KURZPROTOKOLL
BI1407-0030

Öffentlicher Titel	Phase II Studie zu BI730357 bei Patienten mit Schuppenflechte
Wissenschaftl. Titel	Phase 2 evaluation of safety, tolerability, and efficacy of BI730357 in patients with moderate-to-severe plaque psoriasis.
Kurztitel	BI1407-0030
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, mehrarmig
Studienphase	Phase II
Erkrankung	Haut: Schuppenflechte (Psoriasis)

Einschlusskriterien

- Male or female patients. Woman Of Childbearing Potential (WoCBP) must be ready and able to use highly effective methods of birth control per International Conference on Harmonisation (ICH) M3 (R2) that result in a low failure rate of less than 1% per year when used consistently and correctly from date of screening until 4 weeks after last treatment in this trial. A list of contraception methods meeting these criteria is provided in the patient information
- Age 18 to 75 years (both inclusive) at screening
- BMI < 35 kg/m2 at screening
- Diagnosis of chronic plaque psoriasis (with or without psoriatic arthritis) for at least 6 months before the first administration of study drug. Duration of diagnosis may be reported by the patient
- Patients must be candidates for systemic PsO therapy. Moderate-to-severe plaque psoriasis: BSA >=10% and PASI >=12 and sPGA moderate or severe
- Signed and dated written informed consent in accordance with ICH-GCP and local legislation prior to admission to the trial

Ausschlusskriterien

- Nonplaque forms of PsO (including guttate, erythrodermic, or pustular), current drug induced PsO (including a new onset or exacerbation of PsO from, e.g., beta blockers, calcium channel blockers, lithium), active ongoing inflammatory diseases (including but not limited to Inflammatory bowel disease (IBD)) other than PsO that might confound trial evaluations
- Previous enrolment in this trial or previous exposure to BI 730357
- Current enrollment in another investigational device or drug trial, or is less than 30 days (from randomisation) since ending another investigational device or drug trial(s), or receipt of other investigational treatment(s)
- Use of any biologic agent within 12 weeks, or any anti IL-23 biologic agent within 24 weeks prior to randomisation, or systemic anti-psoriatic medications or phototherapy within 4 weeks prior to randomisation, or topical anti-psoriasis medications within 2 weeks prior to randomisation
- Receipt of a live vaccination within 12 weeks prior to randomisation (visit 2), or any plan to receive a live vaccination during the conduct of this trial
- Patients who must or wish to continue the intake of restricted medications or any drug considered likely to interfere with the safe conduct of the trial
- Patients not expected to comply with the protocol requirements or not expected to complete the trial as scheduled
- Chronic alcohol or drug abuse or any condition that, in the investigator's opinion, makes the patient an unreliable trial participant or unlikely to complete the trial
- Major surgery (major according to the investigator's assessment) performed within 12 weeks prior to randomisation or planned within 12 months after screening, e.g., hip replacement
- Women who are pregnant, nursing, or who plan to become pregnant while in the trial

	- Any documented active or suspected malignancy or history of malignancy within 5 years prior to screening, except appropriately treated basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or in situ carcinoma of uterine cervix - Relevant chronic or acute infections including human immunodeficiency virus (HIV), viral hepatitis, candidiasis and tuberculosis. A patient can be re-screened if the patient was treated and is cured from the acute infection - Evidence of a current or previous disease (including known or suspected IBD, and cardiovascular disease), or medical finding that in the opinion of the investigator is clinically significant and would make the study participant unreliable to adhere to the protocol or to complete the trial, compromise the safety of the patient, or compromise the quality of the data - Any suicidal ideation, including grade 4 or 5 in the Columbia Suicide Severity Rating Scale (CSSRS) in the past 3 months (i.e., active suicidal thought with intent but without specific plan, or active suicidal thought with plan and intent) - Unwillingness to adhere to the rules of UV-light protection
Alter	18 - 75 Jahre
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Sponsor	Boehringer Ingelheim Pharmaceuticals
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03635099 (primäres Register) EudraCT 2017-004659-21