BGB-11417-302, a phase 3, randomized, double-blind study of sonrotoclax (BGB-11417) + zanubrutinib vs placebo + zanubrutinib in patients with relapsed or refractory mantle cell lymphoma

Authors: Yuqin Song,[1] Marie Hughes,[2] Martin Dreyling,[3] Toby A. Eyre,[4] Yucai Wang,[5] Jun Zhang,[6] Helen Alalade,[6] Elena Maksimova,[6] Xiaotong Li,[7] Zhao Xu,[7] Christina To,[6] Luhua (Michael) Wang[8]

Affiliations: [1]Peking University Cancer Hospital and Institute, Beijing, China; [2]Tauranga Hospital, Tauranga, New Zealand; [3]Medizinische Klinik III, Klinikum der Universität, LMU München, Munich, Germany; [4]Oxford Cancer and Haematology Centre, Churchill Hospital, Headington, Oxford, UK; [5]Mayo Clinic, Rochester, MN, USA; [6]BeOne Medicines Ltd, San Carlos, CA, USA; [7]BeOne Medicines Ltd, Shanghai, China; [8]University of Texas MD Anderson Cancer Center, Houston, TX, USA

ABSTRACT

Objective: To describe an ongoing phase 3 study that will compare the efficacy and safety of sonrotoclax + zanubrutinib vs sonrotoclax-matched placebo + zanubrutinib in adult patients with previously treated, BTK inhibitor–naive/intolerant, relapsed or refractory MCL.

Methods: BGB-11417-302 (NCT06742996) is a global, randomized, double-blind, phase 3 clinical study performed across 145 sites in 16 countries. Eligible patients are ≥18 years of age with a confirmed diagnosis of MCL who have received 1–5 prior lines of therapy and have relapsed or refractory disease after the last line of therapy. Patients who have had prior treatment with a BCL2 or BTK inhibitor are ineligible, except for those with intolerance to a BTK inhibitor other than zanubrutinib. Approximately 300 patients will be enrolled and randomized 1:1 to receive orally administered sonrotoclax for a fixed duration plus zanubrutinib until progression/intolerance or sonrotoclax-matched placebo for a fixed duration plus zanubrutinib until progression/intolerance. No crossover will be allowed between arms. The primary endpoint is progression-free survival (PFS), as determined by blinded independent review committee per Lugano classification (Cheson et al. *J Clin Oncol*. 2014). Secondary endpoints include overall survival, PFS (assessed by investigator), overall response rate, complete response rate, duration of response, and safety/tolerability. Recruitment is ongoing.