A Real-World Disproportionality Analysis of the Food and Drug Administration Adverse Event Reporting System (FAERS) Events for Asciminib

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Introduction

Asciminib is the first Specifically Targeting ABL Myristoyl Pocket (STAMP) inhibitor, approved in November 2021 for chronic-phase CML after ≥ 2 tyrosine-kinase inhibitors (TKIs) and expanded in October 2023 to newly diagnosed CML-CP. Its allosteric binding site distinguishes it from ATP-competitive TKIs and may confer a distinct safety profile.

Aim

To characterize early real-world toxicities, we analyzed all asciminib-related reports in the FDA Adverse Event Reporting System (FAERS)

Methods

Data Source: Adverse event (AE) data were extracted from the FDA Adverse Event Reporting System (FAERS) from 2021 Q4 through 2025 Q1

Case Selection: All reports listing Asciminib or scemblix as the primary suspect drug were included. Duplicate case IDs were collapsed to retain unique patient-level entries.

Coding and Classification:
AEs were mapped to MedDRA v28 System Organ Class (SOC) and Preferred Term (PT) codes.

Disproportionality Analysis:
Four standard algorithms were applied using Python 3.9: Proportional Reporting Ratio (PRR), Reporting Odds Ratio (ROR), Information Component (IC025), Empirical Bayes Geometric Mean (EBGM05)

Signal criteria: PRR ≥ 2, ROR 95% CI lower > 1, IC025 > 0, or EBGM05 > 2.

Clinical Review:
Excluded terms reflecting procedural codes, or normal laboratory values. Final signals were reviewed for clinical plausibility.

Results

- **1,569 non-duplicate reports** (median age 63 y; 53% women; 56% U.S.).
- **Median onset:** 28 days; **61% serious**, including **210 deaths**.
- **76 PTs** (of 133) exceeded EBGM05 > 2 across **16 SOCs**.

- **Top 5 signals:** lipase increased (EBGM05 41.8), thrombocytopenia (6.6), pericardial effusion (8.2), peripheral arterial occlusive disease (5.9), myocardial infarction (2.0). **Hypertension** met PRR/ROR but not EBGM05.

- 90% of system organ class signals corroborated with preferred terms across algorithms by using all disproportionality analysis

Summary

Using real-world FAERS disproportionate analysis, it identifies pancreatic, arterial signals and highlight pericardial effusion as a potential asciminib-specific toxicity. Routine monitoring of pancreatic enzymes and cardiovascular risk factors is advisable, and further prospective studies are warranted to quantify incidence as frontline use expands