

Supporting Information

Supplementary Tables

Table S1. Complete Disproportionality Analysis Results for All Adverse Events Associated with Mirvetuximab Soravtansine (FAERS 2022Q4–2025Q4). Complete results of multi-algorithm disproportionality analysis for all 174 unique MedDRA Preferred Terms identified in MIRV-associated reports. Columns include: Reporting Odds Ratio (ROR) with 95% CI and signal status; Proportional Reporting Ratio (PRR) with chi-square statistic and signal status; Information Component (IC) with IC025 and signal status; Empirical Bayesian Geometric Mean (EBGM) with EBGM05 and signal status; number of MIRV reports (N); total FAERS reports; number of positive signal algorithms (0–4); and overall signal strength classification. Signal strength: Strong = all 4 algorithms positive; Moderate = 2–3 algorithms positive; Weak = 1 algorithm positive.

Table S2. Age Subgroup Analysis: Comparison of Adverse Event Reporting Rates Between Patients <65 Years and ≥65 Years. Comparison of reporting rates for 12 key adverse events between younger (<65 years) and older (≥65 years) patients. Data are presented as n (%) within each age group. Odds ratios (OR) with 95% confidence intervals and P values (Fisher's exact test) are shown. Statistically significant differences ($P < 0.05$) are highlighted.

Table S3. Geographic Region Subgroup Analysis: Comparison of Adverse Event Reporting Rates Between US and Non-US Reports. Comparison of reporting rates for 12 key adverse events between US-based and non-US reports. Data are presented as n (%) within each geographic group. Odds ratios (OR) with 95% confidence intervals and P values (Fisher's exact test) are shown.

Table S4. Reporter Type Subgroup Analysis: Comparison of Adverse Event Reporting Rates Between Healthcare Professionals and Consumers. Comparison of reporting rates for 12 key adverse events between healthcare professional (HCP) and consumer reporters. Data are presented as n (%) within

each reporter type group. Odds ratios (OR) with 95% confidence intervals and P values (Fisher's exact test) are shown.

Table S5. Time Trend Analysis: Comparison of Adverse Event Reporting Rates Between Early ($\leq 2023Q2$) and Late ($>2023Q2$) Reporting Periods. Comparison of reporting rates for 12 key adverse events between the early post-approval period ($\leq 2023Q2$) and the later period ($>2023Q2$). Data are presented as n (%) within each time period. Odds ratios (OR) with 95% confidence intervals and P values (Fisher's exact test) are shown.

Table S6. Time-to-Onset Analysis for Key Adverse Events Associated with Mirvetuximab Soravtansine. Summary statistics for time-to-onset (days from MIRV initiation to adverse event occurrence) for 9 key adverse events with available date information (N = 174 reports with calculable time-to-onset). Data include: number of reports with date information (N), median time-to-onset, interquartile range (IQR), overall range, and onset category classification (Early: <7 days; Intermediate: 7–30 days; Late: ≥ 30 days).

Table S7. Severity Analysis: Distribution of Serious Outcomes by Adverse Event Type. Distribution of serious outcome categories for 16 key adverse events with ≥ 6 reports. Serious outcomes are classified according to FAERS outcome codes: death, life-threatening, hospitalization, and other serious outcomes. Serious-outcome categories may overlap, as a single report can include multiple outcomes. Data are presented as n (%) of reports within each adverse event category.

Table S8. Sensitivity Analysis: Signal Detection Results Across Conservative, Standard, and Liberal Threshold Criteria. Comparison of total signal counts and key adverse event signal counts across three threshold levels. Conservative thresholds: ROR lower CI ≥ 2.0 , IC025 ≥ 0.5 , EBGM05 ≥ 2.0 , PRR ≥ 2.0 . Standard thresholds: ROR lower CI ≥ 1.5 , IC025 ≥ 0.0 , EBGM05 ≥ 1.5 , PRR ≥ 1.5 . Liberal thresholds: ROR lower CI ≥ 1.0 , IC025 ≥ -0.5 , EBGM05 ≥ 1.0 , PRR ≥ 1.0 .

Supplementary Figures

Figure S1. Time-to-Onset Distribution by Adverse Event Type. Box plots showing the distribution of time-to-onset (days) for 9 key adverse events with available date information. Box color indicates onset category: red = Early (<7 days), yellow = Intermediate (7–30 days), green = Late (≥ 30 days). Boxes represent the interquartile range (IQR); horizontal lines within boxes indicate the median; whiskers extend to $1.5 \times$ IQR; circles represent outliers. N values for each adverse event are provided in Supplementary Table S6.

Figure S2. Severity Distribution by Adverse Event Type for Mirvetuximab Soravtansine (FAERS 2022Q4–2025Q4). Stacked horizontal bar chart showing the proportion of serious outcome categories for 10 key adverse events. Colors represent outcome severity: red = death, orange = life-threatening, yellow = hospitalization, green = other serious outcomes. Percentages are calculated as the proportion of reports within each adverse event category meeting each serious outcome criterion. Detailed data are provided in Supplementary Table S7. FAERS: FDA Adverse Event Reporting System.