## KURZPROTOKOLL MC2-01-C6

## Wissenschaftl, Titel

A Randomised, Open-label, Maximal Use Trial, Evaluating the Pharmacokinetic Profile of Active Ingredients and Their Metabolites After Application of MC2-01 Cream Compared With Active Comparator in Subjects With Extensive Psoriasis Vulgaris

Kurztitel

MC2-01-C6

**Studienart** 

multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig

Studienphase

Phase II

**Erkrankung** 

Haut: Schuppenflechte (Psoriasis)

Einschlusskriterien

- Have provided written informed consent
- Generally healthy males or non-pregnant females, of any race or ethnicity, who are at least 18 years of age at the time of screening
- At Visit 1/Day 0, have a clinical diagnosis of plaque psoriasis (psoriasis vulgaris) of at least 6 months duration involving scalp and body (trunk and/or limbs) that is amenable to topical treatment with a maximum of 100 g of trial medication per week
- Have a Physician's Global Assessment [PGA] of severity of at least moderate on the trunk, limbs and/or scalp, at Visit 1/Day 0
- Have a treatment area between 20% and 30% of the body surface area [BSA] on the trunk, limbs and/or scalp, excluding psoriatic lesions on the face, genitals, and intertriginous areas, at Visit 1/Day 0

## Ausschlusskriterien

- Current diagnosis of unstable forms of psoriasis
- Other inflammatory skin disease in the treatment area
- Pigmentation, extensive scarring, pigmented lesions or sunburn in the treatment areas
- Planned exposure to natural or artificial sunlight
- Phototherapy and ultraviolet B radiation within 4 weeks prior to Visit 1/Baseline and during the trial
- Current or past history of hypercalcemia, vitamin D toxicity, severe renal insufficiency, or severe hepatic disorders
- Oral calcium supplements, vitamin D supplements, bisphosphonates or calcitonin within 4 weeks prior to Visit 1/Day 0 during the trial period
- Planned initiation of, or changes to concomitant medication that could affect calcium metabolism during the trial
- Planned initiation of, or changes to, concomitant estrogen therapy during the trial
- Strong systemic cytochrome P450 3A4 (CYP 3A4) inhibitors within 4 weeks prior to Vist 1/Day 0 and during the trial period
- Use of topical treatments, except for emollients and non-medicated shampoos, with a
  possible effect on psoriasis within 2 weeks prior to Visit 1/Day 0 and during the trial
  period
- Systemic treatment with biological therapies
- Initiation of, or expected changes to, concomitant medication that may affect psoriasis during the trial period
- Depression and endocrine disorders known to affect cortisol levels or HPA axis integrity, non-nocturnal sleep patterns
- Systemic medication that suppresses the immune system within 4 weeks prior to the Visit 1/Day 0 and during the trial period
- Clinical signs of skin infection with bacteria, viruses, or fungi
- Known human immunodeficiency virus [HIV] infection;
- Known or suspected of hypersensitivity to any component of the test product or reference product

## KURZPROTOKOLL MC2-01-C6

- Any chronic or acute medical condition that may pose a risk to the safety of the subject, or may interfere with the assessment of safety or efficacy in this trial

Alter 18 Jahre und älter

Prüfzentren Klinik für Dermatologie, Venerologie und Allergologie (Rekrutierung beendet)

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**Sponsor** MC2 Therapeutics

Registrierung in anderen ClinicalTrials.gov NCT03462927 (primäres Register)

Studienregistern EudraCT 2018-000685-12