KURZPROTOKOLL
morab003-004

Öffentlicher Titel	MorAb-003 bei Platin-sensiblem, rezidiviertem Eierstockkrebs
Wissenschaftl. Titel	A Randomized, Double-blind, Placebo-Controlled, Phase 3 Study to Assess the Efficacy and Safety of Weekly MORAb-003 in Combination With Carboplatin and Taxane in Subjects With Platinum-sensitive Ovarian Cancer in First Relapse
Kurztitel	morab003-004
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, dreiarmig
Studienphase	Phase III
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: Eierstockkrebs (Ovarialkarzinom) - Zweitlinie oder höher
Ziele	- Progression-free survival using by RECIST - Overall Survival, CA-125 PFS, GCIG PFS, Length of first versus second remission, Tumor Response,Serologic Response (CA-125), Quality of Life, Resource utilization and PK DDI substudy.
Einschlusskriterien	- A histologically or cytologically confirmed diagnosis of non-mucinous epithelial ovarian cancer including primary peritoneal or fallopian tube malignancies - Must have measurable disease by CT or MRI scan - Must have relapsed radiologically with a randomization date within 6 and < 24 months of completion of first-line platinum chemotherapy - Have been treated with debulking surgery and first-line platinum and taxane based chemotherapy. - Prior bevacizumbab maintenance is allowed - The last dose of bevacizumab must have been at least 30 days before study Day 1. - No cytotoxic maintenance therapy (e.g. taxane) or cancer vaccine therapy is allowed. - Must be a candidate for carboplatin and taxane therapy - Neurologic function: neuropathy (sensory and motor) CTCAE Grade
Ausschlusskriterien	- Subjects who never responded to first-line platinum-based therapy or whose first relapse occurs <6 months or >24 months from the last platinum therapy - Subjects who have received other therapy to treat their ovarian cancer since relapse - Known central nervous system (CNS) tumor involvement - Evidence of other active invasive malignancy requiring treatment in the past 5 years - Known allergic reaction to a prior monoclonal antibody therapy or have any documented HAHA - Previous treatment with MORAb-003 (farletuzumab) - Clinical contraindications to use of a taxane
Alter	18 Jahre und älter
Molekularer Marker	FOLR1
Sponsor	Morphotek (Hauptsponsor)
Förderer	Morphotek
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT00849667 (primäres Register) EudraCT 2008-005872-29
Therapie	MORAb-003 (farletuzumab; 0,9% Saline