REAL-WORLD SAFETY PROFILE OF LUSPATERCEPT: A PHARMACOVIGILANCE ANALYSIS OF THE FOOD AND DRUG ADMINISTRATION ADVERSE EVENT REPORTING SYSTEM (FAERS).

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INTRODUCTION

Luspatercept was recently approved for treating anemia in thalassemia and myelodysplastic syndromes (MDS). We retrospectively investigated real-world Luspatercept-related adverse events (AEs) through data mining of the U.S. FAERS database.

METHOD

FAERS Public Database Analysis

Data was queried from first approval (Nov 2019) to last reporting (Dec 2022).

Descriptive analyses identified the 10 most common AEs, which were classified into standard preferred terms.

Cardiovascular effects (CVEs) were further classified based on the MedDRA (Medical Dictionary for Regulatory Activities) terminology.

Bayesian factor (BF) was used to correlate AEs with serious outcomes: death and hospitalization.

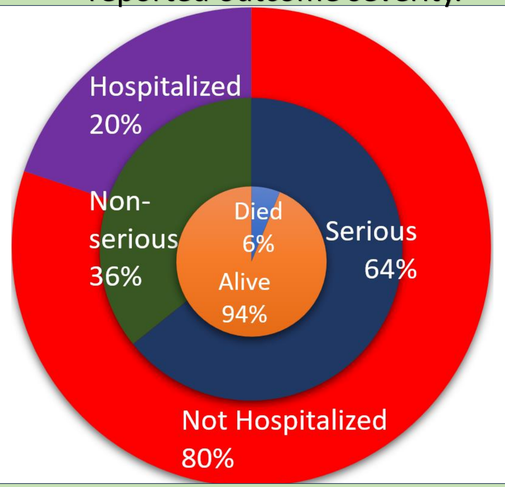
RESULTS

780 AEs reports from 592 patients (329 males, 263 females) were captured. 62.8% of AEs reported were expedited, and most (58.3 %) were from the U.S. Mean age was 69.6 years. AEs occurred in 17 organ systems. Among 51 CVEs, the most common were hypertension (n= 16) and cardiac failure (n= 11). Other less commonly reported AEs included peripheral edema, headache, hemolysis, and thrombosis.

T1: Distribution analysis of reported AEs with Luspatercept.

Reported Adverse Events	Reporting Ratio (PPR)
Fatigue	7.17
CVEs	6.53
Arthralgia	6.15
Dyspnea	1.92
Weight gain	1.80
Fracture	1.79
Thrombosis	1.79

P1: Distribution of Luspatercept AEs reported outcome severity.



T2: Bayes Factor association with outcomes analyses of the reported AEs.

	Hospitalized	Died	Serious
CVS	0.06	4.4	10.1
Liver Injury	25.7	13.4	9.7
Fracture	0.1	23.1	0.7
Kidney Injury	29.7	34.8	32.5
Arthralgia	22.4	0.3	0.1

CONCLUSION

The side effect profile was similar to previously reported clinical trials, but some unique AEs were also reported.

Our data demonstrate the need to closely monitor patients treated with Luspatercept for CVS AEs, especially those with pre-existing heart disease.

CONTACT INFORMATION

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