# ASPEN: Long-Term Follow-Up Results of a Phase 3 Randomized Trial of Zanubrutinib Versus Ibrutinib in Patients With Waldenström Macroglobulinemia

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theatingdom; Australia; Skindowska-Curie National Institute of Oncology, Krakow, Poland; Skindowska-Curie National Institute Institute National Institute Institute Oncology, Krakow, Poland; Skindowska-Curie National Institute In

# BACKGROUND

- Zanubrutinib is a potent, selective, and irreversible next-generation BTK inhibitor designed to maximize BTK occupancy and minimize inhibition of
- Zanubrutinib has demonstrated a complete and sustained BTK occupancy in peripheral blood mononuclear cells and lymph nodes²
- Zanubrutinib has shown equipotency against BTK compared with ibrutinib.¹ Zanubrutinib has high selectivity for BTK and minimal off-target inhibition of TEC- and EGFR-family kinases<sup>1</sup>
- Favorable drug interaction properties allow zanubrutinib to be co-administered with strong or moderate CYP3A inhibitors (eg, antifungals) at a reduced dose, plus proton pump inhibitors, acid-reducing agents, and antithrombotic agents<sup>3,4</sup>

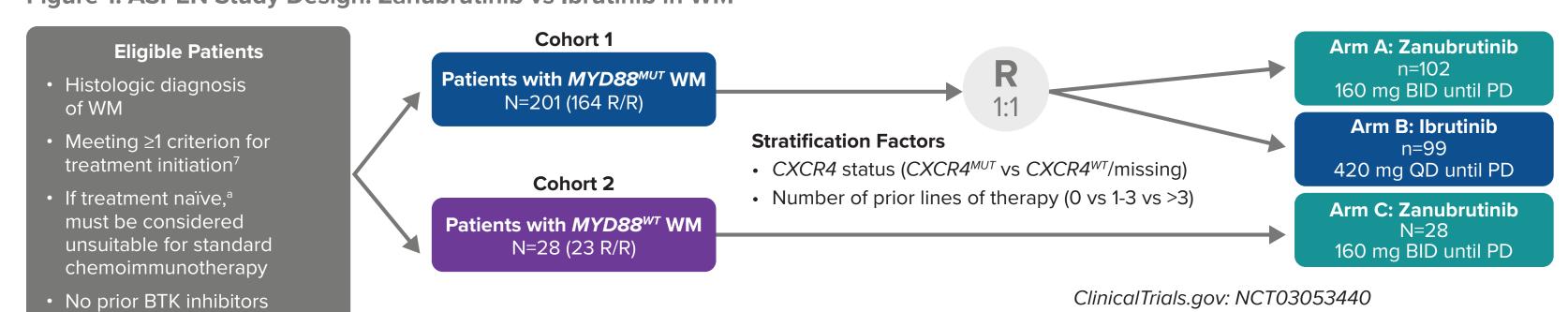
## OBJECTIVES

- Primary Objective: To compare the efficacy of zanubrutinib vs ibrutinib in patients with activating MYD88<sup>MUT</sup> WM; primary endpoint was the CR+VGPR rate **Secondary Objectives:** To further compare the efficacy, clinical benefit, and antilymphoma effects of zanubrutinib vs ibrutinib, and to evaluate safety
- and tolerability of zanubrutinib vs ibrutinib as measured by the incidence, timing, and severity of treatment-emergent AEs according to NCI CTCAE v4.03 **Exploratory Objectives:** To evaluate the efficacy and safety of zanubrutinib in patients with MYD88<sup>WT</sup> WM and the efficacy of zanubrutinib vs ibrutinib according to CXCR4 gene mutation in patients with MYD88<sup>MUT</sup> WM

# METHODS

■ ASPEN is an open-label, multicenter, randomized phase 3 study of zanubrutinib vs ibrutinib in patients with WM (Figure 1)

Figure 1: ASPEN Study Design: Zanubrutinib vs Ibrutinib in WM<sup>5,6</sup>



#### **Cohort Assignments**

<sup>a</sup>Up to 20% of the overall population.

- Bone marrow MYD88 and CXCR4 mutations were assessed centrally at study entry (NeoGenomics Laboratory, Aliso Viejo)<sup>8,9</sup>
- The MYD88<sup>MUT</sup> assay includes a wild-type allele−blocking approach (LOD, 0.5%)<sup>7,8</sup> and detects all mutations in the region encompassing amino acid Alanine<sup>260</sup>-Proline<sup>278</sup>, which includes the predominant mutation in WM, MYD88<sup>L265P</sup>
- Patients were assigned to cohort 1 ( $MYD88^{MUT}$ ; randomized) or exploratory cohort 2 ( $MYD88^{WT}$  or MYD88 unknown; nonrandomized)

#### **CXCR4** Mutation Detection

- Standard polymerase chain reaction/bidirectional Sanger sequencing assay to detect CXCR4WHIM mutation was performed at screening. Randomization in cohort 1 was stratified according to *CXCR4* mutation status (CXCR<sup>WHIM</sup> vs CXCR<sup>WT</sup>/missing; LOD, 10%-15%)
- CXCR4 mutation status was assessed retrospectively by NGS using residual DNA samples or duplicate bone marrow biopsy sample (LOD, 0.25%)<sup>7-9</sup>

#### **Response Assessments** ■ Responses were assessed according to response criteria in the NCCN® WM guidelines and modified Owen criteria<sup>10</sup> as assessed by the independent

review committee (primary analysis) and by the investigator Efficacy endpoints: response rates (CR+VGPR, major and overall responses), duration of response, time to response, time to next treatment, PFS, and OS

# RESULTS

Bold text indicates >10% difference between arms in cohort 1

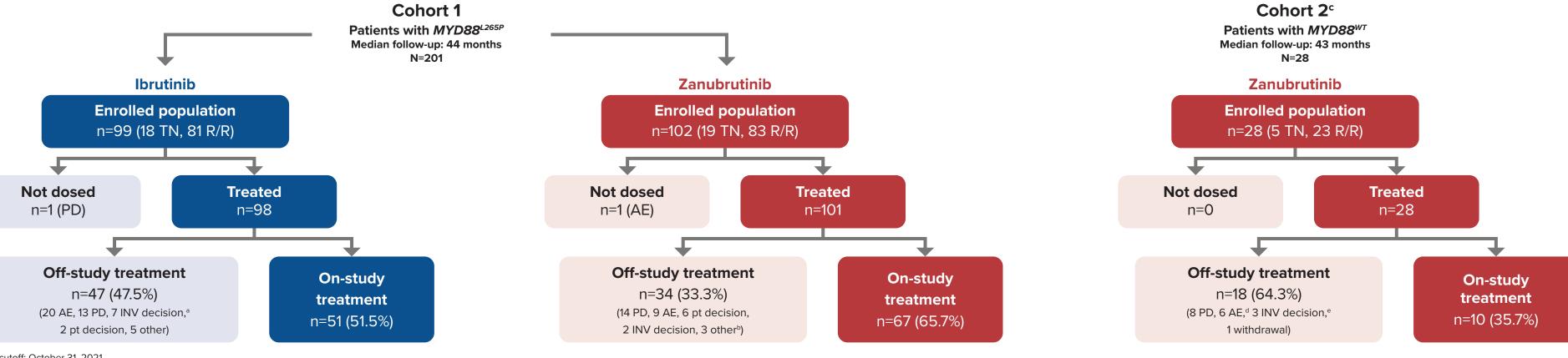
- Both arms in cohort 1 were balanced except for patients aged >75 years, patients with CXCR4<sup>MUT</sup> by NGS, and patients with hemoglobin ≤110 g/L, which were higher on the zanubrutinib arm (**Table 1**)
- In cohort 2, patients aged >75 years were more frequent (42.9%)

	Со	Cohort 2	
Characteristics	Ibrutinib (n=99)	Zanubrutinib (n=102)	Zanubrutinib (N=28)
Age, years median (range)	70 (38-90)	70 (45-87)	72 (39-87)
>65 years, n (%)	70 (70.7)	61 (59.8)	19 (67.9)
>75 years, n (%)	22 (22.2)	34 (33.3)	12 (42.9)
Sex, n (%)			
Male	65 (65.7)	69 (67.6)	14 (50.0)
Prior lines of therapy, n (%)			
0	18 (18.2)	19 (18.6)	5 (17.9)
1-3	74 (74.7)	76 (74.5)	20 (71.4)
>3	7 (7.1)	7 (6.9)	3 (10.7)
Genotype by NGS, n (%)			
CXCR4 <sup>WT</sup>	72 (72.7)	65 (63.7)	27 (96.4)
CXCR4 <sup>MUT</sup>	20 (20.2)	33 (32.4)	1 (3.6)
Unknown	7 (7.1)	4 (3.9)	0 (0.0)
IPSS WM, n (%)			
Low	13 (13.1)	17 (16.7)	5 (17.9)
Intermediate	42 (42.4)	38 (37.3)	11 (39.3)
High	44 (44.4)	47 (46.1)	12 (42.9)
Hemoglobin ≤110 g/L, n (%)	53 (53.5)	67 (65.7)	15 (53.6)
Baseline IgM (g/L, central lab), median (range)	34.2 (2.4-108.0)	31.8 (5.8-86.9)	28.5 (5.6-73.4)
Bone marrow involvement (%), median (range)	60 (0-90)	60 (0-90)	22.5 (0-50)
Extramedullary disease by investigator, n (%)	66 (66.7)	63 (61.8)	16 (57.1)

# RESULTS (cont.)

- In cohort 1, 51 (51.5%) patients treated with ibrutinib and 67 (65.7%) patients treated with zanubrutinib remained in the study (Figure 2); main reasons for discontinuation were PD and AEs. In the zanubrutinib arm, 14 patients discontinued due to PD and 9 due to AEs and in the ibrutinib arm, 20 patients discontinued due to AEs and 13 due to PD
- In cohort 2, 10 (35.7%) patients treated with zanubrutinib remained in the study; main reasons for discontinuation were progressive disease (n=8) and AEs (n=6)

#### **Figure 2: Patient Disposition**



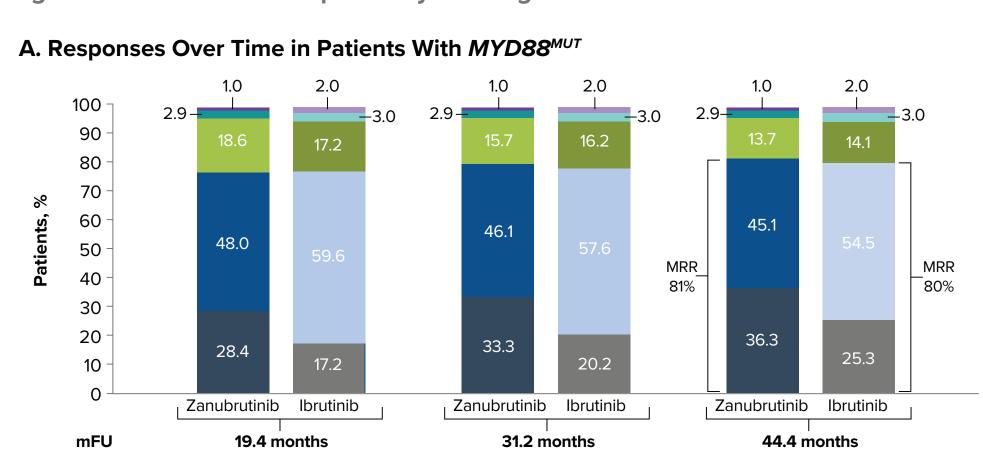
otherapy for endometrial adenocarcinoma; patient started other anticancer therapy (rectal cancer); unwitnessed death (prior hospitalization for heart failure exacerbation but death not due to AE per site and no other information available). In cohort 2 (n=26 MYD88 mutation status unknown). the safety analysis set

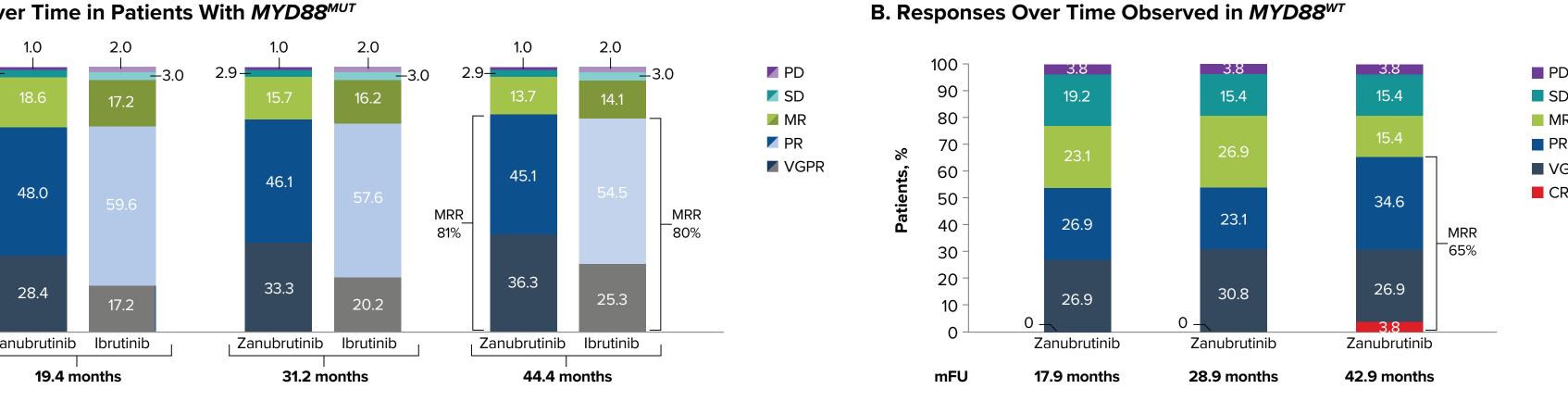
#### **Efficacy**

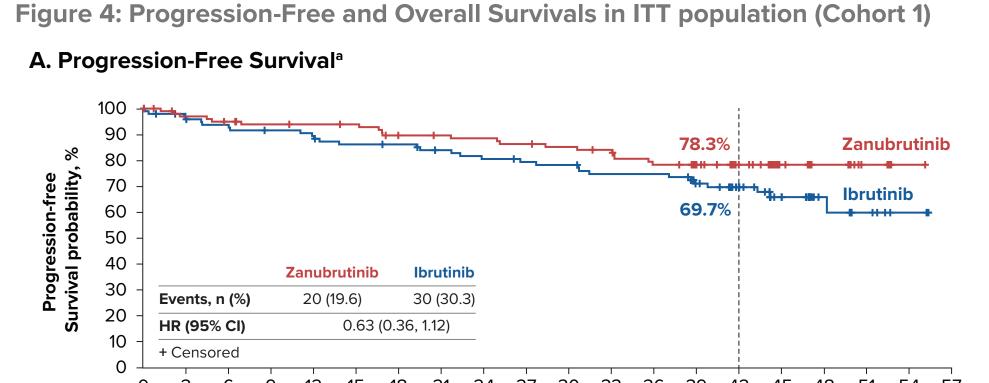
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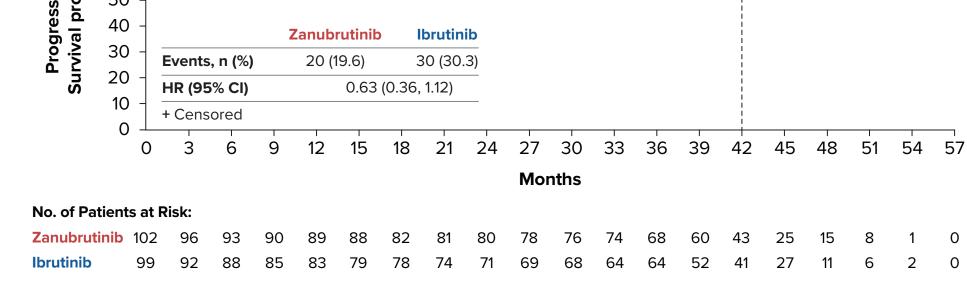
EU Clinical Trial Register: EUDRACT 2016-002980-33

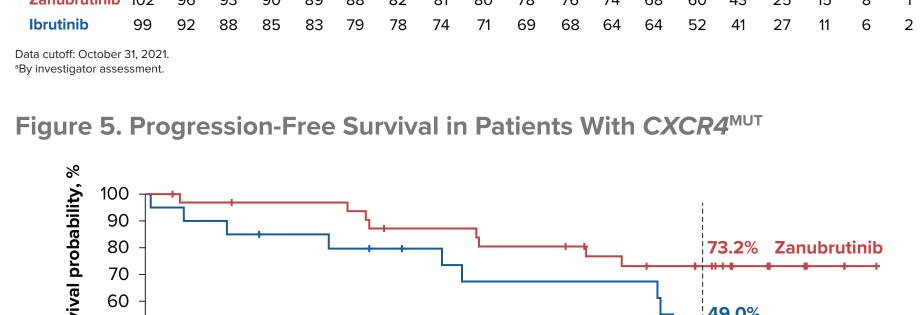
- In cohort 1, the investigator-assessed cumulative response rate increased over time in both treatment arms (Figure 3A) - No CRs were observed in cohort 1. Response rate of CR+VGPR was numerically higher at all time points with zanubrutinib compared with ibrutinib
- At 44.1 months median follow-up, CR+VGPR rates by investigator were 36.3% (zanubrutinib) vs 25.3% (ibrutinib)
- Median time to CR+VGPR was shorter for zanubrutinib: 6.7 months (range, 1.9-42.0) vs ibrutinib: 16.6 months (range, 2.0-49.9)
- Event-free rate for the duration of CR+VGPR at 24 months was higher for zanubrutinib: 90.6% (range, 73.6-96.9) vs ibrutinib: 79.3% (range, 53.5-91.8)
- Median PFS and median OS were not yet reached, with hazard ratio estimates favoring zanubrutinib in cohort 1 (Figure 4)
- In patients with CXCR4<sup>MUT</sup> confirmed by NGS, zanubrutinib demonstrated deeper and faster responses, as well as favorable PFS, compared with ibrutinib (Figure 5 and Table 2) ■ In cohort 2 (MYD88<sup>WT</sup>), zanubrutinib demonstrated a CR in 1 patient with major response rate of 65% (including 31% CR+VGPR) overall (**Figure 3B**)
- Event-free rates of PFS and OS at 42 months were 53.8% (95% CI: 33.3, 70.6) and 83.9% (95% CI: 62.6, 93.7), respectively
- Figure 3: Best Overall Response by Investigator Over Time

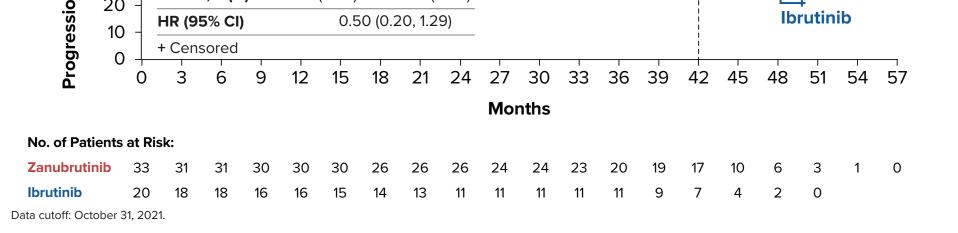


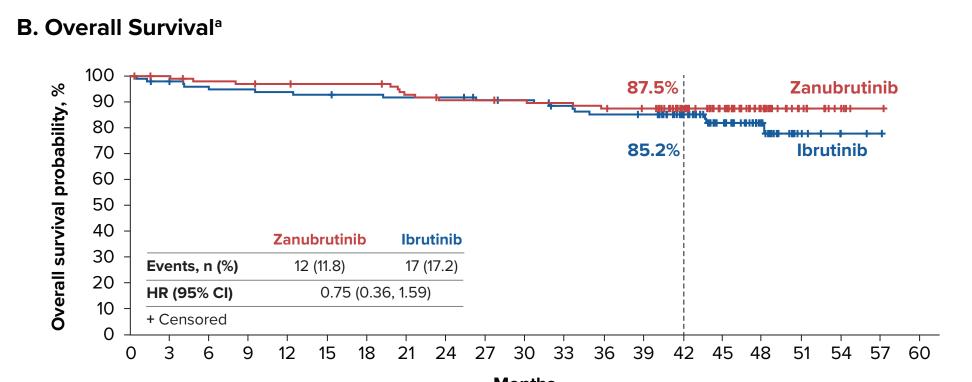












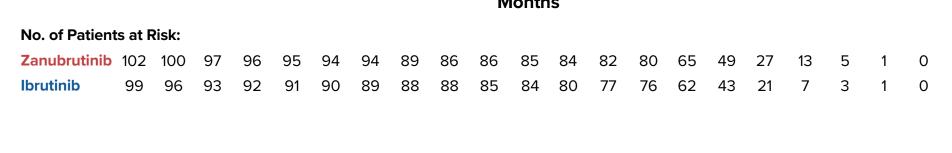


Table 2: Response Assessment by CXCR4 Status<sup>a</sup>

**Bold** text indicates >10% difference between arms. Data cutoff: October 31, 2021

<sup>a</sup>CXCR4 mutation determined by NGS. Ninety-two ibrutinib patients and 98 zanubrutinib patients had NGS results available

# CXCR4WT

#### **Long-Term Safety and Tolerability**

**Table 3: Overall Safety Summary** 

Category, n (%)

Patients with ≥1 AE

AE leading to death

discontinuation

No. of Patients at Risk:

Data cutoff: October 31, 2021.

AE leading to treatmen

AE leading to dose held

COVID-19—related AE

AE leading to dose reduction

Grade ≥3

Zanubrutinib when compared with ibrutinib had fewer AEs leading to death, treatment discontinuation, and dose reduction (Table 3 and Figure 6)

Cohort 2

(N=28)

- Most common AEs that led to discontinuation were cardiac disorder and infection (4% each) with ibrutinib vs second malignancy (4%) with zanubrutinib (**Table 3**) ■ The profile of AEs of interest favored zanubrutinib compared with ibrutinib (Table 4, Table 5, and Figure 7)
- The prevalence of atrial fibrillation, hypertension, and bleeding were lower in the zanubrutinib arm at all time intervals
- Neutropenia occurred early, and prevalence decreased over time for patients receiving zanubrutinib

- Prevalence of infection decreased over time and to a greater extent in the zanubrutinib arm

Cohort 1

#### A similar safety profile for zanubrutinib in cohort 1 was observed in cohort 2

98 (100.0)

ardiac arrest, COVID-19 infection, diarrhea, hepatitis B infection, squamous cell carcinoma of lung, subdural hemorrhage (after a fall).

Figure 6: Time to Treatment Discontinuations Due to AEs (Cohort 1)

#### **Table 4. Most Common AEs (Cohort 1)**

	All grad	All grades (≥20%)		Grade ≥3 (≥5%)	
AEs, <sup>a</sup> n (%)	Ibrutinib (n=98)	Zanubrutinib (n=101)	Ibrutinib (n=98)	Zanubrutinib (n=101)	
Diarrhea	34 (34.7)	23 (22.8)	2 (2.0)	3 (3.0)	
Upper respiratory tract infection	32 (32.7)	33 (32.7)	1 (1.0)	0	
Muscle spasms*	28 (28.6)*	12 (11.9)	1 (1.0)	0	
Contusion	27 (27.6)	19 (18.8)	0	0	
Arthralgia	24 (24.5)	24 (23.8)	0	3 (3.0)	
Hypertension	24 (24.5)	15 (14.9)	19 (19.4)	10 (9.9)	
Peripheral edema	21 (21.4)	18 (17.8)	0	0	
Epistaxis	21 (21.4)	17 (16.8)	0	1 (1.0)	
Atrial fibrillation*	21 (21.4)*	7 (6.9)	6 (6.1)*	2 (2.0)	
Cough	20 (20.4)	19 (18.8)	0	0	
Fatigue	19 (19.4)	26 (25.7)	1 (1.0)	1 (1.0)	
Pneumonia*	18 (18.4)*	5 (5.0)	10 (10.2)*	1 (1.0)	
Syncope	8 (8.2)	5 (5.0)	6 (6.1)	5 (5.0)	

#### **Table 5: AEs of Interest in Cohort 1**

	All grades		Grade ≥3	
AEs, <sup>a</sup> n (%)	lbrutinib (n=98)	Zanubrutinib (n=101)	lbrutinib (n=98)	Zanubrutinib (n=101)
Infection	78 (79.6)	80 (79.2)	27 (27.6)	22 (21.8)
Bleeding	61 (62.2)	56 (55.4)	10 (10.2)	9 (8.9)
Diarrhea	34 (34.7)	23 (22.8)	2 (2.0)	3 (3.0)
Hypertension*	25 (25.5)	15 (14.9)	20 (20.4)*	10 (9.9)
Atrial fibrillation/flutter*	23 (23.5)*	8 (7.9)	8 (8.2)*	2 (2.0)
Anemia	22 (22.4)	18 (17.8)	6 (6.1)	12 (11.9)
Neutropenia*b	20 (20.4)	35 (34.7)*	10 (10.2)	24 (23.8)*
Thrombocytopenia	17 (17.3)	17 (16.8)	6 (6.1)	11 (10.9)
Second primary malignancy/ nonskin cancers	17 (17.3)/ 6 (6.1)	17 (16.8)/ 6 (5.9)	3 (3.1)/ 3 (3.1)	6 (5.9)/ 4 (4.0)

Data cutoff: October 31, 2021. \*Descriptive purposes only, 1-sided P < 0.025 in rate difference in all grades and/or grade  $\geq 3$ .

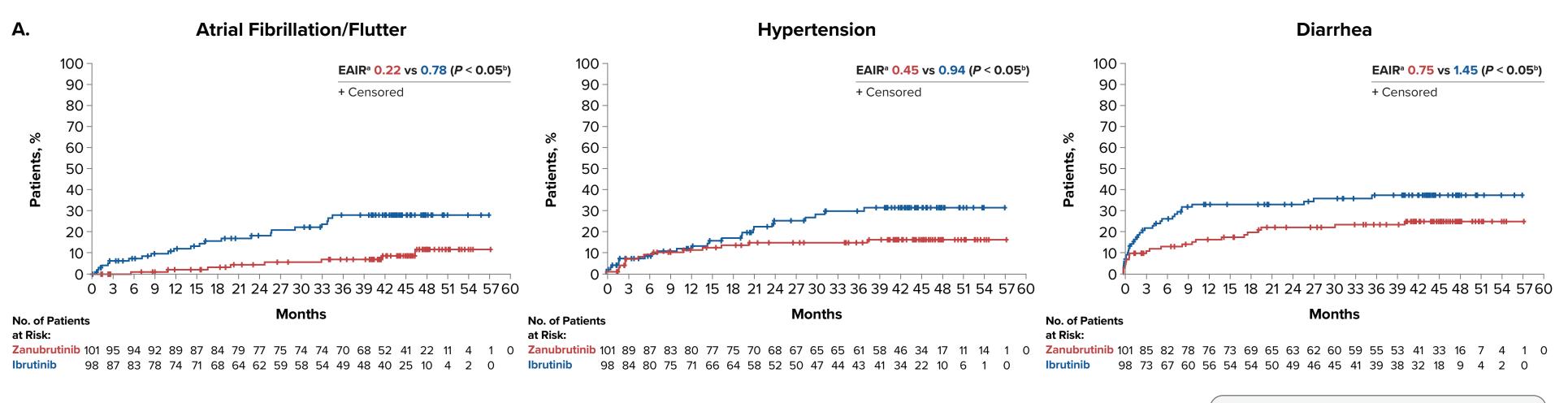
<sup>a</sup>Preferred terms by Medical Dictionary for Regulatory Activities v24.0; excluding cytopenia, cytopenias are reported in **Table 5**.

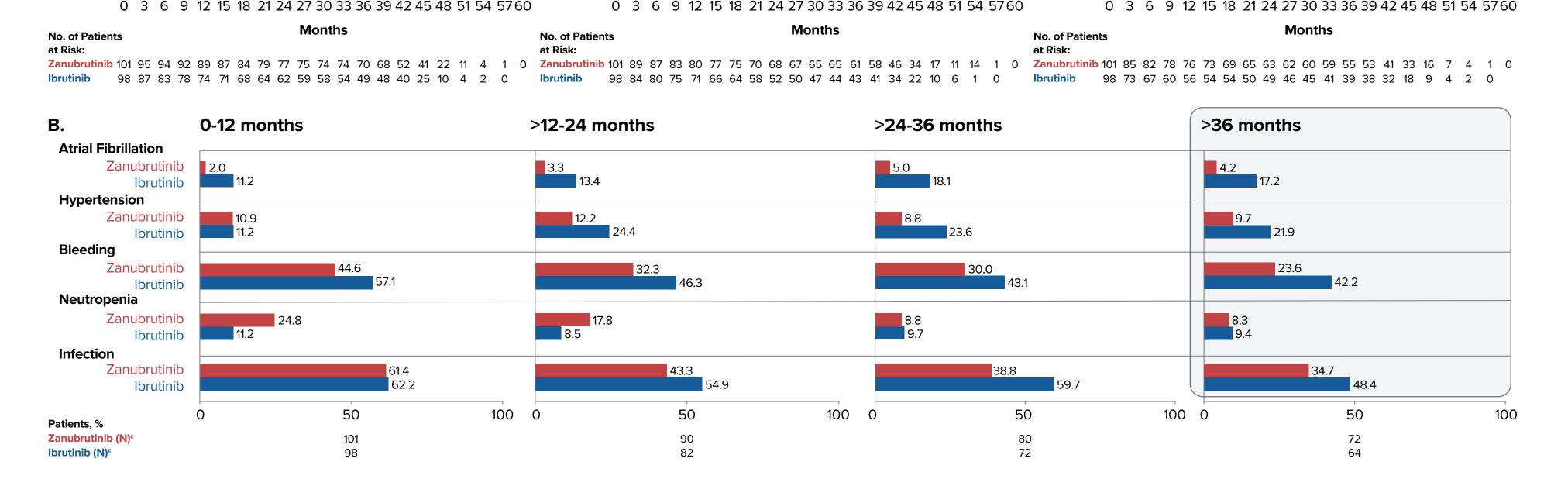
**Bold** text indicates rate of AEs with  $\ge 10\%$  (all grades) or  $\ge 5\%$  (grade  $\ge 3$ ) difference between arms. Data cutoff: October 31, 2021. \*Descriptive purposes only, 1-sided P < 0.025 in rate difference in all grades and/or grade ≥3. <sup>a</sup>AE categories (grouped terms) of preferred terms by Medical Dictionary for Regulatory Activities v24.0. blncluding preferred terms of neutropenia, neutrophil count decreased,

#### Figure 7: (A) Time to and (B) Prevalence Analysis for AEs of Interest (Cohort 1)

**Zanubrutinib** 101 95 94 91 90 86 85 81 80 79 77 77 72 70 55 42 22 11 4 1 0

**Ibrutinib** 98 90 87 84 82 80 79 74 71 70 69 65 64 63 53 33 15 7 2 0





<sup>a</sup>Persons per 100 person-month. <sup>b</sup>Descriptive purpose only, 2-sided P value. <sup>c</sup>N is the number of patients who are on treatment in each time interval or who discontinued treatment but the time from first dose date to the earliest date (last dose date +30 days, initiation of new anticancer therapy, end of study, death or cutoff date) is within the time interval or who discontinued treatment but the time from first dose date to the earliest date (last dose date +30 days, initiation of new anticancer therapy, end of study, death or cutoff date) is within the time interval or who discontinued treatment but the time from first dose date to the earliest date (last dose date +30 days, initiation of new anticancer therapy, end of study, death or cutoff date) is within the time interval or who discontinued treatment but the time from first dose date to the earliest date (last dose date to the earliest date).

# CONCLUSIONS

- Zanubrutinib, with long-term follow-up, continued to demonstrate clinically meaningful efficacy in patients with WM
- Although not statistically significant at primary analysis, a consistent trend of deeper, earlier, and more durable responses (CR+VGPR) compared with ibrutinib was observed over time
- Zanubrutinib provided faster and deeper responses in patients with *CXCR4*<sup>MUT</sup>
- PFS and OS continued to favor zanubrutinib treatment
- At median follow-up of nearly 4 years, 66% of patients remain on treatment with zanubrutinib versus 52% with ibrutinib
- Responses to zanubrutinib in patients with MYD88<sup>WT</sup>
- (cohort 2) continued to deepen over time With longer follow-up, safety advantages of zanubrutinib
- remained consistent with less off-target activity compared with ibrutinib
- Fewer AEs leading to treatment discontinuation, dose reductions, and deaths occurred in the zanubrutinib arm
- Cumulative incidences of atrial fibrillation, diarrhea, hypertension, muscle spasm, and pneumonia were lower in patients receiving zanubrutinib
- Despite a higher rate of neutropenia in the zanubrutinib arm, infection rates were similar and fewer patients in the zanubrutinib arm had grade ≥3 infections

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# AE, adverse event; BID, twice daily; BTK, Bruton tyrosine kinase; CI, confidence interval; CR, complete response; CR+VGPR, complete

response or very good partial response; CTCAE, Common Terminology Criteria for Adverse Events; CXCR4, C-X-C chemokine receptor type 4 gene; CYP3A, cytochrome P450 3A; EAIR, exposure-adjusted incidence rates; EGFR, epidermal growth factor receptor; HR, hazard ratio; IgM, immunoglobulin M; INV, investigator; IPSS, International Prognostic Scoring System; ITT, intent to treat; LOD, limit of detection; mFU, median follow-up; MYD88, myeloid differentiation primary response gene 88; MR, major response; MRR, major response rate; MUT, mutant; NCCN, National Comprehensive Cancer Network; NCI, National Cancer Institute; NGS, next-generation sequencing; OS, overall survival; PFS, progression-free survival; PD, progressive disease; PR, partial response; pt, patient; QD, daily; R, randomization; R/R, relapsed/refractory; SD, stable disease; TEC, tyrosine kinase expressed in hepatocellular carcinoma; TN, treatment naïve; VGPR, very good partial response; WM, Waldenström macroglobulinemia; WHIM, warts, hypogammaglobulinemia, infections, and myelokathexi; WT, wild type.

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