KURZPROTOKOLL CP543.3002

Öffentlicher Titel Phase III Studie zu CTP-543 bei morderater bis schwerer Alopecia areata

Wissenschaftl. Titel A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and

Safety of CTP-543 in Adult Patients with Moderate to Severe Alopecia Areata.

Kurztitel CP543.3002

Studienart multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind,

dreiarmig

Studienphase Phase III

Erkrankung Haut: sonstige

Einschlusskriterien - Clinical presentation compatible with alopecia areata with a current episode lasting at least 6 months and not exceeding 10 years at the time of Screening. Total disease

duration greater than 10 years is permitted.

At least 50% scalp hair loss, as defined by a SALT score >= 50, at Screening and

Baseline.

- Willing to comply with the study visits and requirements of the study protocol.

Ausschlusskriterien - Treatment with other medications or agents within 1 month of Baseline or dur

Treatment with other medications or agents within 1 month of Baseline or during the study that may affect hair regrowth or immune response.

- Active scalp inflammation, psoriasis, or seborrheic dermatitis requiring topical treatment to the scalp, significant trauma to the scalp, or other scalp condition that may interfere with the SALT assessment, or untreated actinic keratosis anywhere on

the body at Screening and/or Baseline.

- Treatment with systemic immunosuppressive medications within 3 months of Screening or during the study, or biologics within 6 months of Screening or during the

study.

- Females who are nursing, pregnant, or planning to become pregnant while in the

study, and for 30 days after last dose of study drug.

 Clinically significant medical condition, psychiatric disease, or social condition, as determined by the Investigator, that may unfavorably alter the risk-benefit of study participation, adversely affect study compliance, or confound interpretation of study

results.

Alter 18 - 65 Jahre

Prüfzentren Klinik für Dermatologie, Venerologie und Allergologie (Geschlossen)

Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. Edith Respondek

Sponsor Concert Pharma

Registrierung in anderen EudraCT 2021-000387-30 (primäres Register)

Studienregistern ClinicalTrials.gov NCT04797650