

KURZPROTOKOLL
TopoTarget, PXD101-CLN-19

Öffentlicher Titel	Belinostat bei rezidiviertem oder refraktärem T-Zell-Lymphom (PTCL)
Wissenschaftl. Titel	A Multicenter, Open-Label Trial of Belinostat in Patients With Relapsed or Refractory Peripheral T-Cell Lymphoma
Kurztitel	TopoTarget, PXD101-CLN-19
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase II
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - rezidiert/refraktär
Ziele	<ul style="list-style-type: none">- Objective response rate-- Safety, further efficacy parameters
Einschlusskriterien	<ul style="list-style-type: none">- A histologically confirmed diagnosis of PTCL- Patients must have relapsed or refractory disease after at least one prior systemic anticancer regimen. Systemic anticancer therapy is defined as chemotherapy or immunotherapy administered systemically.- Patients must have at least one site of disease measurable in two dimensions by computed tomography (CT).- Age 18 years.- Adequate bone marrow, liver, and renal functions.- Eastern Cooperative Oncology Group (ECOG) performance status 0-2.- Negative pregnancy test for women of childbearing potential.
Ausschlusskriterien	<ul style="list-style-type: none">- Relapse within 100 days of autologous or allogeneic bone marrow transplant.- Prior HDAC inhibitor therapy.- Co-existing active infection or any medical condition likely to interfere with trial procedures.- Severe cardiovascular disease.- Clinically significant central nervous system disorders with altered mental status or psychiatric disorders precluding understanding of the informed consent process and/or completion of the necessary studies.- Active concurrent malignancy (except adequately treated non-melanoma skin cancer or carcinoma in situ of the cervix).- Symptomatic or untreated central nervous system (CNS) metastases.- Pregnant or breast-feeding women.- Known infection with HIV, hepatitis B or hepatitis C
Alter	18 Jahre und älter
Sponsor	Spectrum Pharmaceuticals, Inc (Hauptsponsor) Universitätsmedizin der Johannes Gutenberg-Universität Mainz
Förderer	Spectrum Pharmaceuticals, Inc Universitätsmedizin der Johannes Gutenberg-Universität Mainz
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT00865969 (primäres Register) EudraCT 2008-005843-40
Therapie	Belinostat (PXD101)