# *KURZPROTOKOLL*
# *BI1407-0005*

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| **Öffentlicher Titel** | Phase II Langzeitstudie zu BI730357 bei Patienten mit Schuppenflechte |
| **Wissenschaftl. Titel** | Phase 2 long-term extension study to assess the safety, tolerability and efficacy of BI730357 in patients with moderate-to-severe plaque psoriasis. |
| **Kurztitel** | BI1407-0005 |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig |
| **Studienphase** | Phase II |
| **Erkrankung** | Haut: Schuppenflechte (Psoriasis) |
| **Einschlusskriterien** | - Woman Of Child Bearing 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<br>- Patients with moderate-to-severe plaque Psoriasis (PsO) who have completed treatment in the preceding trial without early discontinuation, agree to continue treatment in 1407-0005, and for patients entering from Part 1 of trial 1407-0030 and achieve a >=PASI50 response upon completing the trial 1407-0030 at Week 24 end-of-treatment visit and for patients entering from Part 2 of trial 1407-0030 and achieve a >=PASI50 response upon completing the trial 1407-0030 at Week 12 end-of-treatment visit or perceived patient improvement, at the discretion of the Investigator<br>- 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<br>- Previous enrolment in this trial<br>- Currently enrolled in another investigational device or drug trial or is receiving other investigational treatment(s) (with the exception of 1407-0030)<br>- Intake of any restricted medication or any drug considered likely to interfere with the safe conduct of the trial<br>- Any plan to receive a live vaccination during the conduct of the trial<br>- Patients not expected to comply with the protocol requirements or not expected to complete the trial as scheduled<br>- 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<br>- Women who are pregnant, nursing, or who plan to become pregnant while in the trial<br>- Any documented active or suspected malignancy, except appropriately treated basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or in situ carcinoma of uterine cervix<br>- Relevant chronic or acute infections including human immunodeficiency virus (HIV), viral hepatitis and tuberculosis<br>- Evidence of a disease (including known or suspected IBD, 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<br>- Any suicidal ideation, including grade 4 or 5 in the Columbia Suicide Severity Rating Scale (C-SSRS) in the past 12 months (i.e., active suicidal thought with intent but without specific plan), or active suicidal thought with plan and intent in the past |

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| | - Unwillingness to adhere to the rules of UV-light protection<br>- Ongoing AEs consistent with intolerance of trial medication (including gastric intolerance) from 1407-0030, that in the opinion of the investigator would compromise the safety of the patient |
| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Klinik für Dermatologie, Venerologie und Allergologie** (Rekrutierung beendet)<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Dr. med. Andreas Pinter<br>Tel: 069 6301-83115<br>Fax: 069 6301-83175<br>andreas.pinter@unimedizin-ffm.de |
| **Sponsor** | Boehringer Ingelheim Pharmaceuticals |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT03835481 (primäres Register)<br>EudraCT 2018-003487-31 |