

## **KURZPROTOKOLL** **Magnify**

<b>Öffentlicher Titel</b>	Phase III Studie zu Lenalidomid und Rituximab bei rezidivierten/refraktären Non-Hodgkin-Lymphomen
<b>Wissenschaftl. Titel</b>	Eine randomisierte Phase 3b Studie zur Erhaltungstherapie durch Kombination von Lenalidomid (CC-5013) und Rituximab und anschließender Monotherapie mit Lenalidomid oder Rituximab im Vergleich bei Patienten mit rezidiviertem/refraktärem follikulärem Marginalzellen- oder Mantelzellymphom
<b>Kurztitel</b>	Magnify
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Rezidiviert/refraktär Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - rezidiviert/refraktär
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Age <math>\geq</math>18 years</li><li>- Histologically confirmed Follicular Lymphoma (Grade 1, 2 or 3a), Marginal Zone Lymphoma, or Mantle Cell Lymphoma</li><li>- Must have documented relapsed, refractory or Progressive Disease after last treatment with systemic therapy</li><li>- Bi-dimensionally measurable disease</li><li>- Eastern Cooperative Oncology Group (ECOG) Performance status <math>\leq</math> 2</li><li>- Adequate bone marrow function</li><li>- Willingness to follow pregnancy precautions</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Histology other than follicular or marginal zone lymphoma or clinical evidence of transformation or Grade 3b follicular lymphoma</li><li>- Any medical condition (other than the underlying lymphoma) that requires chronic steroid use</li><li>- Subjects taking corticosteroids during the last 1 week prior treatment, unless administered at a dose equivalent to <math>&lt;</math> 20 mg/day of prednisone</li><li>- Systemic anti-lymphoma therapy within 28 days or use of antibody agents within 8 weeks use of radioimmunotherapy within 3 months</li><li>- Known seropositive for or active viral infection with hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV)</li><li>- Known sensitivity or allergy to murine products</li><li>- Presence or history of central nervous system involvement by lymphoma. Subjects who are at a risk for a thromboembolic event and are not willing to take prophylaxis for it.</li><li>- Any condition that places the subject at unacceptable risk if he/she were to participate in the study or that confounds the ability to interpret data from the study</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Prüfzentren</b>	<b>Centrum für Hämatologie und Onkologie Bethanien</b> (Rekrutierung beendet) Im Prüfling 17-19 60389 Frankfurt am Main Prof. Dr. med Wolfgang Knauf Tel: 069 451080 Fax: 069 458257 <a href="mailto:wolfgang.knauf@telemed.de">wolfgang.knauf@telemed.de</a>
<b>Sponsor</b>	Celgene GmbH
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT01996865 (primäres Register)