Real-world evidence on eflapegrastim: global demographics and clinical outcomes in general oncology practice

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*Employed by Assertio Holdings, Inc. at the time of this study.

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INTRODUCTION

- Chemotherapy-induced neutropenia and febrile neutropenia (FN) are clinically significant complications associated with myelosuppressive chemotherapy regimens that can lead to hospitalization, treatment delays, and chemotherapy dose modifications, which may negatively impact treatment outcomes[1-3]
- Granulocyte colony-stimulating factors (G-CSFs) are a conventional intervention used to prevent chemotherapy-induced neutropenia, particularly in patients receiving myelosuppressive regimens[4,5]
- Eflapegrastim and pegfilgrastim are long-acting G-CSFs that provide sustained neutrophil production during chemotherapy[3-5]
  - Eflapegrastim (FDA-approved in 2022) is a novel long-acting G-CSF engineered with Fc fragment conjugation to extend half-life, enabling once-per-cycle fixed-dose administration approximately 24 hours after chemotherapy[3,6]
  - Clinical evidence for eflapegrastim is primarily derived from phase 3 trials in patients with breast cancer receiving docetaxel and cyclophosphamide (TC)[3,7]
- In clinical practice, G-CSFs are used across diverse tumor types and chemotherapy regimens beyond 21-day breast cancer TC therapy[4]; however, real-world data on eflapegrastim use in non-breast cancer populations remain limited, highlighting the need to better characterize outcomes across heterogeneous oncology populations

OBJECTIVE

- To evaluate demographics, comorbidities, and clinical outcomes in patients receiving eflapegrastim or pegfilgrastim outside of 21-day breast cancer TC therapy

METHODS

- This retrospective, cross-sectional cohort analysis extracted data from the electronic health records of > 60 million US patients in the Atropos Health Apollo data source (version 1.1.0) from 2023 to 2025
- Patients with non-breast cancer diagnoses (eg, gastrointestinal [GI], lung, pancreatic, prostate, non-Hodgkin lymphoma [NHL]) who received ≥ 1 dose of eflapegrastim or pegfilgrastim during chemotherapy were included
- Data extracted included demographics, comorbidities, cancer types, chemotherapy regimens, FN (defined as the co-occurrence of fever and neutropenia), absolute neutrophil count (ANC), and adverse events (AEs)
- Clinical outcomes were assessed at Days 15 and 30 following G-CSF administration

RESULTS

- 14,964 patients with non-breast cancer diagnoses who received long-acting G-CSFs were evaluated (**Table 1**):
  - Eflapegrastim: 440 patients (56% female)
  - Pegfilgrastim: 14,524 patients (60% female)
- Patients receiving eflapegrastim were older and had a higher comorbidity burden compared with those receiving pegfilgrastim (**Table 1**):
  - Mean (standard deviation [SD]) age: 71 (10) years versus 62 (16) years
  - Mean (SD) Charlson Comorbidity Index score: 11 (4) versus 9 (5)

Table 1. Demographics and baseline characteristics

Characteristic	Eflapegrastim (n = 440)	Pegfilgrastim (n = 14,524)
Female, n (%)	244 (55.5)	8751 (60.3)
Age, years, mean (SD)	71.2 (9.8)	61.8 (16.0)
Age category, years, n (%)		
< 18	0	342 (2.4)
18–29	2 (0.5)	342 (2.4)
30–39	5 (1.1)	758 (5.2)
40–49	15 (3.4)	1502 (10.3)
50–59	25 (5.7)	2385 (16.4)
60–69	123 (28.0)	4127 (28.4)
70–79	202 (45.9)	3870 (26.6)
80–89	68 (15.5)	1198 (8.2)
Race, n (%)		
White	347 (78.9)	9650 (66.4)
Other	82 (18.6)	2954 (20.3)
Black	8 (1.8)	1348 (9.3)
Asian	3 (0.7)	572 (3.9)
Ethnicity, n (%)		
Hispanic	5 (1.1)	614 (4.2)
Charlson Comorbidity Index score, mean (SD)	11.4 (4.4)	9.0 (4.6)

n, number; SD, standard deviation.

- The most common non-breast cancers (> 5% in both treatment groups) are shown in **Table 2**:
  - Eflapegrastim: GI (25%), NHL (19%), lung (15%), prostate (10%), pancreatic (9%), and colon (7%)
  - Pegfilgrastim: GI (23%), NHL (16%), lung (11%), prostate (5%), pancreatic (8%), and colon (6%)
- Chemotherapy regimens in each treatment group included (**Table 2**):
  - Eflapegrastim: Anthracyclines (16%), FOLFOX (12%), and FOLFIRI (8%)
  - Pegfilgrastim: Anthracyclines (22%), FOLFOX (8%), and FOLFIRI (5%)

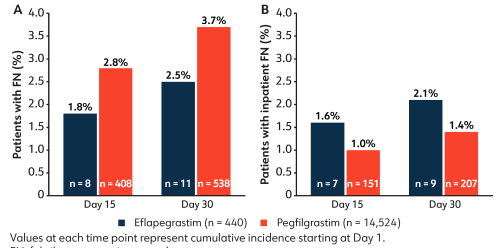
Table 2. Non-breast cancer types and chemotherapy regimens

	Eflapegrastim (n = 440)	Pegfilgrastim (n = 14,524)
Cancer type, n (%)		
GI	109 (24.8)	3314 (22.8)
NHL	83 (18.9)	2351 (16.2)
Lung	66 (15.0)	1667 (11.5)
Prostate	42 (9.5)	729 (5.0)
Pancreatic	39 (8.9)	1207 (8.3)
Colon	29 (6.6)	934 (6.4)
Ovarian	23 (5.2)	545 (3.8)
Multiple myeloma	13 (3.0)	208 (1.4)
Bladder	11 (2.5)	405 (2.8)
Rectosigmoid	11 (2.5)	614 (4.2)
Liver/intrahepatic	11 (2.5)	360 (2.5)
Esophagus	11 (2.5)	244 (1.7)
Gastric	9 (2.0)	334 (2.3)
Bone	6 (1.4)	283 (1.9)
Soft tissue	6 (1.4)	528 (3.6)
Biliary tract	4 (0.9)	127 (0.9)
Hodgkin lymphoma	4 (0.9)	398 (2.7)
Head/neck	4 (0.9)	116 (0.8)
Melanoma	4 (0.9)	65 (0.4)
Anus/anal	3 (0.7)	61 (0.4)
Small intestine	3 (0.7)	80 (0.6)
Myeloid leukemia	2 (0.5)	151 (1.0)
Gall bladder	1 (0.2)	47 (0.3)
Lymphoid leukemia	0	142 (1.0)
Chemotherapy regimen, n (%)		
Anthracyclines	72 (16.4)	3259 (22.4)
FOLFOX	51 (11.6)	1120 (7.7)
FOLFIRI	37 (8.4)	691 (4.8)

FOLFIRI, folinic acid (leucovorin), fluorouracil, and irinotecan; FOLFOX, folinic acid (leucovorin), fluorouracil, and oxaliplatin; GI, gastrointestinal; n, number; NHL, non-Hodgkin lymphoma.

- Overall FN incidence was low for both eflapegrastim and pegfilgrastim, with numerically higher rates in the pegfilgrastim group at both time points (**Figure 1A**):
  - Day 15: 1.8% vs 2.8%
  - Day 30: 2.5% vs 3.7%
- Inpatient visit FN incidence was also low between the eflapegrastim and pegfilgrastim groups, with no meaningful differences (**Figure 1B**):
  - Day 15: 1.6% vs 1.0%
  - Day 30: 2.1% vs 1.4%

Figure 1. (A) Overall FN incidence and (B) inpatient FN incidence



Values at each time point represent cumulative incidence starting at Day 1.
FN, febrile neutropenia; n, number.

- ANC values were higher with eflapegrastim compared with pegfilgrastim at Days 15 and 30, while platelet counts were lower (**Table 3**)

Table 3. ANC and platelet counts

	Eflapegrastim (n = 440)	Pegfilgrastim (n =14,524)
ANC (×10⁹/L), mean (SD)		
Day 15	10.0 (8.7)	5.9 (5.2)
Day 30	10.5 (8.7)	5.9 (5.1)
Platelets (×10⁹/L), mean (SD)		
Day 15	104 (89)	239 (120)
Day 30	129 (100)	244 (129)

Values at each time point represent cumulative incidence starting at Day 1.
ANC, absolute neutrophil count; L, liter; n, number; SD, standard deviation.

- AEs were similar between groups; thrombocytopenia occurred more frequently with eflapegrastim than with pegfilgrastim (**Table 4**)

Table 4. Occurrence of All-Grade AEs

	Eflapegrastim (n = 440)		Pegfilgrastim (n = 14,524)	
AE, n (%)	**Day 15**	**Day 30**	**Day 15**	**Day 30**
Thrombocytopenia	44 (10.0)	65 (14.8)	952 (6.6)	1287 (8.9)
Back pain	12 (2.7)	19 (4.3)	417 (2.9)	629 (4.3)
Bone pain	10 (2.3)	18 (4.1)	221 (1.5)	343 (2.4)
GI bleed	6 (1.4)	8 (1.8)	203 (1.4)	290 (2.0)
Myalgia	5 (1.1)	5 (1.1)	83 (0.6)	136 (0.9)
Non-traumatic head bleed	1 (0.2)	1 (0.2)	20 (0.1)	35 (0.2)
Localized skin reaction	0	1 (0.2)	17 (0.1)	32 (0.2)
Acute respiratory distress syndrome	0	0	2 (0.01)	8 (0.1)

Values at each time point represent cumulative incidence of all-grade AEs starting at Day 1.
AE, adverse event; GI, gastrointestinal; n, number.

CONCLUSIONS

- In this real-world analysis of patients with non-breast cancers, eflapegrastim was more commonly used in older patients with a higher comorbidity burden compared with pegfilgrastim
- FN incidence at Days 15 and 30 (including cases documented during inpatient visits) was low in both the eflapegrastim and pegfilgrastim groups
  - **At both time points, ANC was higher and platelet counts were lower with eflapegrastim than with pegfilgrastim; however, bleeding events occurred at similar rates between groups despite the greater age of patients receiving eflapegrastim**
- Overall, AE rates were low in both groups; thrombocytopenia was more frequent with eflapegrastim, while other AEs, including bone or back pain, myalgia, and bleeding events, were infrequently reported
- These real-world findings support the safety and effectiveness profile of eflapegrastim in patients with non-breast cancers, including older populations with a higher comorbidity burden