

Bulevirtide Monotherapy is Safe and Well Tolerated in Chronic Hepatitis Delta: An Integrated Safety Analysis of Bulevirtide Clinical Trials at Week 96

Tarik Asselah¹, Soo Aleman², Maurizia Brunetto^{3,4}, Vladimir Chulanov⁵, Adrian Streinu-Cercel^{6,7}, George Sebastian Gherlan^{7,8}, Viacheslav Morozov⁹, Olga Sagalova¹⁰, Tatiana Stepanova¹¹, Sreenivasu Yalamanchili¹², Steve Tseng¹², Florence Christian-Cox¹³, Danielle Shing¹³, Lei Ye¹², Amos Lichtman¹², Dmitry Manuilov¹², Heiner Wedemeyer¹⁴, Pietro Lampertico^{15,16}

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Viral Hepatitis B and D: Current Therapies

Conclusions

- Bulevirtide (BLV) monotherapy at both 2 mg and 10 mg was safe and well tolerated for up to 96 weeks, including in patients with compensated cirrhosis
- Most treatment-emergent adverse events (AEs) were mild to moderate in severity, and the incidence of Grade ≥3 AEs and serious AEs was low and comparable across BLV dose levels
- The most common AEs (in ≥10% of patients in either treatment group) associated with BLV treatment included injection site reactions, headache, fatigue, pruritus, and eosinophilia
 - These typically occurred in the first 48 weeks of BLV treatment
- Bile salt elevations associated with the mechanism of action of BLV were asymptomatic
 - No association was observed between bile salt levels and AEs of interest, including pruritus
- Safety outcomes were consistent across patient subgroups, including age, sex, race, cirrhosis status, and renal function (for more details, see poster WED-576)
- Overall, long-term treatment with BLV is safe in patients with chronic hepatitis delta

Plain Language Summary

- Bulevirtide is used to treat patients with chronic hepatitis delta
- This analysis evaluated safety outcomes in patients with chronic hepatitis delta treated with bulevirtide (2 mg or 10 mg for 96 weeks)
- Safety outcomes were generally similar across both bulevirtide treatment groups
- As expected, given how the medication works, patients who received bulevirtide experienced asymptomatic elevations in bile salts
- These results show that long-term bulevirtide treatment is generally safe and well tolerated

References: 1. Alfaiate D, et al. *J Hepatol*. 2020;73(3):533-9. 2. Rizzetto M, et al. *J Hepatol*. 2021;74(5):1200-11. 3. Stockdale AJ, et al. *J Hepatol*. 2020;73(3):523-32. 4. Hepcludex (bulevirtide). European Medicines Agency, Gilead Sciences, Inc.; 2023. 5. Hepcludex (bulevirtide acetate). Australian Register of Therapeutic Goods, Gilead Sciences, Inc.; 2024. 6. Hepcludex. Product monograph. Gilead Sciences Canada, Inc.; 2025. 7. Blank A, et al. *J Hepatol*. 2016;65(3):483-9. 8. Asselah T, et al. *Liver Int*. 2025;45(4):e16174. 9. Asselah T, et al. *N Engl J Med*. 2024;391(12):133-43. 10. Wedemeyer H, et al. *J Hepatol*. Accepted manuscript. 2026. doi:10.1016/j.jhep.2026.03.046.

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Introduction

- Hepatitis delta virus (HDV) infection causes the most severe form of viral hepatitis, affecting approximately 12 million people globally¹⁻³
- Bulevirtide (BLV), a first-in-class entry inhibitor of HDV, is approved in the United States, the European Economic Area, and several other countries for the treatment of patients with chronic hepatitis delta infection with compensated liver disease⁴⁻⁶
- BLV binds to the sodium taurocholate cotransporting polypeptide receptor, preventing hepatitis B virus and HDV from entering hepatocytes⁷
- BLV monotherapy at doses of 2 mg/day or 10 mg/day sc demonstrated a favourable safety profile in an integrated safety analysis at week (W) 48 of two Phase 2 studies (MYR203 and MYR204) and one Phase 3 study (MYR301)⁸

Objective

- To evaluate the long-term integrated safety data from the MYR204 and MYR301 studies, focusing on 96 weeks of BLV 2 mg or 10 mg monotherapy

Results

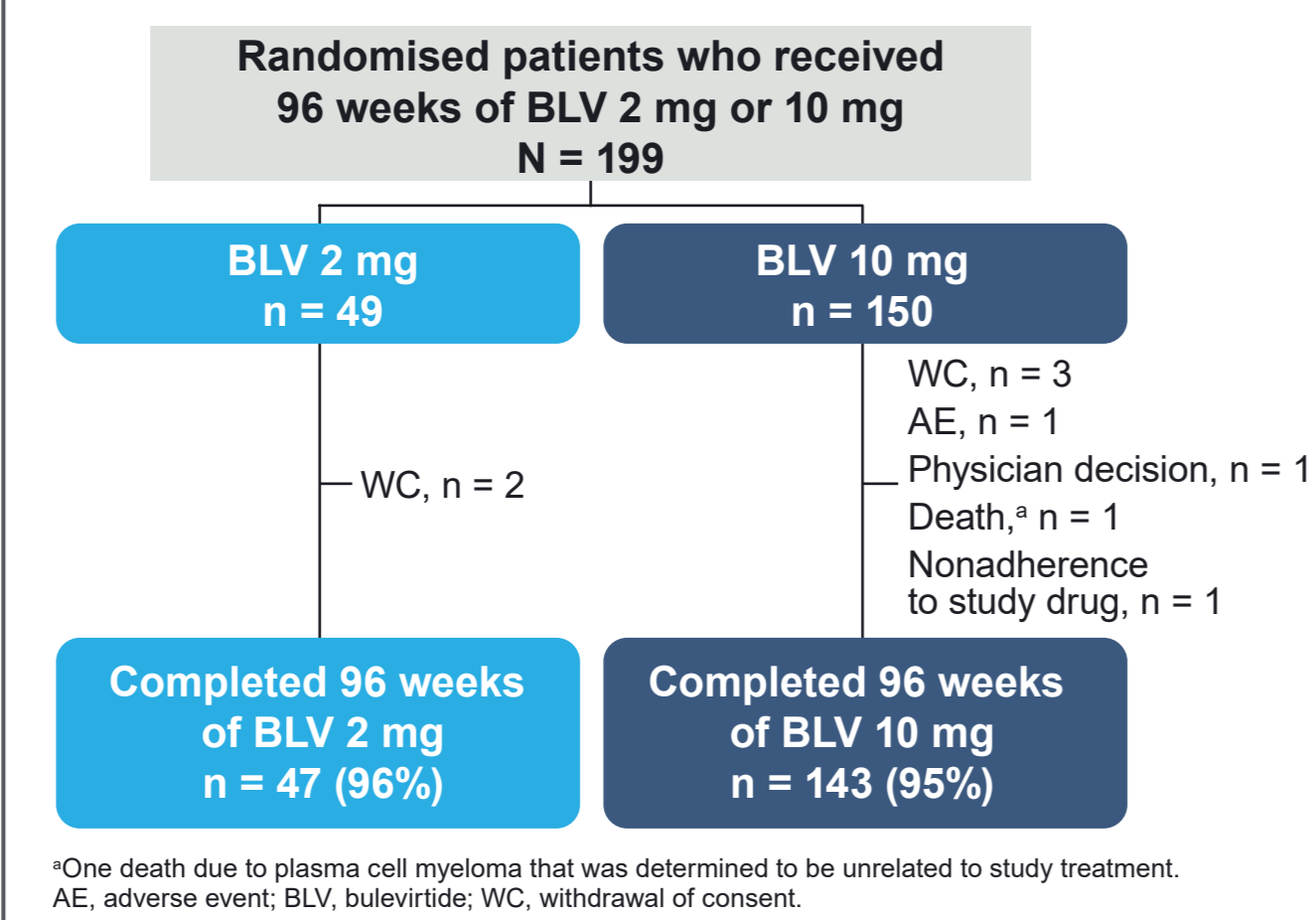
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Age, years, mean (SD)	44 (9.0)	41 (8.2)
Male sex, n (%)	30 (61)	94 (63)
Race, n (%)		
Asian	8 (16)	21 (14)
Black	0	3 (2)
White	41 (84)	126 (84)
Body mass index, kg/m ² , mean (SD)	24.4 (3.09)	25.5 (3.83)
Cirrhosis present, n (%)	23 (47)	65 (43)
HDV RNA, log ₁₀ IU/mL, mean (SD)	5.1 (1.19)	5.2 (1.40)
HDV genotype 1, n (%)	49 (100)	147 (98)
HBV DNA, log ₁₀ IU/mL, mean (SD)	1.3 (1.28)	1.2 (1.38)
ALT, U/L, median (Q1, Q3)	90 (65, 136)	86 (57, 128)
ALT category, n (%)		
>ULN to ≤1.5 × ULN	8 (16)	27 (18)
>1.5 × ULN	39 (80)	109 (73)
Concomitant HBV treatment, n (%)	32 (65)	83 (55)
Prior IFN therapy, n (%)	26 (53)	79 (53)

ALT, alanine aminotransferase; BLV, bulevirtide; HBV, hepatitis B virus; HDV, hepatitis delta virus; IFN, interferon; Q, quartile; ULN, upper limit of normal.

- Demographics and baseline characteristics were generally similar across groups (Table 1)

Figure 2. Patient Disposition

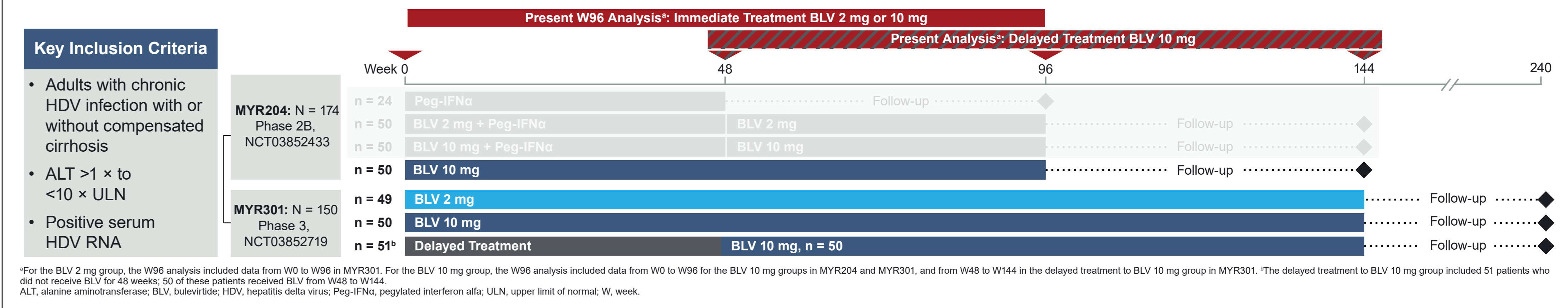


- Discontinuations were infrequent in all groups, with ≥95% of patients completing 96 weeks of BLV 2 mg or 10 mg treatment (Figure 2)

Methods

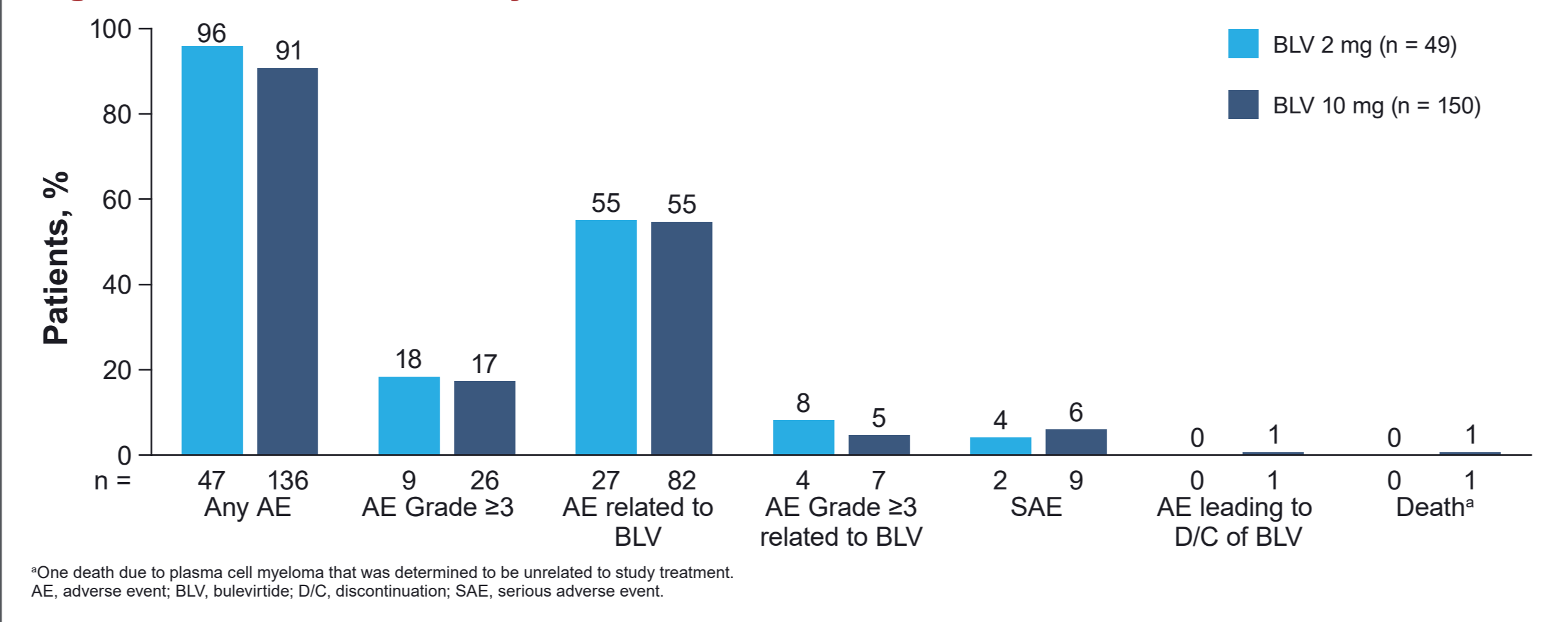
- Data were included from 2 multicentre, open-label, randomised studies: one Phase 2 (MYR204, NCT03852433) and one Phase 3 (MYR301, NCT03852719)^{9,10}
- The W96 integrated safety analysis included patients with HDV who received BLV 2 mg/day or BLV 10 mg/day (approved as 8.5 mg delivered dose in the United States) for 96 weeks in the MYR204 and MYR301 studies (Figure 1)
- Outcomes assessed included treatment-emergent adverse events (AEs), Grade ≥3 AEs, serious AEs (SAEs), and laboratory abnormalities

Figure 1. Study Design



*For the BLV 2 mg group, the W96 analysis included data from W0 to W96 in MYR204 and MYR301. For the BLV 10 mg group, the W96 analysis included data from W0 to W96 for the BLV 10 mg groups in MYR204 and MYR301, and from W48 to W144 in the delayed treatment to BLV 10 mg group in MYR301. *The delayed treatment to BLV 10 mg group included 51 patients who did not receive BLV for 48 weeks; 50 of these patients received BLV from W48 to W144. ALT, alanine aminotransferase; BLV, bulevirtide; HDV, hepatitis delta virus; Peg-IFNα, pegylated interferon alpha; ULN, upper limit of normal; W, week.

Figure 3. Overall Summary of AEs With 96 Weeks of BLV Treatment



- The AE profile was generally consistent between dosage groups through 96-week treatment (Figure 3)
 - Of patients receiving BLV 2 mg or BLV 10 mg, 96% and 91%, respectively, experienced an AE
 - The incidence of Grade ≥3 AEs was similar with BLV 2 mg (18%) and BLV 10 mg (17%)
- Most AEs were mild to moderate in severity
- SAEs were infrequent, and none were considered related to BLV
- One (1%) patient experienced an AE of myalgia (nonserious, Grade 2) on day 543 leading to discontinuation of BLV on the same day; the AE was considered related to BLV

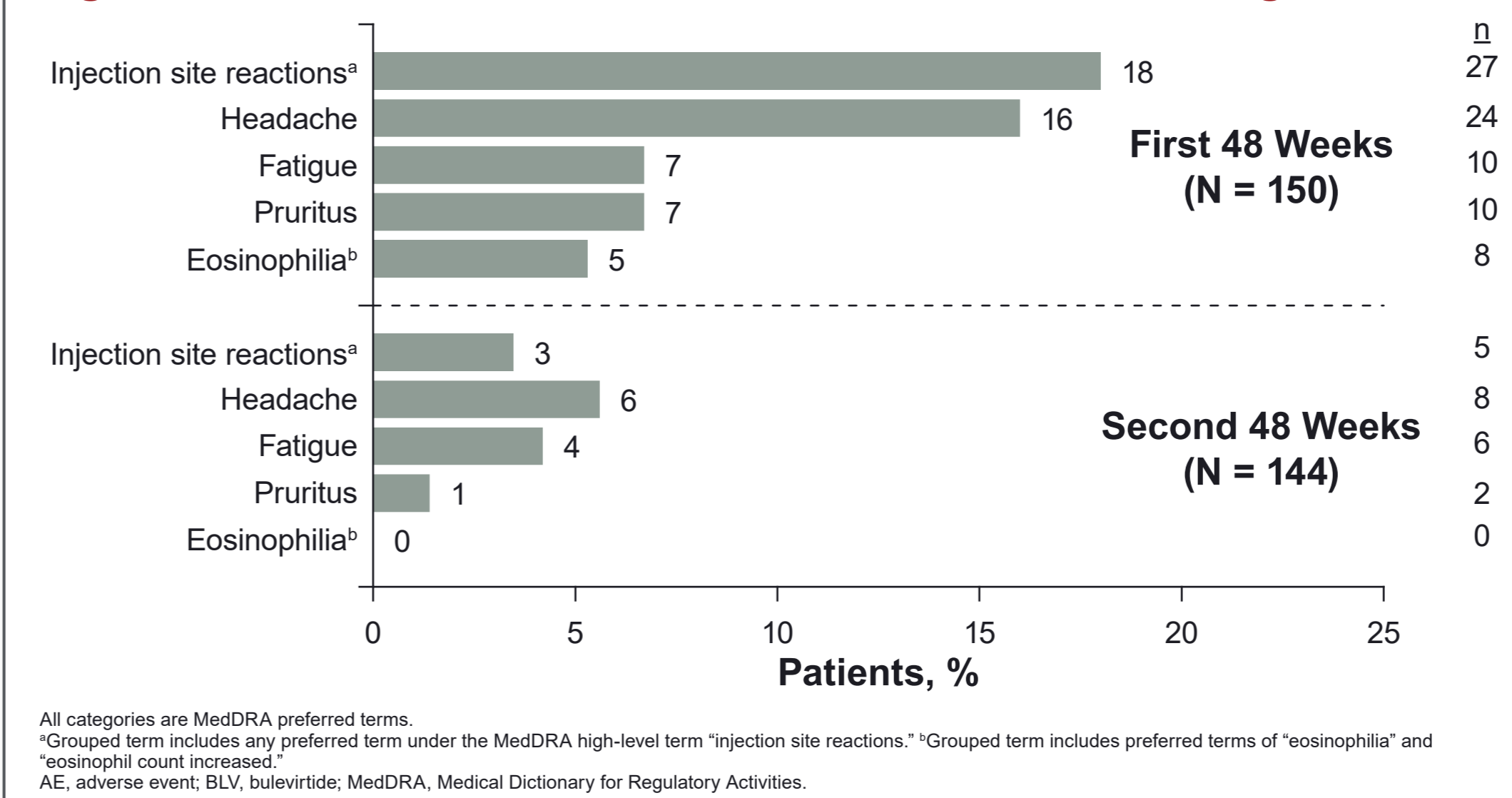
Table 2. Most Common AEs (in ≥10% of Patients) With 96 Weeks of BLV Treatment

Patients, n (%)	BLV 2 mg (n = 49)	BLV 10 mg (n = 150)
Vitamin D deficiency	17 (35)	45 (30)
Injection site reactions ^a	10 (20)	28 (19)
Headache	9 (18)	26 (17)
Leukopenia	9 (18)	23 (15)
Thrombocytopenia	7 (14)	22 (15)
Neutropenia	8 (16)	20 (13)
Lymphopenia	7 (14)	18 (12)
Fatigue	7 (14)	15 (10)
Pruritus	6 (12)	11 (7)
Eosinophilia ^b	5 (10)	8 (5)
Arthralgia	6 (12)	7 (5)

All categories are MedDRA preferred terms. AEs shown in grey rows are considered to be associated with BLV based on review of the W48 integrated safety summary data. ^aGrouped term includes any preferred term under the MedDRA high-level term "injection site reactions". ^bGrouped term includes preferred terms of "eosinophilia" and "eosinophil count increased". AE, adverse event; BLV, bulevirtide; MedDRA, Medical Dictionary for Regulatory Activities; W, week.

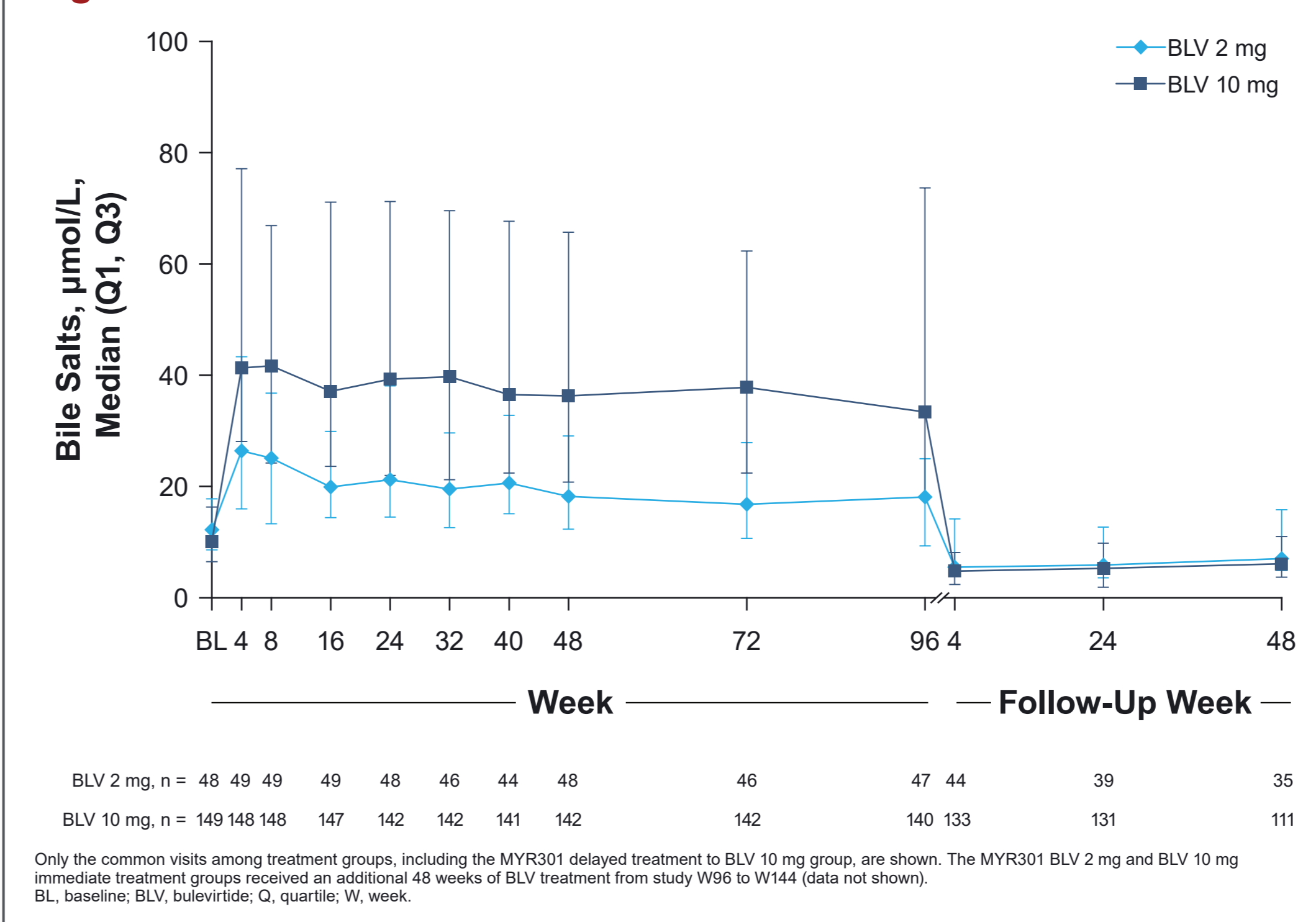
- The safety profile of BLV through 96 weeks of treatment was consistent with that observed in the W48 integrated analysis⁸
- AEs previously shown to occur more frequently with BLV vs without BLV treatment⁸ and reported in ≥10% of patients in either group by 96 weeks of BLV treatment were injection site reactions, headache, fatigue, pruritus, and eosinophilia (Table 2)
 - Other common AEs, including vitamin D deficiency and cytopenias, are associated with underlying liver disease
- Injection site reactions occurred at similar frequencies in the BLV 2 mg and 10 mg groups (20% and 19%, respectively)
- Most (26/28, 93%) pruritus events resolved by 96 weeks of BLV treatment, and the median (quartile [Q1, Q3]) total duration of pruritus per patient was 119 (37, 239) and 49 (1, 272) days for the BLV 2 mg and 10 mg groups, respectively
 - Seven of the 17 patients with pruritus also experienced injection site reactions, of which 4 were concurrent with pruritus

Figure 4. Onset of Common AEs Associated With BLV 10 mg Treatment



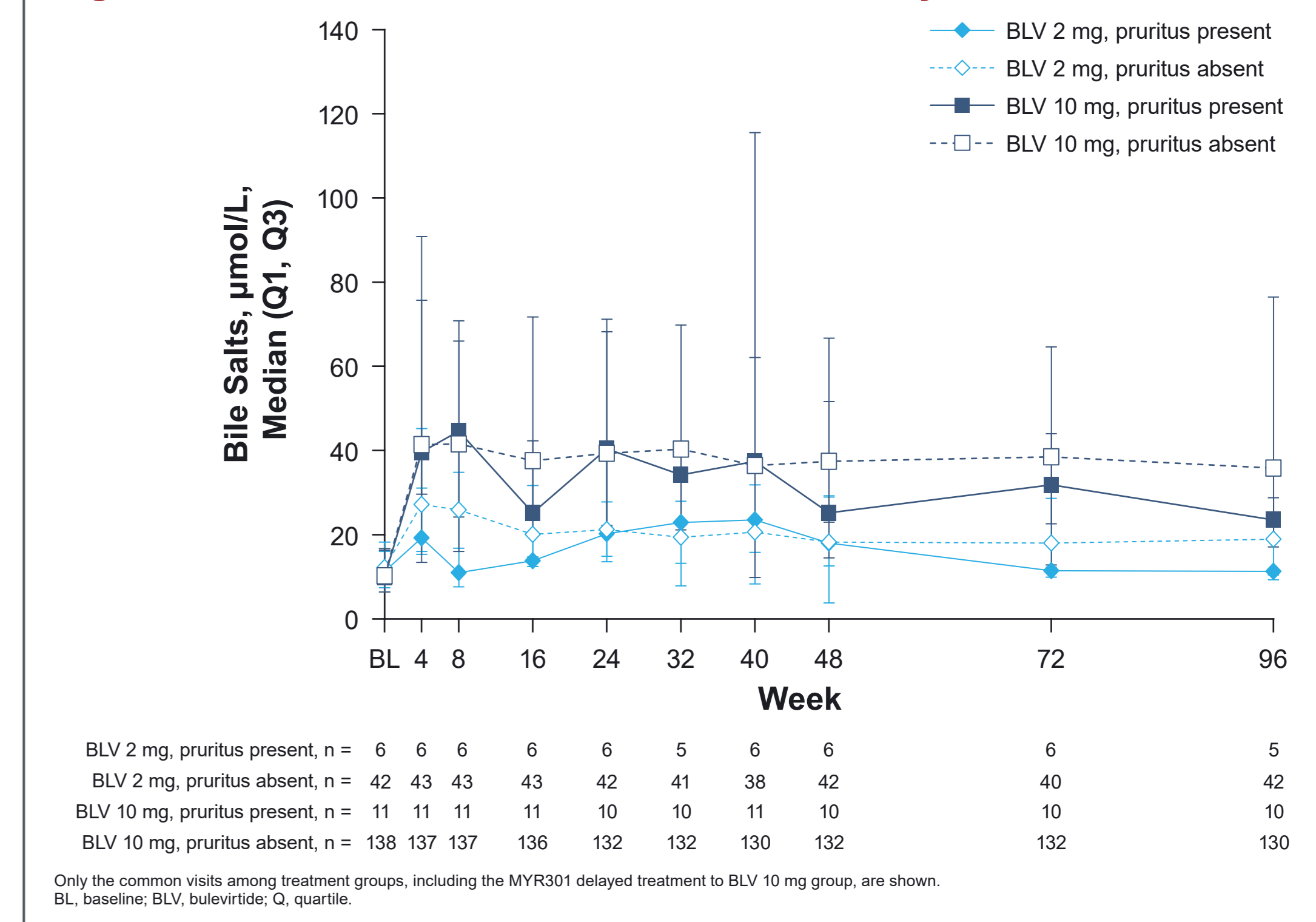
- Onset of most AEs associated with BLV treatment occurred within the first 48 weeks of BLV therapy (Figure 4)
 - AEs with onset in the second 48 weeks of treatment were less frequent

Figure 5. Bile Salt Levels Over Time



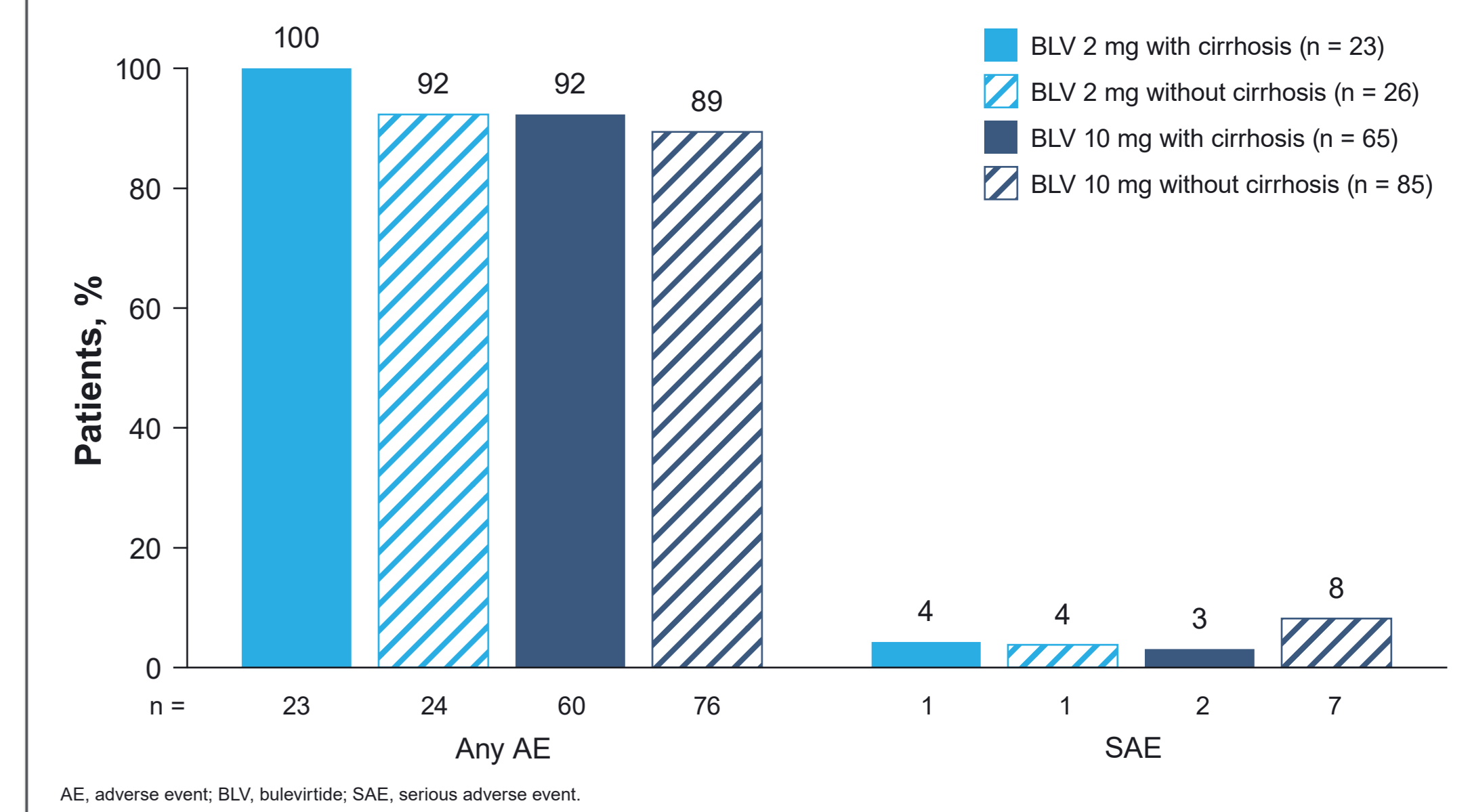
- Asymptomatic bile salt elevations were more pronounced in patients treated with BLV 10 mg than in those who received BLV 2 mg (Figure 5)
 - These dose-dependent elevations were expected based on the mechanism of action of BLV
- After stopping BLV, bile salts quickly returned to baseline levels in both dose groups

Figure 6. Bile Salt Levels Over Time Stratified by Pruritus



- Bile salt levels were not associated with the presence or absence of AEs of interest, including pruritus (Figure 6), cardiac disorders, vitamin D deficiency, gallstone and gallbladder disorders, lipid metabolism disorders, sex hormone disorders, and bone events (data not shown)

Figure 7. Summary of AEs by Cirrhosis Status



- The safety profile of BLV was similar between patients with and without cirrhosis for both the 2 mg and 10 mg doses (Figure 7)

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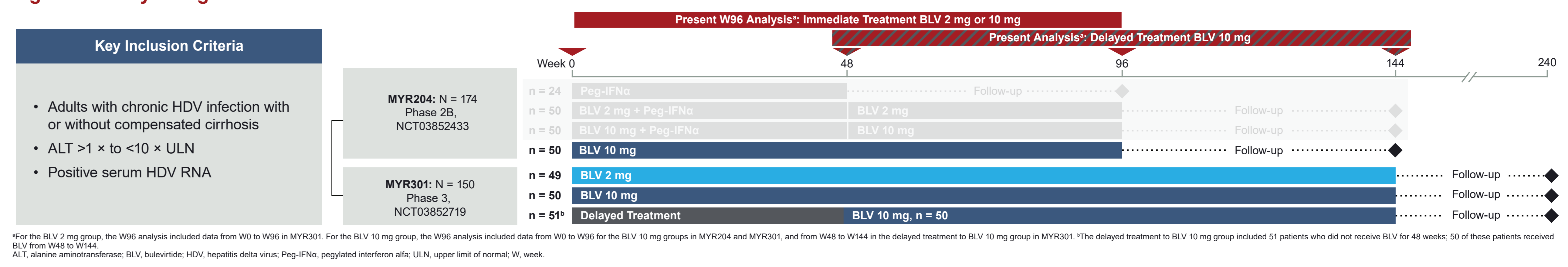
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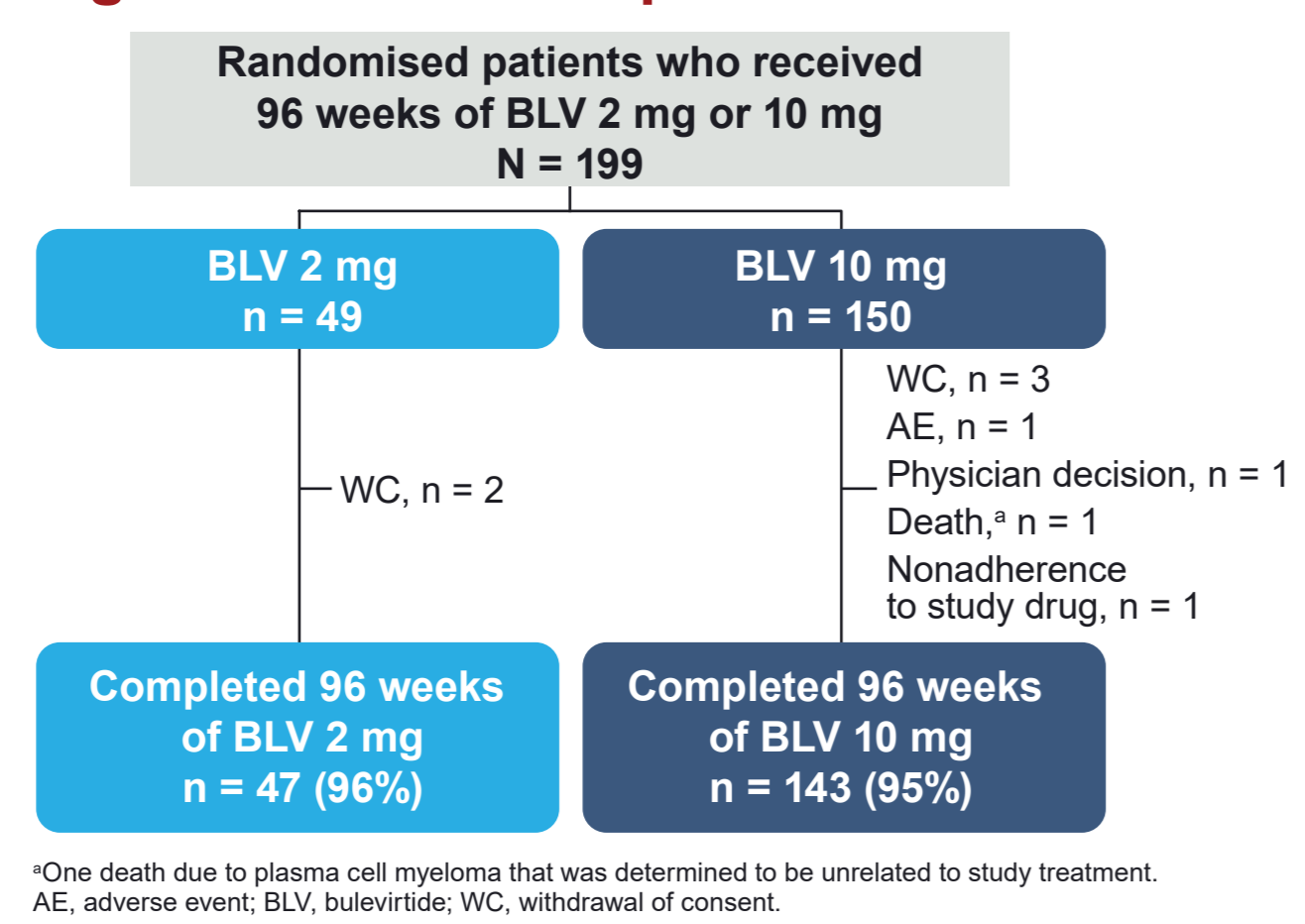
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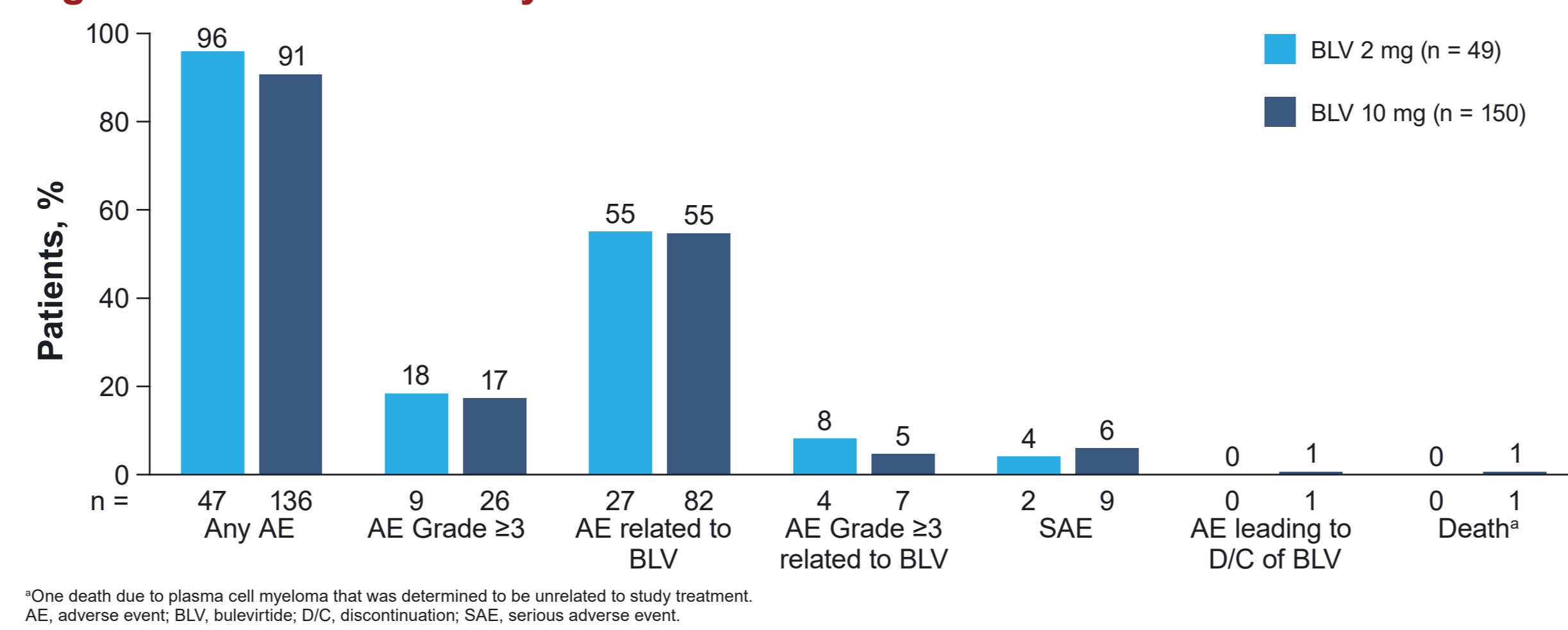
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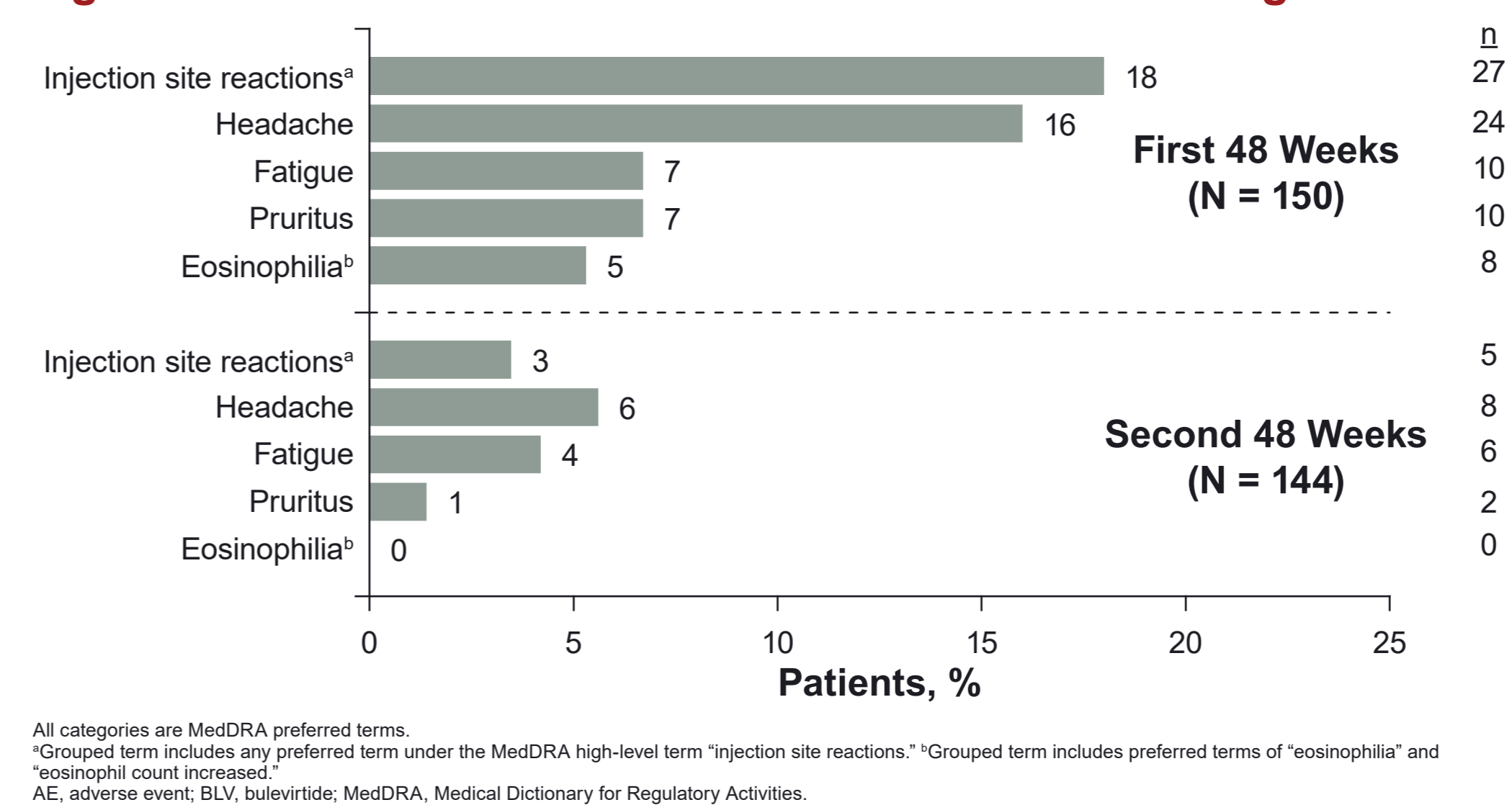
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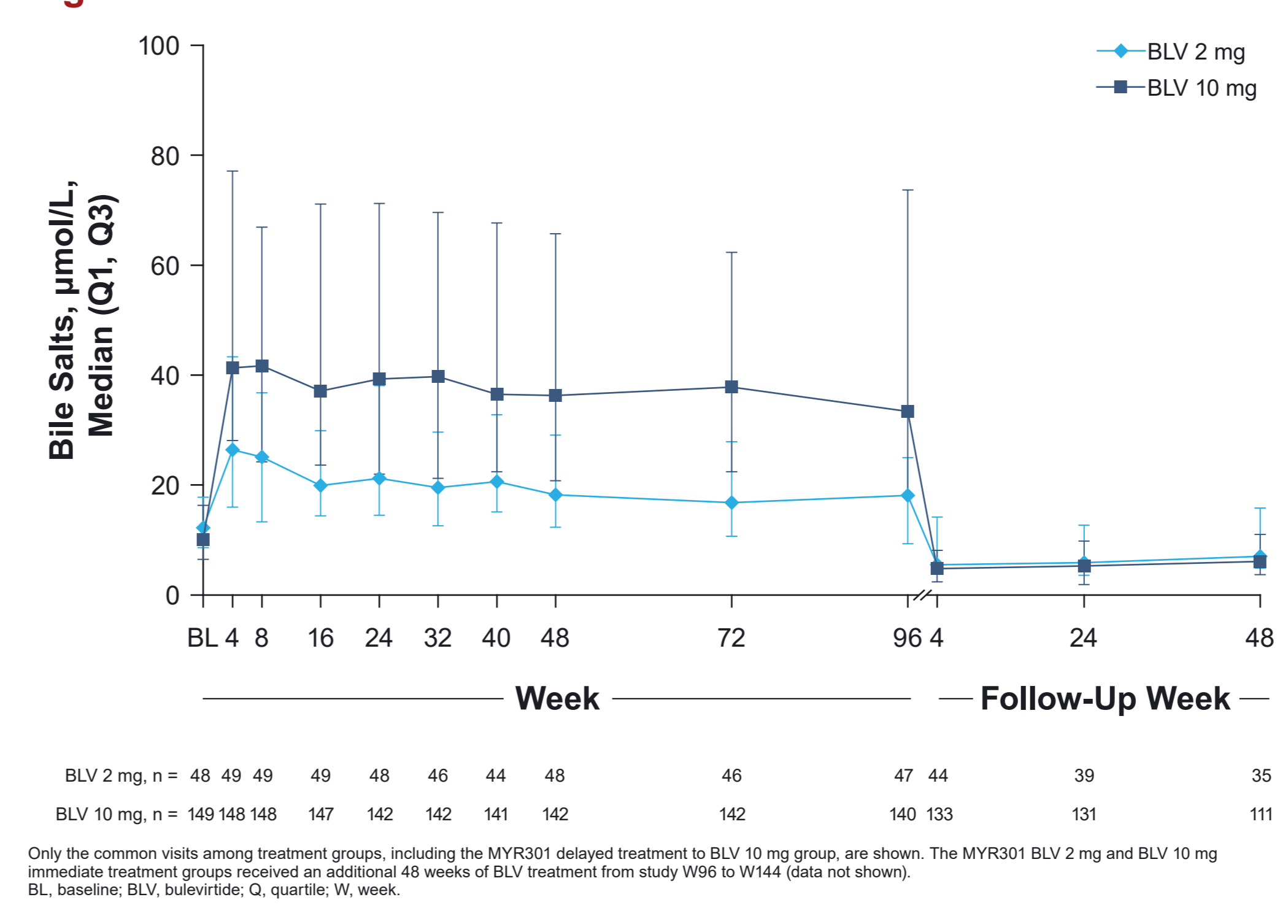
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Figure 4. Onset of Common AEs Associated With BLV 10 mg Treatment



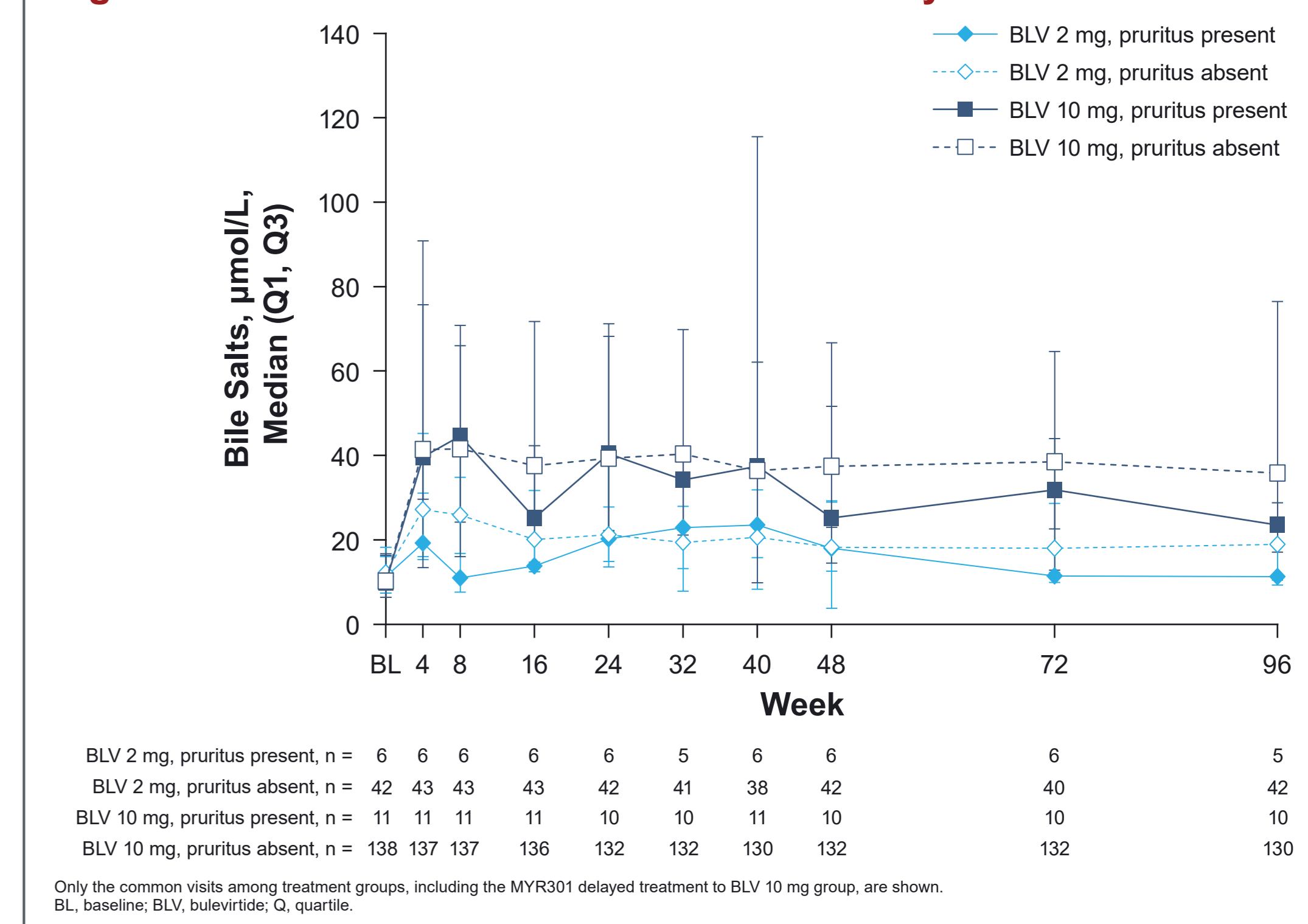
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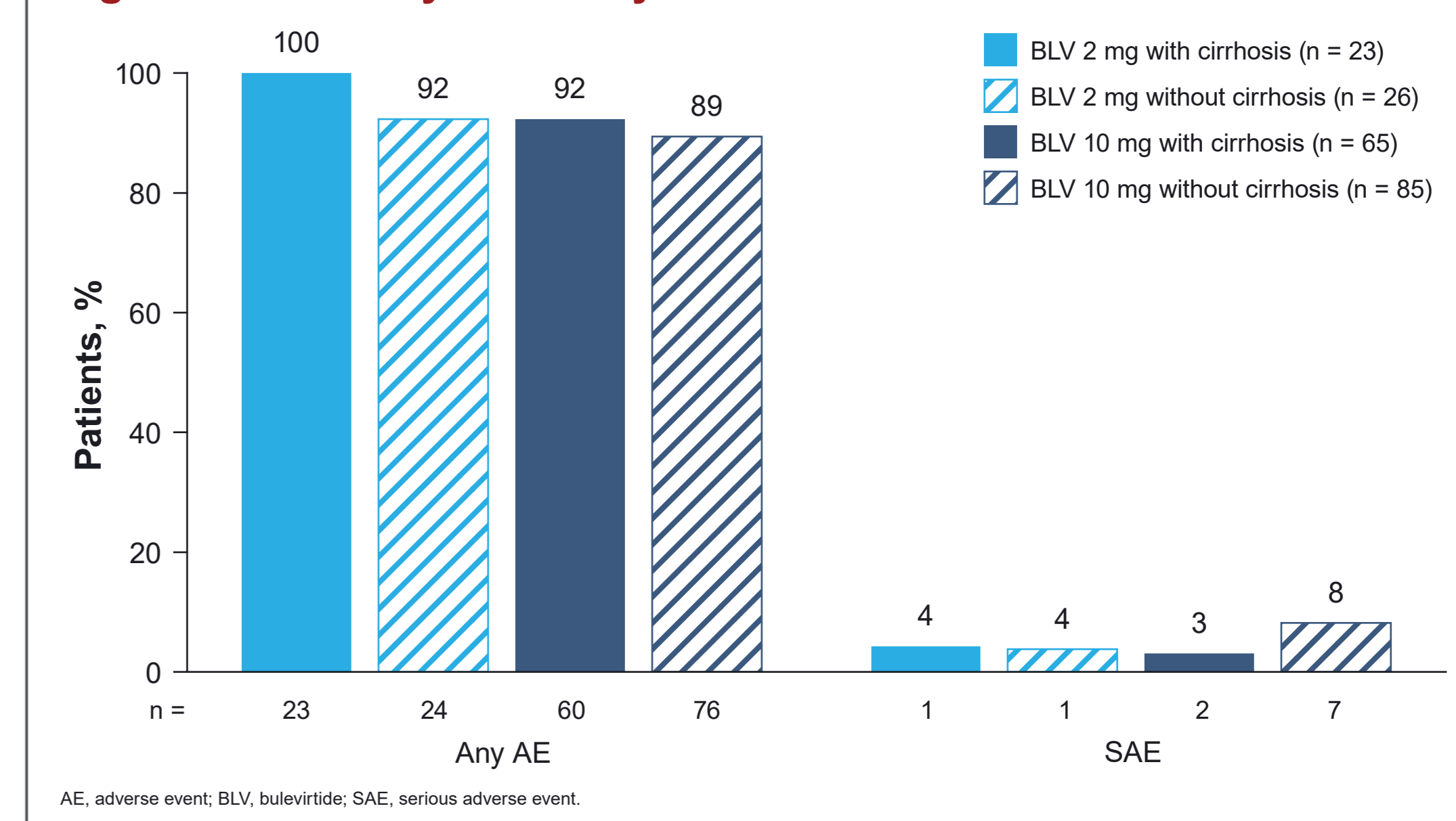
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