KURZPROTOKOLL
ABP654

Öffentlicher Titel	Phase III Studie zu Ustekinumab und ABP 654 bei moderater bis schwerer Schuppenflechte
Wissenschaftl. Titel	A Multicenter, Randomized, Double-blinded Study Evaluating the Pharmacokinetics, Efficacy and Safety of Multiple Switches Between Ustekinumab and ABP 654 Compared With Continued Use of Ustekinumab in Subjects with Moderate to Severe Plaque Psoriasis
Kurztitel	ABP654
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Haut: Schuppenflechte (Psoriasis)
Einschlusskriterien	- Participant has stable moderate to severe plaque psoriasis for at least 6 months - Participant has a score of PASI >= 12, involvement of >= 10% body surface area and static Physician Global Assessment >= 3 at screening and at baseline - Participant is a candidate for phototherapy or systemic therapy - Participant has previous failure, inadequate response, intolerance, or contraindication to at least 1 conventional antipsoriatic systemic therapy - Female participant should have a negative serum pregnancy test during screening and a negative urine pregnancy test at baseline - Participant or legally acceptable representative is capable of giving signed Institutional Review Board (IRB)/Independent Ethics Committee (IEC) informed consent - Participant has no known history of latent or active tuberculosis - Participant with a positive purified protein derivative (PPD) test and a history of Bacillus Calmette-Guérin (BCG) vaccination is allowed with a negative Quantiferon/T-spot test - Participant with a positive PPD test or participant with a positive or indeterminate Quantiferon/T-spot test is allowed if he/she has all the following: - a. No symptoms per tuberculosis worksheet provided by the sponsor, Amgen Inc. - b. Documented history of adequate prophylaxis initiation prior to receiving investigational product in accordance with local recommendations - c. No known exposure to a case of active tuberculosis after most recent prophylaxis - d. No evidence of active tuberculosis on chest radiograph within 3 months prior to the first dose of investigational product
Ausschlusskriterien	- Participant has erythrodermic psoriasis, pustular psoriasis, guttate psoriasis, medication induced psoriasis, or other skin conditions at the time of screening (eg, eczema) that would interfere with evaluations of the effect of investigational product of psoriasis - Participant has an active infection or history of infections - Participant has uncontrolled, clinically significant systemic disease, such as uncontrolled diabetes mellitus, cardiovascular disease, renal disease, liver disease, or hypertension - Participant has a mean QT internal or abnormal long QT syndrome corrected using Fridericia's formula (QTcF) of > 450 msec (for male participant) or > 470 msec (for female participant) at baseline that, in the opinion of the Investigator, is abnormal or clinically significant - Participant has moderate to severe heart failure (New York Heart Associate class III/IV)

- Participant has known hypersensitivity to the investigational product or to any of the excipients
- Participant has laboratory abnormalities at screening
- Participant has had previous treatment with any agent specifically targeting interleukin (IL)-12 or IL-23 within 1 year prior to enrollment
- Participant has received biologic treatment for psoriasis within the previous month or 5 drug half-lives (whichever is longer) prior to enrollment
- Participant has received any investigational agents within the previous month or 5 half-lives (whichever is longer) prior to enrollment
- Participant has received non-biologic systemic psoriasis therapy within 4 weeks prior to enrollment
- Participant has received ultraviolet A phototherapy (with or without psoralen) or excimer laser within 4 weeks prior to enrollment, or ultraviolet B phototherapy within 2 weeks prior to enrollment
- Participant has received topical psoriasis treatment within 2 weeks prior to enrollment
- Participant has received other investigational procedures within 4 weeks prior to enrollment and during the course of the study
- Female participant is pregnant or breastfeeding or planning to become pregnant while participating in the study and for at least 5 months after the last dose of investigational product
- Sexually active participants and their partners who are of childbearing potential and not agreeing to use adequate protocol defined contraception methods while participating in the study and for 5 months after the last dose of investigational product

Alter	18 - 75 Jahre
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Nachbeobachtung) Theodor-Stern-Kai 7 60590 Frankfurt am Main Kerstin Peter Tel: 069 6301 4985 kerstin.peter@unimedizin-ffm.de
Sponsor	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04761627 EudraCT 2020-005205-42 (primäres Register)