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ARIADNE IWWM Abstract 2024

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Medical resource utilization in patients with Waldenström's macroglobulinemia (WM) treated with zanubrutinib: First real-world results of the ARIADNE study from interim analysis 1 (IA1)

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Background: Treatment with Bruton's tyrosine kinase inhibitors (BTKi) in Waldenström's macroglobulinemia (WM) is recommended for treatment-naïve and relapsed/refractory patients. Zanubrutinib is a second-generation BTKi, which was approved for WM in 11/2021. Real-world insights into patient- and disease characteristics, medical resource utilization, effectiveness and QoL are important and complementary to clinical trial data.

Methods: The prospective, non-interventional ARIADNE study aims to enroll up to 400 patients from 70 sites across Germany and Austria to gain insights into effectiveness, tolerability, and patient-reported outcomes (PROs) of zanubrutinib in WM, CLL, MZL and FL. Here, we present the results of IA1 for the WM cohort including patient- and disease characteristics as well as the primary endpoint medical resource utilization, which compiles any hospitalization and emergency unit visits during zanubrutinib treatment regardless of association with the disease.

Results: Between 04/2022 and 11/2023, 195 patients were enrolled. 100 were followed >6 months. 95 patients of the total population including 49 WM patients were evaluable for analyses. 32.7% of WM patients were included for 1st-line and 67.3% for later-line treatment. At the database cut on the 30-11-2023, 73.5% of patients were still on treatment. The median age was 75.8 years (range 50-94), 55.1% were male and 44.9% female and 32.7% had ECOG

≥2 at inclusion. Median WM cell infiltration in the bone marrow was 45.0% measured in 10 patients. In 57.1% of patients, no organ involvement was present at inclusion. 51.0% of patients had a watch and wait phase before start of 1st-line, which was in median 17.58 months. All later-line patients received a 1st-line treatment regimen containing either bendamustine or rituximab. 40.8% of patients received rituximab/bendamustine. None of the patients received a prior stem cell transplantation and only two patients (4.1%) received prior plasmapheresis. Regarding medical resource utilization, 69.4% of patients did not require hospitalization. 28.6% had a hospital stay and 6.1% had an emergency room visit. The overall response rate (ORR) (i.e., CR, VGPR, PR) was 55.1% (95% CI: 40.2, 69.3). Moreover, ORR was comparable in 1st- vs later-line patients (56.2% vs 54.5%). As best response, two patients (4.1%) achieved complete response (CR), five (10.2%) very good partial response (VGPR), 20 (40.8%) partial response (PR), two (4.1%) minor response (MR), eight (16.3%) stable disease (SD) and one patient (2.0%) had PD. For 11 patients no assessment was documented so far. The depth of response was comparable in 1st- vs later-line: CR: 0% vs 6.1%, VGPR: 6.2% vs 12.1%, PR: 50.0% vs 36.4%, MR: 0% vs 6.1%, SD: 12.5 vs 18.2% and PD: 6.2 vs 0.0%.

Conclusion: The ARIADNE IA1, 19 months after FPI, shows a real-world WM patient population, that is older and more frail than in the pivotal trial. About one third of patients receiving zanubrutinib as 1st-line treatment. Furthermore, more than two-thirds of patients did not require hospitalization regardless of association with WM. The ORR was 55.1% and both the ORR and the depth of response were comparable in 1st- vs later-line patients. Response might deepen over time with longer follow-up of patients.