SEVERE OPPORTUNISTIC INFECTION SIGNALS ASSOCIATED WITH BCMA- AND GPRC5D-DIRECTED BISPECIFIC ANTIBODIES IN MULTIPLE MYELOMA: A FAERS PHARMACOVIGILANCE ANALYSIS

A. Den Boef, Z. Rahman, B. Clark, O Elmanaseer
1. University of Florida, Jacksonville, Florida

INTRODUCTION

Bispecific antibodies targeting B-cell maturation antigen (BCMA) and GPRC5D have transformed the treatment of relapsed/refractory multiple myeloma. However, T-cell redirection, hypogammaglobulinemia, cytopenias, and cumulative immune dysfunction may predispose patients to serious and opportunistic infections. As the use of these therapies expands, the spectrum and relative burden of opportunistic infections across individual bispecific antibodies remain incompletely characterized. Postmarketing pharmacovigilance provides an opportunity to identify emerging infectious safety signals not fully captured in clinical trials.

AIM

To characterize and compare opportunistic infection reporting patterns associated with **elranatamab, teclistamab, and talquetamab** using the FDA Adverse Event Reporting System (FAERS), with particular attention to clinically important bacterial, viral, fungal, and opportunistic infections.

METHOD

We performed a retrospective pharmacovigilance analysis of FAERS reports involving **elranatamab, teclistamab, and talquetamab**. Drug exposures were identified using standardized generic and product-name mappings, and infection-related adverse events were classified using reported preferred terms.
Infections were grouped into clinically relevant categories including **bacterial infection/sepsis, respiratory viral infection, cytomegalovirus (CMV), HSV/VZV, fungal infection, Pneumocystis jirovecii pneumonia (PJP), and other opportunistic infections**. Duplicate reports were addressed at the case level, and infection reporting proportions were calculated as the proportion of exposed FAERS cases containing an infection event. Infection patterns and individual preferred terms were compared descriptively across agents.
Because FAERS is a spontaneous reporting system, these measures represent **reporting patterns rather than incidence or relative risk**.

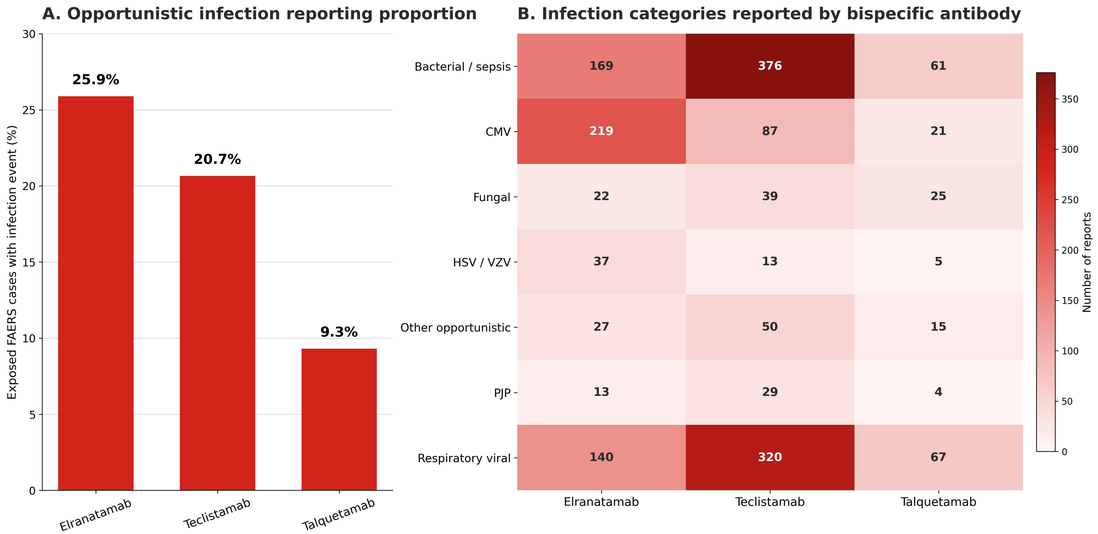
CONCLUSIONS

Opportunistic infections represented a substantial component of postmarketing adverse-event reports involving multiple myeloma bispecific antibodies, with marked differences in reporting patterns across agents. **Elranatamab had the highest overall infection reporting proportion (25.9%), followed by teclistamab (20.7%) and talquetamab (9.3%).**
Bacterial/sepsis and respiratory viral infections accounted for a substantial number of reports, while **CMV emerged as a particularly notable opportunistic infection signal**. These findings highlight the importance of infection surveillance in patients receiving T-cell–redirecting therapies and support further prospective investigation of **risk-adapted antimicrobial prophylaxis, immunoglobulin replacement, and viral monitoring strategies**.

RESULTS

Opportunistic infections were reported across all three bispecific antibodies, with substantial variation in reporting burden by agent.
Elranatamab demonstrated the highest infection reporting proportion (25.9%), followed by teclistamab (20.7%) and talquetamab (9.3%).
Across infection categories, **bacterial infection/sepsis and respiratory viral infections** accounted for the largest number of reports.
Bacterial/sepsis events were most frequently reported with teclistamab (**n=376**), followed by elranatamab (**n=169**) and talquetamab (**n=61**); respiratory viral infections showed a similar pattern (**n=320, 140, and 67**, respectively).
CMV represented a prominent opportunistic infection signal, with **219 reports for elranatamab, 87 for teclistamab, and 21 for talquetamab**. Fungal infections, HSV/VZV, and Pneumocystis jirovecii pneumonia were less frequently reported but occurred across all three agents.
Overall, the FAERS data demonstrated **distinct infection-reporting patterns among individual bispecific antibodies**, with a greater overall opportunistic infection reporting proportion observed for the BCMA-directed agents elranatamab and teclistamab compared with GPRC5D-directed talquetamab.

RESULTS | OPPORTUNISTIC INFECTIONS



KEY FINDING **Elranatamab had the highest opportunistic-infection reporting proportion (25.9%), followed by teclistamab (20.7%) and talquetamab (9.3%).**
FAERS reporting proportions are not incidence estimates.

CONTACT INFORMATION

Alexander den Boef, DO PGY-3 – alexander.denboef@jax.ufl.edu

REFERENCES

- Raje N, Anderson K, Einsele H, et al. Monitoring, prophylaxis, and treatment of infections in patients with multiple myeloma receiving bispecific antibody therapy: consensus recommendations from an expert panel. *Blood Cancer J.* 2023;13(1):116. doi:10.1038/s41408-023-00879-7.
- Mohan M, Chakraborty R, Bal S, et al. Recommendations on prevention of infections during chimeric antigen receptor T-cell and bispecific antibody therapy in multiple myeloma. *Br J Haematol.* 2023.
- Ludwig H, Terpos E, van de Donk NWCJ, et al. Prevention and management of adverse events during treatment with bispecific antibodies and CAR T cells in multiple myeloma: a consensus report of the European Myeloma Network. *Lancet Oncol.* 2023;24(6):e255-e269. doi:10.1016/S1470-2045(23)00159-6.
- U.S. Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) Database. Accessed 2026.
- Teh BW, Reynolds G, Slavin MA, et al. Executive summary of consensus clinical practice guidelines for the prevention of infection in patients with multiple myeloma. *Intern Med J.* 2023;53(8):1469-1477. doi:10.1111/imj.16100.