PASS INFORMATION

Title	Granulocyte Colony-Stimulating Factor ("G-CSF"): Patient profiles, Scheduling Patterns and Clinical Outcomes
Version Identifier of the Final Study Report	20200230, Version 1.0
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EU PAS Register No:	EUPAS38906
Clinicaltrials.gov Identifier No:	Not applicable
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Medicinal Product	Neulasta® (pegfilgrastim)
Product Reference:	Not applicable
Procedure Number:	Not applicable
Marketing Authorization Holder	Amgen
Joint PASS	No
Research Question and Objectives	The aim of this study is to understand the patient profiles, scheduling patterns and clinical outcomes among patients with breast cancer, colorectal cancer, lung cancer, ovarian cancer, or NHL treated with pegfilgrastim in the US community setting.
Country of Study	United States
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1. ABSTRACT

- **Title**

Granulocyte Colony-Stimulating Factor ("G-CSF"): Patient profiles, Scheduling Patterns and Clinical Outcomes

- **Keywords**

Pegfilgrastim, on-body injector, prefilled syringe, administration patterns, resource utilization

- **Rationale and Background**

Treatment injections with long-acting (pegylated) G-CSFs (pegfilgrastim) at least 24 hours after administration of cytotoxic chemotherapy has been shown to be safe and effective in decreasing the incidence of chemotherapy-induced febrile neutropenia (FN). However, limited data is available on the treatment scheduling and clinical outcomes with traditional G-CSF treatment by pre-filled syringe (PFS) and with use of the Onpro on-body injector (OBI) in the real-world community setting. Approximately 27 hours after the OBI is applied to the patient's skin, pegfilgrastim will be delivered, which can reduce the travel burden on the patient by not having the patient return to the clinic on the day after chemotherapy in order to receive pegfilgrastim by PFS.

- **Research Question and Objectives**

This study was designed to describe real-world patient profiles, treatment patterns and clinical outcomes with use of the different G-CSF products in US Oncology Network (USON) clinics.

- **Study Design**

This was a retrospective cohort study adult patients with a diagnosis of breast cancer, colorectal cancer, NHL, NSCLC, or ovarian cancer, treated with pegfilgrastim within US Oncology Network (USON) clinics during January 1, 2018 and October 31, 2019, with follow-up until December 31, 2019.

- **Setting**

The USON includes 1,400 affiliated physicians operating in over 400 sites of care across the United States, representing approximately 12% of newly diagnosed US cancer patients.

- **Subjects and Study Size, Including Dropouts**

11,965 patients met study eligibility criteria. Chart review population consisted of 479 eligible patients.

- **Data Sources and Methods**

Study data were extracted from USON's iKM electronic healthcare record (EHR) and the Social Security Death Index. Descriptive analyses were performed in 2 phases:

Phase 1 (structured data analysis): Structured data fields within the EHR were sufficient to provide the information needed to address most research questions.

Phase 2 (chart review): To supplement the structured data analysis, a targeted chart review of up to 500 patients was performed to capture additional information recorded in the chart, such as that noted in free-text fields.

For the cycle level analysis, each cycle which included pegfilgrastim (either by PFS or OBI) was classified into one of three timing categories, depending on the day that pegfilgrastim was delivered:

1. Recommended. Any cycle which pegfilgrastim was delivered on Day 1 (the day after chemotherapy) according to the recommended schedule; or
2. Non-recommended. Any cycle which pegfilgrastim was delivered outside of the recommended schedule, but before Day 6; or
3. Day 6+. Any cycle which pegfilgrastim was delivered outside of the recommended schedule, between Day 6 to end of cycle.

- **Results**

Phase 1 (structured data analysis): The mean age of patients (n=11,965) was 59.5 (SD 12.9) years. Majority of the patients were Caucasian (68%), female (79%), and had ECOG score of 0-1 (67%). The majority of patients had a breast cancer diagnosis (57%), followed by NHL (20%), colorectal (10%), NSCLC (8%), and ovarian cancer (6%). During the first 6 chemotherapy cycles prescribed with pegfilgrastim as prophylaxis: PFS cycles totaled 10,135, the timing of which were: 4,148 (41%) recommended cycles, 5,597 (55%) non-recommended cycles, and 390 (4%) day 6+ cycles; OBI cycles totaled 34,196, the timing of which were: 32,329 (95%) recommended cycles, 1,746 (5%) non-recommended cycles, and 121 (0.4%) day 6+ cycles.

Phase 2 (chart review): The mean age of patients (n=479) was 60 (SD 13) years. Majority of the patients were Caucasian (67%), female (77%), and had ECOG score of 0-1 (62%). The majority of patients had a breast cancer diagnosis (51%), followed by NHL (19%), colorectal (18%), NSCLC (10%), and ovarian cancer (4%). Febrile neutropenia was documented in a small percentage of patients (15/479, 3%), with a decreasing trend seen from cycles 1 to 6. Chemotherapy cycle delay was documented in <5% of patients per cycle.

- **Discussion**

This study represents pegfilgrastim use in a real-world setting in the US. Regarding day of administration, a higher proportion of PFS cycles were either non-recommeded or day 6+ vs. OBI cycles. By both increasing optimal cycles and reducing missed cycles of pegfilgrastim compared to PFS, OBI can potentially reduce the risk of FN among appropriate chemotherapy patients.

- **Marketing Authorization Holder**

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- **Names and Affiliations of Principal Investigators**

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