KURZPROTOKOLL
JNJ-77474462

Öffentlicher Titel	Phase IIb Studie zu JNJ-77474462 bei schwerer atopischer Dermatitis
Wissenschaftl. Titel	A Phase 2b, Multicenter, Randomized, Placebo- and Active-comparator-controlled, Double-blind Study to Evaluate the Safety and Efficacy of Bermekimab (JNJ-77474462) for the Treatment of Participants With Moderate to Severe Atopic Dermatitis
Kurztitel	JNJ-77474462
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, mehrarmig
Studienphase	Phase II
Erkrankung	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis)
Einschlusskriterien	- Be otherwise healthy on the basis of physical examination, medical history, vital signs, and 12-lead electrocardiograms (ECGs) performed at screening. Any abnormalities, must be consistent with the underlying illness in the study population and this determination must be recorded in the participant's source documents and initialed by the investigator - Have atopic dermatitis (AD) for at least 1 year (365 days) prior to the first administration of study intervention as determined by the investigator through participant interview and/or review of the medical history - Have a history of inadequate response to treatment for AD with topical medications or for whom topical treatments are otherwise medically inadvisable (example [eg], due to important side effects or safety risks) - Be considered, in the opinion of the investigator, a suitable candidate for dupilumab (DUPIXENT) therapy according to their country's approved DUPIXENT product labeling - Have an eczema area and severity index (EASI) score greater than or equal (>=) to 16 at screening and at baseline - Have an investigator global assessment (IGA) score >=3 and involved body surface area (BSA) >=10 percent (%) at screening and baseline
Ausschlusskriterien	- Has a current diagnosis or signs or symptoms of severe, progressive, or uncontrolled renal, cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic, psychiatric, or metabolic disturbances - Has unstable cardiovascular disease, defined as a recent clinical deterioration (eg, unstable angina, rapid atrial fibrillation) in the last 3 months or a cardiac hospitalization within the last 3 months - Has or has had a serious infection (eg, sepsis, pneumonia, or pyelonephritis), or has been hospitalized or received intravenous (IV) antibiotics for an infection during the 2 months before screening - Has or has had herpes zoster within the 2 months before screening - Has a history of being human immunodeficiency virus (HIV) antibody-positive, or tests positive for HIV at screening
Alter	18 Jahre und älter
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Geschlossen) Theodor-Stern-Kai 7 60590 Frankfurt am Main Daniela Hoffmann
Sponsor	Janssen Research & Development
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04791319 EudraCT 2020-002587-31 (primäres Register)