REAL-WORLD DATA ON QUALITY OF LIFE (QoL) AND SAFETY OF SELINEXOR IN COMBINATION WITH BORTEZOMIB AND DEXAMETHASONE (SVD) IN PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (R/RMM)

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SUMMARY

SEATTLE will provide clinically relevant insights into QoL, safety and effectiveness of SVd in the routine clinical setting in Germany and Austria, with a focus on AE management and the effect of selinexor dosage on endpoints.

BACKGROUND

The pivotal BOSTON-trial[1] demonstrated significant improvement in progression-free survival (PFS; 13.93 vs. 9.46 months) with the addition of selinexor (S; 100mg/QW) to bortezomib and dexamethasone (Vd). Subgroup analysis revealed prolonged PFS in patients naïve to proteasome inhibitors or lenalidomide-refractory. Most common non-hematological AEs included, nausea, fatigue, decreased appetite, weight loss, diarrhea, peripheral neuropathy and vomiting. AEs were generally reversible, and manageable with dose modifications and supportive care. A post hoc analysis showed that patients with selinexor dose reductions had a higher PFS than patients without (16.6 vs. 9.2 months). Since treatment options for MM are various and one of the most important factors is to keep or improve quality of life (QoL) of those patients, there is a need for real-world data from clinical routine on the treatment with selinexor.

METHODS

The objective of this ongoing prospective, non-interventional study SEATTLE is to analyze real-world treatment of patients with R/RMM with SVd in ≥2nd-line. Data will be described for pts in clinical routine practice with persistent medical need in daily care, that are often underrepresented in clinical trials. The study plans to enroll up to 100 patients in up to 35 sites in Germany and Austria. The recruitment began in June 2023. Eligible adult patients, as indicated by their treating physician and in accordance with the current summary of product characteristics, are invited to participate (**Figure 1**). Patient demographics, prior- and subsequent-line therapies, and patient relevant endpoints will be documented until the end of study (i.e., 16 months after the inclusion of the last patient), patient's withdrawal or death, whichever comes first. The primary endpoint is QoL (**Figure 2**). Secondary endpoints include effectiveness and safety, with a focus on concomitant medication, dose intensity and dose reductions. Additionally, the revised myeloma comorbidity index (R-MCI) at baseline will be assessed according to selinexor starting dose. Data will be described for the overall study population and specific subgroups, such as age, cytogenetic risk, and selinexor starting dose. Descriptive statistics will be used to summarize all endpoints.

Figure 1: Expected timelines of SEATTLE.

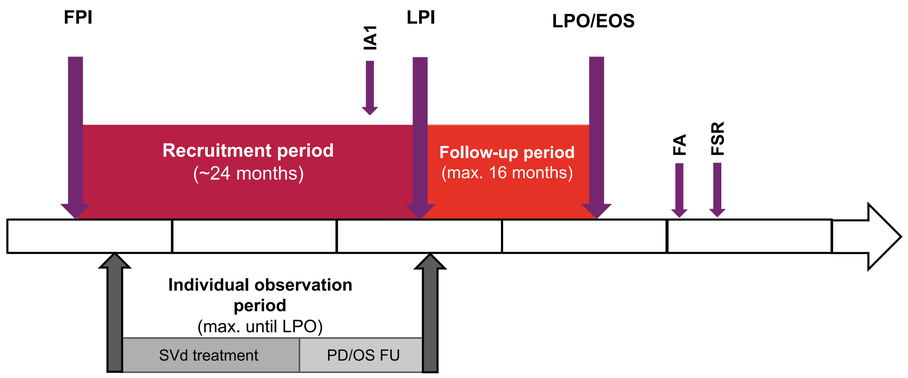
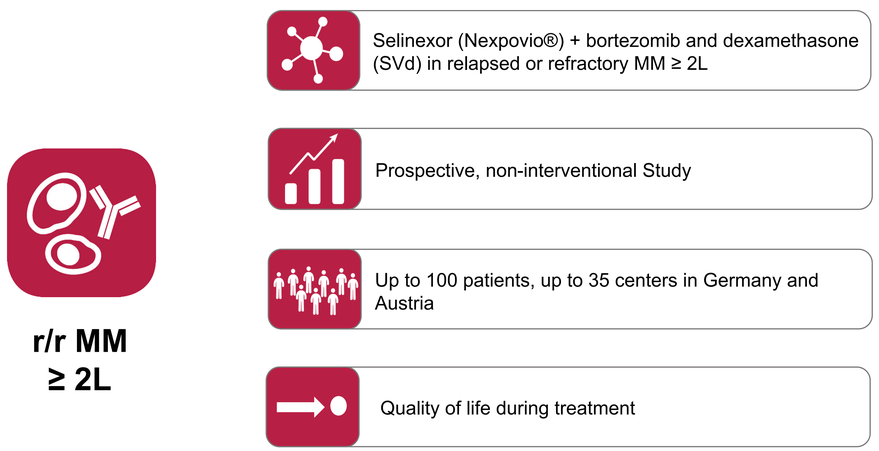


Figure 2: Benchmark data of SEATTLE



Abbreviations:

AE: Adverse event | EOS: End of Study | FA: Final Analysis | FPI: First-patient in | FSR: Final Study Report | FU: Follow-up | IA: Interim Analysis | LPI: Last-patient in | LPO: Last-patient out | mg: Milligram | OS: Overall Survival | PD: Progressive Disease | PFS: Progression-free survival | QoL: Quality of life | QW: weekly | R/RMM: Relapsed and/or refractory Multiple Myeloma | R-MCI: Revised Myeloma Comorbidity Index | SVd: Selinexor, Bortezomib, Dexamethasone | Vd: Bortezomib, Dexamethasone

References:

1. Grosicki, et al. Once-per-week selinexor, bortezomib, and dexamethasone versus twice-per-week bortezomib and dexamethasone in patients with multiple myeloma (BOSTON): a randomised, open-label, phase 3 trial. The Lancet 2020 Nov;396(10262):1563-1573.

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Conflicts of interest, presenting author:

Patrick Marschner: Employment or management position: iOMEDICO; Consultancy or expert opinion: Lilly, Novartis, Otsuka; Fees: Lilly, abbVie, Beigene, Novartis, BMS, Otsuka; Other financial relationships (travel expenses): AOP, MSD, BMS; Intangible conflicts of interest

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