KURZPROTOKOLL
Millenium (C16010)

Öffentlicher Titel	MLN9708 und Lenalidomid/Dexamethason bei rezidiviertem oder refraktärem MM
Wissenschaftl. Titel	A Phase 3, Randomized, Double-Blind, Multicenter Study Comparing Oral MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Relapsed and/or Refractory Multiple Myeloma
Kurztitel	Millenium (C16010)
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Multiples Myelom: rezividiert/refraktär
Einschlusskriterien	- Male or female patients 18 years or older - Diagnosed Multiple Myeloma according to standard criteria - Measurable disease as specified in study protocol - Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 - Patients with relapsed and/or refractory Multiple Myeloma who have received 1 to 3 prior therapies - Meet the clinical laboratories criteria as specified in the protocol - Patients who received prior allogenic transplant must have no active graft-versus-host disease (GVHD) - Female patients who are post menopausal, surgically sterile, or agree to practice 2 effective methods of contraception or agree to abstain from heterosexual intercourse; must also adhere to the guidelines of the lenalidomide pregnancy prevention program - Male patients who agree to practice effective barrier contraception or agree to abstain from heterosexual intercourse AND must adhere to the guidelines of the lenalidomide pregnancy prevention program - Must be able to take concurrent aspirin 325 mg daily - Voluntary written consent
Ausschlusskriterien	- Patient who were refractory to lenalidomide or proteasome inhibitor-based therapy - Female patients who are lactating or pregnant - Major surgery or radiotherapy within 14 days before randomization - Infection requiring systematic antibiotics within 14 days before the first dose of study drug - Central nervous system involvement - Failure to have fully recovered from the effects of prior chemotherapy regardless of the interval since last treatment - Systemic treatment with strong inhibitors of CYP1A2, strong inhibitors of CYP3A, or strong CYP3A inducers, or use of Ginko biloba or St. John's wort within 14 days before the first dose of study treatment - Diagnosis of Waldenstrom's macroglobulinemia, POEMS syndrome, plasma cell leukemia, primary amyloidosis, myelodysplastic syndrome, or myeloproliferative syndrome - Diagnosis of Waldenstrom's macroglobulinemia, POEMS syndrome, plasma cell leukemia, primary amyloidosis, myelodysplastic syndrome, or myeloproliferative syndrome - Serious medical or psychiatric illness that could, in the investigator's opinion, potentially interfere with the completion of treatment according to the protocol - Known allergy to any of the study medications - Known gastrointestinal condition or procedure that could interfere with swallowing or the oral absorption of tolerance of MLN9708

	- Diagnosed or treated for another malignancy within 2 years before randomization or previously diagnosed with another malignancy and have any evidence of residual disease with the exception of nonmelanoma skin cancer or any completely resected carcinoma in situ - Ongoing or active systemic infection, active hepatitis B virus infect, active hepatitis C infection, or known human immunodeficiency virus (HIV) positive
Alter	18 Jahre und älter
Fallzahl	703
Sponsor	Millenium Pharmaceuticals (Hauptsponsor)
Förderer	Millenium Pharmaceuticals
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01564537 (primäres Register) EudraCT 2011-005496-17