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 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 Studienregistern	EudraCT 2021-000387-30 (primäres Register) ClinicalTrials.gov NCT04797650