

BGB-11417-203, an Ongoing, Phase 2 Study of Sonrotoclax (BGB-11417), a Next-Generation BCL2 Inhibitor, in Patients With Waldenström Macroglobulinemia

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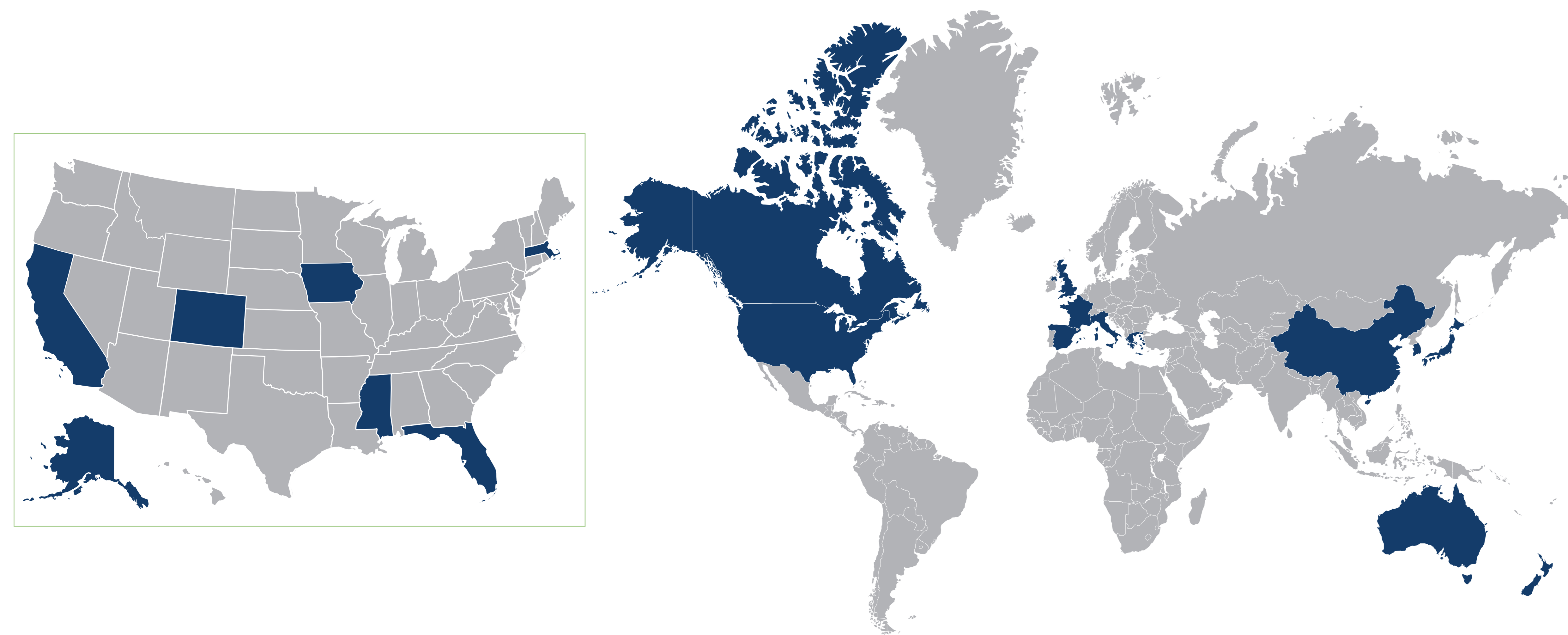
INTRODUCTION

- Waldenström macroglobulinemia (WM) is a rare, incurable, B-cell malignancy for which BTK inhibitors and anti-CD20 antibody-based therapies are preferred treatment options¹
 - To date, no treatments have been approved for patients with WM that is refractory to both BTK inhibitors and anti-CD20 antibody-based therapy
- Venetoclax, the first-generation BCL2 inhibitor, has demonstrated clinical activity in patients with relapsed/refractory (R/R) WM but is not currently approved for WM²
- Sonrotoclax (BGB-11417), a next-generation BCL2 inhibitor, is more selective and a more pharmacologically potent inhibitor of BCL2 than venetoclax³
- In the ongoing phase 1 BGB-11417-101 (NCT04277637) study, sonrotoclax monotherapy has been well tolerated at doses up to 640 mg and has shown preliminary antitumor activity in patients with R/R WM⁴
- Based on these encouraging preclinical and clinical data, a phase 2 study of sonrotoclax monotherapy and sonrotoclax in combination with zanubrutinib in WM was designed and is currently enrolling globally

STUDY STATUS

- Enrollment for BGB-11417-203 began in September 2023, and the study is currently recruiting
- Approximately 72 study sites in Australia, China, Europe (Italy, Spain, France, Greece), the UK, Canada, and the US are planned (**Figure 1**)

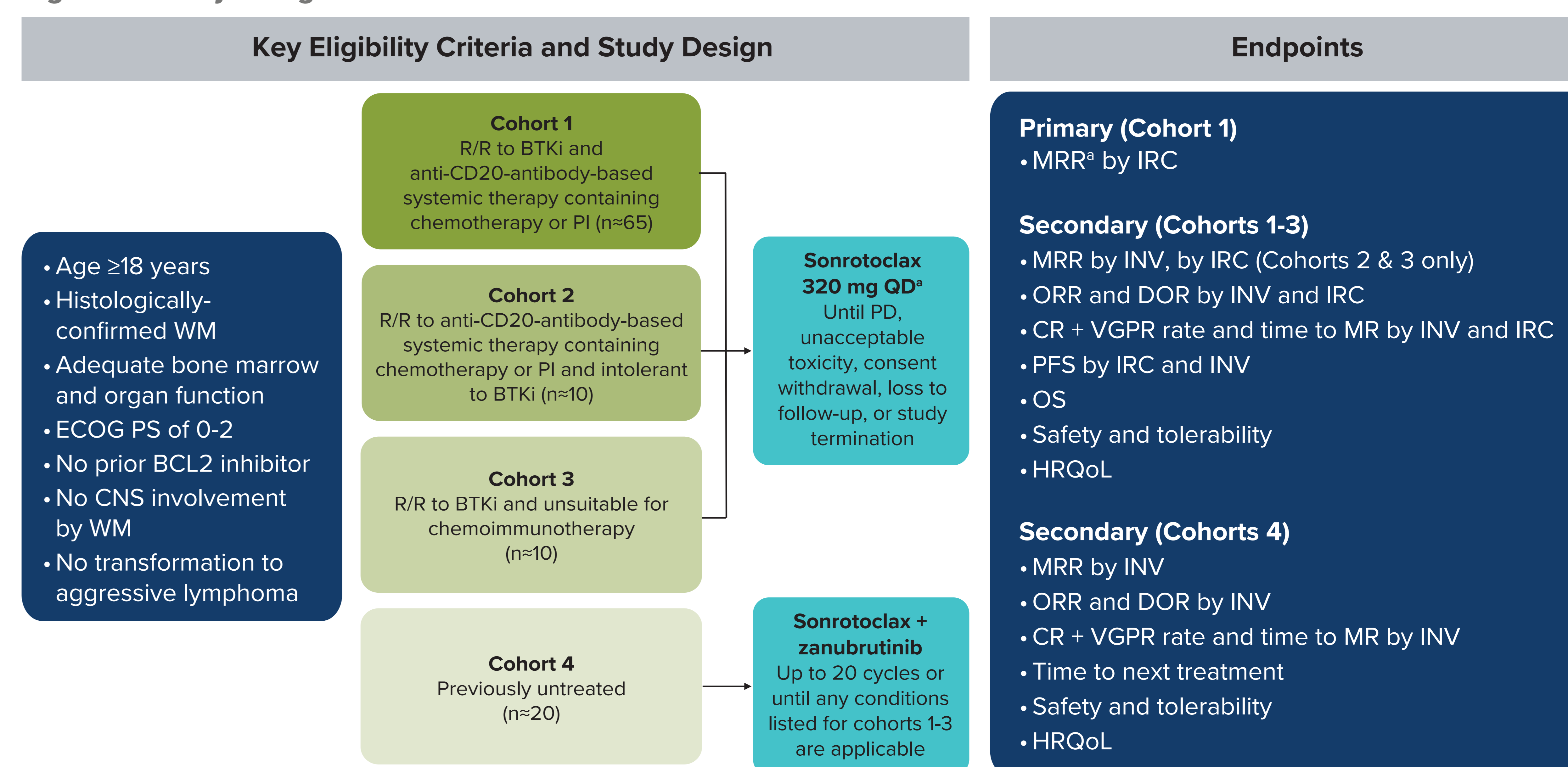
Figure 1. Study Sites (Planned)



METHODS

- BGB-11417-203 (NCT05952037) is an open-label, multicenter, international, phase 2 study to evaluate the efficacy and safety of sonrotoclax in patients with R/R WM (**Figure 2**)
- Approximately 105 patients will be enrolled to receive 320 mg sonrotoclax once daily

Figure 2. Study Design



^aTo monitor and mitigate TLS risk, TLS prophylaxis and laboratory monitoring are used, and clinical visits are required on ramp-up days. ^bProportion of patients achieving PR or better per IWWM-11 response criteria.

BTKi, BTK inhibitor; CNS, central nervous system; DOR, duration of response; HRQoL, health-related quality of life; INV, assessed by investigator; IRC, assessed by independent review committee; MRR, major response rate; PI, proteasome inhibitor; R/R, relapsed/refractory; TLS, tumor lysis syndrome; VGPR, very good partial response; WM, Waldenström macroglobulinemia.

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