

Analysis of Mice Skin Distribution Using MALDI-MSI after Subcutaneous Injections of a Potent Novel Peptide Hair Growth Promoter, FOL-005.

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Hair loss, such as androgenic alopecia or other forms of alopecia, often causes major psychological distress. Today only few and unsatisfactory therapeutic options are available and hence new treatment strategies need to be developed. The multifunctional, immunomodulatory glycoprotein, osteopontin, is expressed by hair follicles (HFs) and a newly generated, modified osteopontin-derived peptide, FOL-005, has been shown to highly and reproducibly induce hair growth in mice. In a recently completed clinical phase I/IIa study, subcutaneous injections of FOL-005 were shown to be a safe treatment that resulted in 8 % increase in hair growth at one of the doses tested.

As part of the preclinical program for further development of a new formulation and an optimal treatment regimen with FOL-005, the distribution of subcutaneously injected FOL-005 into mice was followed in skin for up to 24 hours using the MALDI-MSI technology. MALDI-MSI, an advanced label free technique based on the combination of mass spectrometry imaging and histology, provides qualitative and quantitative data on the drug distribution and hence can add information on efficiency or potential toxicity.

FOL-005 was found to be distributed exclusively in the treated skin after injection and the concentration was shown to decrease with time. No distribution was detected outside the skin indicating that FOL-005 is locally degraded. The obtained data identify only a local distribution of FOL-005 peptide and further supports the clinical development as a new, much-needed treatment principle for alopecia patients.