

Short name: Mangrove studie (Beigene-3111-306)

Study title: A Phase 3 Randomized, Open-Label, Multicenter Study Comparing Zanubrutinib (BGB-3111) plus Rituximab Versus Bendamustine plus Rituximab in Patients with Previously Untreated Mantle Cell Lymphoma Who Are Ineligible for Stem Cell Transplantation

Meest relevante in-/exclusie criteria

Inclusie criteria

1. ≥ 70 years of age at the time of informed consent,
OR
 ≥ 65 and < 70 years of age with comorbidities precluding autologous stem cell transplantation including at least one of the following:
 - a. Cardiac ejection fraction $\leq 40\%$
 - b. Diffusing capacity for carbon monoxide (DLCO) $\leq 60\%$ predicted
 - c. Creatinine clearance < 70 but ≥ 30 mL/min
2. Histologically confirmed diagnosis of MCL, including demonstration of positive cyclin D1 and/or t(11;14)
3. No prior systemic treatments for MCL
4. Presence of measurable disease
5. Availability of archival tissue confirming diagnosis of MCL, or willing to undergo fresh tumor biopsy
6. ECOG performance status of 0, 1, or 2
7. Life expectancy of ≥ 3 months
8. Adequate organ function

Exclusie criteria

1. Known central nervous system involvement by lymphoma
2. Prior hematopoietic stem cell transplantation
3. Prior exposure to a BTK inhibitor, rituximab, or bendamustine
4. Patients for whom the goal of therapy is tumor debulking prior to SCT
5. Prior malignancy within the past 3 years, except for curatively treated basal or squamous cell skin cancer, superficial bladder cancer, carcinoma in situ of the cervix or breast, or localized Gleason score 6 prostate cancer
6. Clinically significant cardiovascular disease