

**KURZPROTOKOLL**  
**TopoTarget, PXD101-CLN-19**

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