KURZPROTOKOLL
GAP

Öffentlicher Titel	Phase II Studie zu Guselkumab bei mittelschwerer bis schwerer palmoplantarer Pustulose (PPP)
Wissenschaftl. Titel	Multizentrische, offene, einarmige Pilotstudie zur Bewertung der Wirksamkeit und Sicherheit von Guselkumab bei Patienten mit mittelschwerer bis schwerer, palmoplantarer Pustulose (PPP)
Kurztitel	GAP
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase II
Erkrankung	Haut: Schuppenflechte (Psoriasis)
Einschlusskriterien	- 1. Male or female, aged 18 years or more at screening visit - 2. given written consent to participate in the study - 3. has moderate to severe PPP defined as a ppPPPASI >= 12 at baseline (week 0) with or without concomitant plaque-type psoriasis - 4. a candidate for systemic treatment defined as having PPP inadequately controlled by topical treatment and/or phototherapy and/or previous sys-temic therapy - 5. has chronic disease of PPP of 6 months calculated from date at which first symptoms were reported by subject to date of screening visit - 6. Agree not to receive a live virus or live bacterial vaccination during the study, or within 3 months after the last administration of study drug - 7. Agree not to receive a BCG vaccination during the study, or within 12 months after the last administration of study drug - 8. Subjects with the ability to follow study instructions and likely to attend and complete all required visits - 9. Before first administration of study drug, a woman must be - a. Not of childbearing potential - b. Of childbearing potential and practicing a highly effective method of contraception (failure rate of <1% per year when used consistently and correctly) and agrees to remain on a highly effective method method while receiving study treatment and until 12 weeks after last dose - the end of relevant systemic exposure. Examples of highly effective methods of contraception are located in section 9.4. - 10. A woman of childbearing potential must have a negative urine preg-nancy test at screening and agree to urine pregnancy testing before re-ceiving injections and at safety follow-up. - 11. A woman must agree not to donate eggs (ova, oocytes) for the pur-poses of assisted reproduction during the study and for a period of 12 weeks after receiving the last administration of guselkumab. - 12. A male subject must wear a condom when engaging in any activity that allows for passage of ejaculate to another person. - 13. A male subject must agree not to donate sperm for the purpose of reproduction during the study and for a minimum 12 weeks after receiving the last dose of study treatment. - 14. It is the responsibility of the investigator to verify the adequacy of previous anti-TB treatment and provide appropriate documentation. - a. Have no history of latent or active TB before screening - b. Have no signs or symptoms suggestive of active TB upon medical history and/or physical examination. - c. Have had no recent close contact with a person with active TB or, if there has been such contact, will be referred to a physician specializing in TB

- d. Within 2 months before the first administration of study drug, have a negative QuantiFERON®-TB Gold test result, or have a newly identified positive QuantiFERON-TB Gold test result in which active TB has been ruled out and for which appropriate treatment for latent TB has been initiated before the first administration of study drug.
- e. NOTE: The QuantiFERON-TB Gold test is not required at screening for subjects with a history of latent TB and ongoing treatment for latent TB or documentation of having completed ad-equate treatment as described above; subjects with documenta -tion of having completed adequate treatment as described above are not required to initiate additional treatment for latent TB
- f. Have a chest radiograph (posterior-anterior and lateral views, or per country regulations where applicable), taken within 3 months before the first administration of study drug and read by a quali-fied radiologist, with no evidence of current, active TB or old, inactive TB
- 15. An exception is made for subjects who have a history of latent TB and
- a) are currently receiving treatment for latent TB, which must be started at least four weeks until baselinevisit
- b) will initiate treatment for latent TB conform to the Paul-Ehrlich- In-stitute guidelines before the first administration of study drug,
- c) or have documentation of having completed appropriate treatment for latent TB within 5 years before the first administration of study drug.

Ausschlusskriterien

- 1. Subject without legal capacity or is unable to understand the nature, scope, significance and consequences of this clinical trial
- 2. Simultaneously participation in another clinical trial or participation in any clinical trial involving administration of an investigational medicinal product within 4 weeks or 5 pharmacokinetic/pharmacodynamics half-lives (which-ever is longer)prior to participation in present clinical trial
- 3. Subjects with a physical or psychiatric condition which at the investigator’s discretion may put the subject at risk, may confound the trial results, or may interfere with the subject’s participation in this clinical trial
- 4. Known or persistent abuse of medication, drugs or alcohol
- 5. Known history of hypersensitivity to the investigational drug or to drugs with a similar chemical structure or to any components of guselkumab
- 6. Evidence of skin conditions (eg eczema) other than psoriasis that would interfere with evaluations of the effect of study medication on psoriasis.
- 7. Ultraviolet B (UVB) therapy, topical steroids, topical calcineurin inhibitors, topical Vitamin A or D analog preparations, or anthralin within 14 days of baseline.
- 8. Psoralen plus ultraviolet A radiation (PUVA), ciclosporin, acitretin, ale-facept (AmeviveTM), anakinra (KineretTM), systemic corticosteroids, methotrexate, fumaric acids, apremilast or any other systemic anti-psoriasis therapy within 28 days of baseline
- 9. antipsoriatic biologic therapy with TNF- blockers or IL-17 blockers within 3 months and/or ustekinumab within 4 months
- 10. Prior treatment with guselkumab or other IL23-blockers
- 11. Receipt of ANY live (attenuated) vaccine within 3 months prior to baseline (week 0), and BCG vaccination within 12 months of screening.
- 12. Significant concurrent medical conditions at the time of screening, includ-ing:
- a. Risk factors for renal toxicity (renal inflammation)
- b. Severe hepatic dysfunction
- c. Unstable angina pectoris

	- d. Uncompensated congestive heart failure - e. Severe pulmonary disease requiring hospitalization or supple-mental oxygen therapy - f. Immunodeficiency disorders: primary or secondary - g.Previous test positive for Human immunodeficiency virus (HIV, test result may not be older than 8 weeks at screening date) - h. Previous tests positive for hepatitis B virus (HBV) infection or tests seropositive for antibodies to hepatitis C virus (HCV), unless the patient has 2 negative HCV RNA test results 6 months apart after completing antiviral treatment and prior to baseline and has a third negative HCV RNA test result at baseline (test results may not be older than 8 weeks at screening date). - i. history of active granulomatous infection, including histoplasmosis or coccidioidomycosis, before screening. Refer to inclusion criterion 15 and 16 for information regarding eligibility with a history of latent TB - j. Uncontrolled Insulin-dependent diabetes mellitus - k. Currently has a malignancy or has a history of malignancy within 5 years before screening (with the exception of a nonmelanoma skin cancer that has been adequately treated with no evidence of recurrence for at least 3 months before the first study drug administration or cervical carcinoma in situ that has been treated with no evidence of recurrence for at least 3 months before the first study drug administration) - l. Has a history of lymphoproliferative disease, including lymphoma; a history of monoclonal gammopathy of undetermined significance (MGUS); or signs and symptoms suggestive of possible lymphoproliferative disease, such as lymphadenopathy or splenomegaly - m. Open cutaneous ulcers - 13. pustular psoriasis lesions on the part of body other than hands or feet - 14. when having a concomitant psoriasis with a PASI 12 or BSA 10% at screening and/or at baseline
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