

KURZPROTOKOLL
Magnify

Öffentlicher Titel	Phase III Studie zu Lenalidomid und Rituximab bei rezidierten/refraktären Non-Hodgkin-Lymphomen
Wissenschaftl. Titel	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 rezidiertem/refraktärem follikulärem Marginalzellen- oder Mantelzelllymphom
Kurztitel	Magnify
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Rezidiert/refraktär Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - rezidiert/refraktär
Einschlusskriterien	- Age ≥ 18 years - Histologically confirmed Follicular Lymphoma (Grade 1, 2 or 3a), Marginal Zone Lymphoma, or Mantle Cell Lymphoma - Must have documented relapsed, refractory or Progressive Disease after last treatment with systemic therapy - Bi-dimensionally measurable disease - Eastern Cooperative Oncology Group (ECOG) Performance status ≤ 2 - Adequate bone marrow function - Willingness to follow pregnancy precautions
Ausschlusskriterien	- Histology other than follicular or marginal zone lymphoma or clinical evidence of transformation or Grade 3b follicular lymphoma - Any medical condition (other than the underlying lymphoma) that requires chronic steroid use - Subjects taking corticosteroids during the last 1 week prior treatment, unless administered at a dose equivalent to < 20 mg/day of prednisone - Systemic anti-lymphoma therapy within 28 days or use of antibody agents within 8 weeks use of radioimmunotherapy within 3 months - Known seropositive for or active viral infection with hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV) - Known sensitivity or allergy to murine products - 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. - 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
Alter	18 Jahre und älter
Sponsor	Celgene GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01996865 (primäres Register)