

## **KURZPROTOKOLL** **JWGKDVAAP0117**

<b>Öffentlicher Titel</b>	Phase IV Studie zu Adalimumab bei aktiver, mittelschwerer-schwerer Hidradenitis suppurativa
<b>Wissenschaftl. Titel</b>	Exploratory study to evaluate changes in inflammatory pattern and analysis for serum biomarkers in patients with active, moderate-to-severe hidradenitis suppurativa after 2-week and 6-week treatment with a TNF-alpha Inhibitor
<b>Kurztitel</b>	JWGKDVAAP0117
<b>Studienart</b>	prospektiv, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase IV
<b>Erkrankung</b>	Haut: Acne inversa
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Diagnosis of HS for minimum of six months</li><li>- Disease state diagnosed to be active and moderate to severe HS, requiring systemic therapy</li><li>- No severe or otherwise clinically significant abnormalities found within the patient's medical/medication history, nor during physical examination</li><li>- Minimum of one previously failed or insufficiently responded to systemic therapy for HS</li><li>- Women of childbearing age who are sexually active must use a highly effective form of contraception (Pearl Index &lt; 1%) for the duration of the study</li><li>- Negative test for tuberculosis (TB) according to local guidelines, obtained no more than three months prior to screening</li><li>- Written informed consent and availability of any locally required authorization obtained from the subject, prior to performing any protocol-related procedures</li><li>- Patients must be able and willing to comply with the requirements of this protocol</li><li>- Age 18–65 years</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Main exclusion criteria: Previous use of Adalimumab (Humira®) or any other TNF-inhibitors</li><li>- Exclusion criteria related to IMP: According to SmPC; According to approval status of EMA; According to approval status of Adalimumab for treatment of HS in Germany; Known hypersensitivity to any component of the IMP</li><li>- Exclusion criteria related to general health:</li><li>- Active dermatologic conditions that may confound the diagnosis of HS or would interfere with the assessment of treatment (e.g., atopic dermatitis, seborrheic dermatitis, ichthyosis, psoriasis vulgaris, folliculitis)</li><li>- History of a clinically significant infection four weeks prior to baseline visit, which, in the opinion of the investigator, may compromise the safety of the subject</li><li>- History of chronic alcohol/drug abuse within the last 12 months before screening</li><li>- Pregnant or breastfeeding women</li><li>- Severe kidney insufficiency (GFR &lt; 30 ml/min)</li><li>- Any severe diseases that may, in the opinion of the investigator, interfere or worsen the hidradenitis suppurativa or result in safety concerns for patients being treated with an anti-TNF-alpha Inhibitor</li><li>- History or presence of human immunodeficiency virus (HIV), and/or hepatitis B (HBV) or C virus (HCV) infections</li><li>- History of active tuberculosis (TB), or untreated or inadequately treated latent TB (LTBI). Subjects must have a negative QuantiFERON, T-SPOT, or purified protein derivative (PPD) test, performed less than three months before the screening visit</li><li>- Any active medication which suppresses the immune system</li><li>- History, current signs, symptoms, or diagnosis of a demyelinating disorder</li></ul>

## **KURZPROTOKOLL**

### **JWGKDVAAP0117**

- History of or current Class III or IV congestive heart failure, as defined by the New York Heart Association
- History or current signs, symptoms, or diagnosis of lymphoproliferative disorders, lymphoma, leukemia, myeloproliferative disorders, or multiple myeloma
- Current malignancy or history of any malignancy, except for adequately treated or excised non-metastatic basal cell or squamous cell cancer of the skin, or cervical carcinoma in situ; no more than a total of three lifetime basal cell or squamous cell carcinomas permitted
- Concurrent enrolment in another clinical trial, in which the subject is receiving an investigational product
- Any major surgery in the last four weeks, that in the opinion of investigator, study related procedures or treatment with an anti-TNF-alpha inhibitor is contraindicated
- Severe, progressive, or uncontrolled renal, hepatic, metabolic, hematologic, gastrointestinal, endocrine, pulmonary, cardiac, or neurologic disease, including pleural effusions or ascites, which, in the opinion of the investigator pose an unacceptable safety risk
- History of latex allergy

#### **Alter**

18 - 65 Jahre

#### **Prüfzentren**

**Klinik für Dermatologie, Venerologie und Allergologie** (Geschlossen)

Theodor-Stern-Kai 7

60590 Frankfurt am Main

Dr. med. Andreas Pinter

Tel: 069 6301-83115

Fax: 069 6301-83175

[andreas.pinter@unimedizin-ffm.de](mailto:andreas.pinter@unimedizin-ffm.de)

#### **Sponsor**

Goethe-Universität Frankfurt

#### **Registrierung in anderen Studienregistern**

EudraCT 2017-000435-13 (primäres Register)

#### **Links**

[Zu den Ein- und Ausschlusskriterien](#)