, innovation processes and medical affairs.