KURZPROTOKOLL
BI-1368-0120

Öffentlicher Titel	Phase IV Studie zu Spesolimab bei Schüben von Schuppenflechten nach Spesolimab-Behandlung
Wissenschaftl. Titel	An open-label, multicenter, single-arm, post-marketing trial to evaluate efficacy and safety and the impact of immunogenicity on efficacy, safety, and pharmacokinetics of spesolimab i.v. in treatment of patients with Generalized Pustular Psoriasis presenting with recurrent flare following their initial GPP flare treatment with spesolimab i.v.
Kurztitel	BI-1368-0120
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig
Studienphase	Phase IV
Erkrankung	Haut: Schuppenflechte (Psoriasis)
Einschlusskriterien	- Patients with a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub-score of 0 or 1 and a known and documented history of Generalized Pustular Psoriasis (GPP) (per European Rare And Severe Psoriasis Expert Network - ERASPEN - criteria), regardless of Interleukin 36 Receptor Antagonist (IL-36RN) gene mutation status or Patients with a GPP flare and a known and documented history of GPP (per ERASPEN criteria) regardless of IL-36RN gene mutation status - Patients must have a history of frequent GPP flares in the past - Male or female patients, aged >=18 years (if local legislation for age of consent differs, then local legislation will be followed) at screening - Signed and dated written informed consent prior to admission to the trial in accordance with International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) and local legislation prior to start of any screening procedures - Women of childbearing potential (WOCBP) must be ready and able to use highly effective methods of birth control per ICH M3 (R2) that result in a low failure rate of less than 1% per year when used consistently and correctly
Ausschlusskriterien	- Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP) - Patients with primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques - Patients with primary erythrodermic psoriasis vulgaris - Patients with SAPHO (Synovitis-acne-pustulosis-hyperostosis-osteitis) syndrome - Immediate life-threatening flare of GPP or requiring intensive care treatment, according to the investigator's judgement. Life-threatening complications mainly include, but are not limited to, cardiovascular/cytokine driven shock, pulmonary distress syndrome, or acute renal failure - Severe, progressive, or uncontrolled hepatic disease, defined as >3-fold upper limit normal (ULN) elevation in Aspartate Aminotransferase (AST) or Alanine Aminotransferase (ALT) or alkaline phosphatase, or >2-fold ULN elevation in total bilirubin - Presence of acute demyelinating neuropathy - Treatment with any drug considered likely to interfere with the safe conduct of the trial, as assessed by the investigator - Further exclusion criteria apply
Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Klinik für Dermatologie, Venerologie und Allergologie Theodor-Stern-Kai 7 60590 Frankfurt am Main T. O'Connor
Sponsor	Boehringer Ingelheim Pharmaceuticals

Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT06013969 EudraCT 2022-502128-38-00
Links	Zu den Ein- und Ausschlusskriterien