KURZPROTOKOLL
CLYS006X2201

Öffentlicher Titel	Phase II Studie zu LYS006 bei mittelschwerer bis schwerer entzündlicher Akne
Wissenschaftl. Titel	A randomized, subject and investigator blinded, placebocontrolled, multi-center study in parallel groups to assess the efficacy and safety of LYS006 in patients with moderate to severe inflammatory acne
Kurztitel	CLYS006X2201
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind
Studienphase	Phase II
Erkrankung	Haut: Acne inversa
Einschlusskriterien	- Male and female subjects aged 18 to 45 years of age inclusive, and otherwise in good health as determined by medical history, physical examination, vital signs, ECGs and laboratory tests at screening - Body weight between 50 and 120 kg, both inclusive, at screening - Patients with papulo-pustular acne vulgaris (inflammatory acne) presenting with 20 to 100 facial inflammatory lesions (papules, pustules and nodules) at baseline, no more than 2 facial inflammatory nodules or cysts at screening and baseline, and a minimun number of 10 non-inflammatory facial lesions (open and closed comedones) - Patients who are candidates for systemic treatment and for whom in the opinion of the investigator, an appropriate previous treatment with topical anti-acne medication failed, or was not well tolerated, or is not indicated (e.g., due to large body surface area affected, e.g., on the back) - Patients with Grade 3 (moderate) or Grade 4 (severe) IGA score confirmed by central reading of standardized image capture (Visia® system) by an independent dermatologist at screening and by the investigator's clinical evaluation at baseline
Ausschlusskriterien	- Appropriate wash out periods are required for investigational drugs, any oral/systemic treatment for acne, systemic or lesional injected (for acne) corticosteroids or systemic immunomodulators, any systemic hormonal treatments, previous treatment with biologics, oral retinoids (in particular isotretinoin) and any topical anti-acne treatment - Previous surgical, physical (such as ThermaClear™), light (including blue or UV light, photodynamic therapy or laser therapy within 4 weeks prior to baseline - Use of facial medium depth chemical peels (excluding home regimens) within 3 months prior to baseline - Any other forms of acne - Any severe, progressive or uncontrolled medical or psychiatric condition or other factors at randomization that in the judgment of the investigator prevents the patient from participating in the study - Active systemic infections (other than common cold) during the 2 weeks prior to baseline - History of immunodeficiency diseases, including a positive HIV (ELISA and Western blot) test result at screening - Chronic infection with Hepatitis B or Hepatitis C virus - Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive Human chorionic gonadotropin (HCG) laboratory test - Sexually active males or women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using basic methods of contraception during dosing of study treatment
Alter	18 - 45 Jahre

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Sponsor	Novartis Pharma
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03497897 EudraCT 2017-003191-30 (primäres Register)