Japanese Title: 国内外の慢性リンパ性白血病・小リンパ球性リンパ腫へのザヌブルチニブの担当医師判定での有効性と安全性

English Title: Activity of Zanubrutinib in Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

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Abstract: Zanubrutinib (zanu) is a Bruton tyrosine kinase inhibitor that has shown superior efficacy and improved safety outcomes compared with ibrutinib for patients (pts) with relapsed/refractory (R/R) CLL/SLL. Here, we present efficacy assessed by investigator (INV) and safety of zanu in Japanese pts with CLL/SLL enrolled in BGB-3111-111, a phase 1/2 study (NCT04172246), compared to global zanu studies in CLL/SLL (NCT03734016; NCT03336333). As of May 10, 2022, 17 pts with CLL/SLL (14 treatment naïve [TN]; 3 R/R) were enrolled. Median age was 71 years; 71% were male. Three (18%) pts discontinued treatment (1 progressive disease, 1 adverse event [AE], 1 INV decision). At a median follow-up of 16.1 months (mo), the rate of partial response with lymphocytosis (PR-L) or better by INV was 92.9% in TN and 100% in R/R CLL/SLL. Similar responses by INV were seen in global zanu studies (TN CLL/SLL without del[17p]: 26.4-mo median follow-up, 97.5% PR-L or higher; R/R CLL/SLL: 15.3-mo median follow-up, 88.4% PR-L or higher). Median progression-free survival was not reached in BGB-3111-111. Sixteen (94%) pts experienced ≥1 AE; 7 (41%) grade ≥3 AEs. Most common AEs were constipation (4 pts), platelet count decreased, neutrophil count decreased, dental caries, and anemia (3 pts each). No cardiac toxicities, including atrial fibrillation, were observed. A similar safety profile was observed globally, including low incidences (3% CLL/SLL) of atrial fibrillation. Study results trend comparably with global zanu studies, supporting zanu as a treatment option for Japanese pts with CLL/SLL.