A Prospective Observational Study to Estimate the Incidence of Febrile Neutropenia (FN) among Subjects with Non-myeloid Malignancies at High Risk for FN and receiving Neulasta® (pegfilgrastim) Onpro® kit or Other Physician Choice Options for Prophylaxis of FN (20170758)

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Study Finalised

Administrative details

EU PAS number

EUPAS24626

Study ID

44447

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 150 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/01/2018

Actual: 03/01/2018

Study start date

Planned: 14/11/2018

Actual: 07/11/2018

Data analysis start date

Planned: 03/10/2020

Actual: 01/12/2020

Date of final study report

Planned: 04/06/2021

Actual: 25/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS24626-25197.pdf(1.64 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To estimate the incidence of FN among subjects treated with myelosuppressive chemotherapy for the treatment of non myeloid malignancies and receiving Neulasta Onpro kit, Neulasta Onpro kit with every administered chemotherapy cycle, or other physician choice options for FN prophylaxis

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Neulasta Onpro kit

Medical condition to be studied

Febrile neutropenia

Population studied

Short description of the study population

The study population will consist of subjects diagnosed with biopsy-proven confirmed breast cancer, lung cancer, NHL, or prostate cancer, who are receiving myelosuppressive chemotherapy and are at “high risk” for FN. Subjects at “high risk” for FN will be defined as subjects receiving high risk chemotherapy regimens with FN risk > 20%, or intermediate risk chemotherapy regimen with FN risk between 10% to 20% and 1 additional risk factor for FN.

Inclusion Criteria

1. Subject ≥ 18 years of age at the time of signing the informed consent form.
2. Subject with biopsy-proven breast cancer, lung cancer, NHL or prostate cancer starting myelosuppressive chemotherapy in the neoadjuvant/adjuvant or first line advanced/metastatic setting with at least 4 anticipated chemotherapy cycles.
3. Life expectancy > 6 months
4. Subject is starting or has recently (within the past 7 days) started myelosuppressive chemotherapy regimen with every 3 or 4-week cycle with a high FN risk > 20%, OR intermediate FN risk 10% to 20% risk (refer to Appendix E [only regimens listed within this appendix are allowed for enrollment]) and at least 1 risk factor for FN per Appendix F. Addition of non-cytotoxic targeted agents (eg, monoclonal antibodies, anti-angiogenic agents, and kinase inhibitors) to the listed chemotherapy regimens is permitted.
5. Subject who is starting adjuvant chemotherapy, neoadjuvant chemotherapy or first line chemotherapy in the metastatic setting and will be receiving at least 4 cycles of planned chemotherapy

Exclusion Criteria

1. Subject initiating chemotherapy regimen with < 14 days between cytotoxic and G-CSF drug dosing.
2. Planned chemotherapy dose reduction for cycle 1.
3. Known history of serious allergic reactions to pegfilgrastim or filgrastim.

4. Contraindication to short acting G-CSFs, Neulasta PFS, pegfilgrastim biosimilar PFS, or Neulasta Onpro kit.
5. Currently receiving treatment in another investigational device or drug study, or ≤ 28 days before screening/enrollment since ending treatment on another investigational device or drug study(ies).
6. Subject who started first line chemotherapy for metastatic disease who completed adjuvant/neoadjuvant chemotherapy < 6 months prior to study enrollment.
7. Subject who has received radiation < 2 weeks prior to study enrollment.
8. Any co-morbidity (refer to Appendix H) in the opinion of investigator will prevent the subject from receiving chemotherapy.
9. Subject has significant abnormalities on the most recent laboratory test prior to screening/enrollment per the Investigator including but not limited to the following: • white blood cell (WBC) < 4, ANC < lower limit of normal (LLN), hemoglobin < 10 g/dL, hematocrit < 30%, platelet count < 100,000, creatinine ≥ 1.5 or glomerular filtration rate < 30 (as calculated by Cockcroft-Gault Equation), total Bilirubin ≥ 2.0, aspartate aminotransferase/alanine aminotransferase (AST/ALT) ≥ 3 x upper limit of normal (ULN), and a subject without liver metastasis or AST/ALT ≥ 5 ULN in a subject with liver metastasis
10. Known human immunodeficiency virus (HIV) infection by history.
11. History of solid organ or stem cell transplant.
12. Concurrent primary cancers except non-melanoma skin cancer, or adequately treated carcinoma in situ (CIS)

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Febrile neutropenia patients

Estimated number of subjects

5440

Study design details

Data analysis plan

Estimation Analysis, Confidence Intervals

Documents

Study results

20170758_ORSR_Abstract.pdf(262.81 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025.
The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No