KURZPROTOKOLL
ACT16852

Öffentlicher Titel	Phase-2-Studie zu SAR442970 bei Acne inversa
Wissenschaftl. Titel	A Randomized, Double-blind, Placebo-controlled, Proof-of-concept Study Assessing the Efficacy and Safety of an Anti-TNF-OX40L NANOBODY® Molecule, SAR442970, in Participants With Moderate to Severe Hidradenitis Suppurativa
Kurztitel	ACT16852
Studienphase	Phase II
Erkrankung	Haut: Acne inversa
Einschlusskriterien	- Participants with a history of signs and symptoms consistent with hidradenitis suppurativa (HS) for at least 1 year prior to Baseline - Participants must have HS lesions present in at least 2 distinct anatomic areas (eg, left and right axilla; or left axilla and left inguinocrural fold), one of which must be Hurley Stage II or Hurley Stage III - Participant must have had an inadequate response to a trial of an oral antibiotic for treatment of HS, exhibited recurrence after discontinuation of antibiotics, demonstrated intolerance to antibiotics, or has a contraindication to oral antibiotics for treatment of their HS as assessed by the Investigator through participant interview and review of medical history - Participants must be either biologic and small molecule immunosuppressive-naïve or TNF-experienced - Participant must have a total abscess and inflammatory nodule (AN) count of >=3 at the Baseline visit - Participant must have a draining tunnel count of <=20 at the Baseline visit - Participant must have a C-reactive protein (CRP) >3 mg/L at the screening visit - Participant who is a candidate for systemic treatment per Investigator's judgment
Ausschlusskriterien	- Any other active skin disease or condition (eg, bacterial, fungal or viral infection) that may interfere with assessment of HS - History of recurrent or recent serious infection - Known history of or suspected significant current immunosuppression - History of solid organ transplant - History of splenectomy - History of moderate to severe congestive heart failure - Receipt of a live vaccine 12 week prior to Baseline visit or receipt of a killed vaccine 2 weeks prior to Baseline visit - History of demyelinating disease (including myelitis) or neurologic symptoms suggestive of demyelinating disease - Participants with a history of malignancy or lymphoproliferative disease other than adequately treated or nonmetastatic squamous cell carcinoma, or nonmetastatic basal cell carcinoma of the skin that was excised and completely cured - Participants with a diagnosis of inflammatory conditions other than HS - Presence of active suicidal ideation, or positive suicide behavior or participant has a lifetime history of suicide attempt, or participant has had suicidal ideation in the past 6 months as indicated by a positive response using the screening or Baseline version of the Columbia-Suicide Severity Rating Scale (C-SSRS) or as assessed by the Investigator through participant interview and review of medical history - A history of an adverse event (AE) to anti-TNF therapy (examples include, but are not limited, to serum sickness or anaphylaxis) for an HS or non-HS indication that would contraindicate readministration of an anti-TNF class therapy

	- Sensitivity to any of the study interventions, or components thereof, or drug or other allergy that, in the opinion of the Investigator, contraindicates participation in the study - Female participants who are breastfeeding or considering becoming pregnant during the study - History (within last 2 years prior to Baseline) of prescription drug or substance abuse, including alcohol, considered significant by the Investigator - Laboratory exclusion criteria apply
Alter	18 - 70 Jahre
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Geschlossen) Theodor-Stern-Kai 7 60590 Frankfurt am Main Annette Gaul Tel: 069 6301-6820 Fax: 069 6301-83175 annette.gaul@unimedizin-ffm.de
Sponsor	Sanofi Aventis GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT05849922 EudraCT 2022-502370-17
Links	Zu den Ein- und Ausschlusskriterien