COMPARATIVE PHARMACOVIGILANCE OF CD20-DIRECTED BISPECIFIC ANTIBODIES IN B-CELL LYMPHOMA: A FAERS OBSERVATIONAL STUDY

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INTRODUCTION

CD20-directed bispecific antibodies, including mosunetuzumab, epcoritamab, and glofitamab, have demonstrated significant efficacy in relapsed or refractory B-cell lymphomas. However, there is currently limited comparative real-world safety data available for these agents.

AIM

The objective of this study was to conduct a pharmacovigilance analysis to evaluate and compare differences in adverse event (AE) reporting patterns among the three FDA-approved CD20-directed bispecific antibodies.

METHOD

We analyzed FDA Adverse Event Reporting System (FAERS) data from January 2023 through December 2025. The study focused on reports where mosunetuzumab, epcoritamab, or glofitamab was the primary suspect in B-cell lymphoma indications. Outcomes measured included cytokine release syndrome (CRS), neurologic toxicity, infection-related events, hematologic toxicity, hospitalization, and death.

Disproportionality was assessed using reporting odds ratios (RORs) with 95% confidence intervals (CIs).

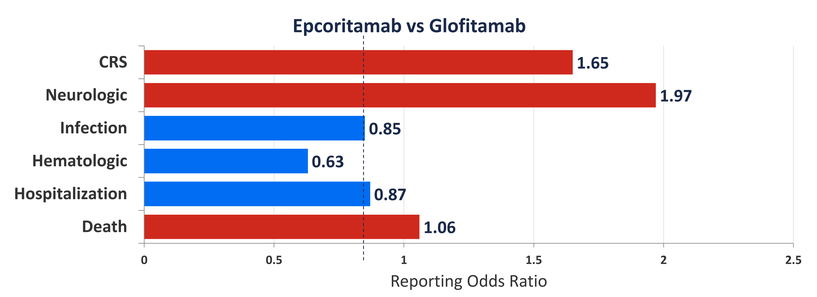
Drug	Reports	CRS	Neuro	Infxn	Heme	Hosp	Death
Mosun.	557	127 (22.8%)	12 (2.2%)	123 (22.1%)	24 (4.3%)	374 (67.1%)	70 (12.6%)
Epcor.	1,893	714 (37.7%)	198 (10.5%)	258 (13.6%)	100 (5.3%)	519 (27.4%)	728 (38.5%)
Glofit.	802	215 (26.8%)	45 (5.6%)	125 (15.6%)	65 (8.1%)	243 (30.3%)	298 (37.2%)

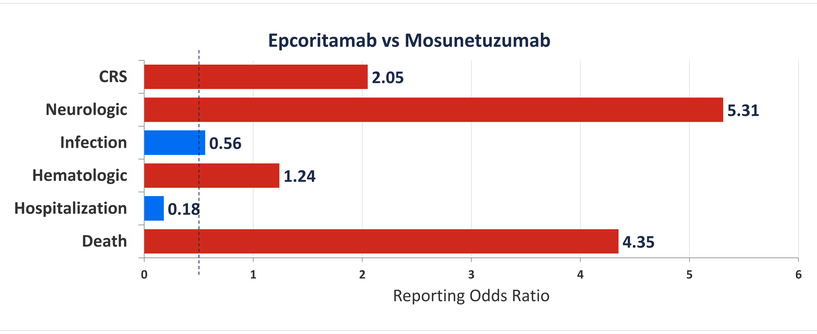
Abbreviations: CRS, cytokine release syndrome; Neuro, neurologic toxicity; Infxn, infection-related events; Heme, hematologic toxicity; Hosp, hospitalization. Mosun, Mosunetuzumab; Epcor, Epcoritamab; Glofit, Glofitamab; Data source: FAERS, Jan 1, 2023–Dec 31, 2025.

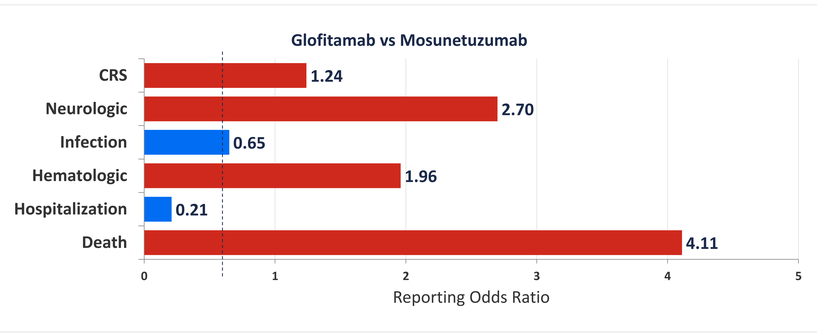
TABLE 1. PRIMARY OUTCOME COUNTS BY DRUG

RESULTS

MOSUNETUZUMAB SAFETY SIGNAL — reporting of death was over 4-fold higher for epcoritamab (ROR 4.35, 95% CI 3.33–5.68) and glofitamab (ROR 4.11, 95% CI 3.08–5.49) relative to mosunetuzumab, which showed the lowest mortality reporting of the three agents.







FAERS data are reporting signals, not incidence or causality

CONCLUSIONS

Distinct adverse event reporting patterns were observed among CD20-directed bispecific antibodies. Epcoritamab was associated with higher reporting of CRS and neurologic toxicity, while glofitamab showed increased hematologic toxicity. Mosunetuzumab demonstrated higher reporting of hospitalization and infection-related events but lower mortality reporting. These findings likely reflect differences in patient populations, disease characteristics, different dosing strategies and should be interpreted as hypothesis-generating. Further comparative studies in controlled settings are warranted.

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