From:	Paula O"Connor
To:	Submissions
Cc:	O"Connor, Paula; Gregory, Kris
Subject:	Submission request for Myeloid Growth Factor Guideline inclusion
Date:	Tuesday, February 12, 2019 12:24:54 AM
Attachments:	Randomized, Single-Blind, Crossover Study to Assess the Pharmacokinetic and Pharmacodynamic Bioequivalence of CHS-1701 to Pegfilgrastim in Healthy Subjects (Abstract # 187286).pdf Proposed Pegfigrastim Biosimilar CHS-1701 Demonstrates PK-PD Similarity to Pegfilgrastim in Rat Neutropenia Model and Healthy Subjects EHA Abstract -2775 (002).pptx Coherus Biosciences UDENYCA™ Clinical Overview.pdf UDENYCA™-EPAR_Public-Assessment-Report.pdf UDENYCA Package Insert.pdf

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Submitted by: Paula O'Connor, MD
Company/Organization: Coherus BioSciences
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Date of Request: 2/11/19
NCCN Guidelines Panel: Myeloid Growth Factors

Re: UDENYCA™ (pegfilgrastim-cbqv)

Coherus BioSciences, respectfully requests the review of the attached data for UDENYCA™, a pegfilgrastim biosimilar, for inclusion as a recommended option in the NCCN Guidelines for Myeloid Growth Factors.

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) approved Marketing Authorization and 351(k) Biologics License Applications for UDENYCA™ in September and November 2018, respectively. UDENYCA was approved as a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

The UDENYCA™ development program demonstrated UDENYCA™ to be highly similar to Neulasta in regard to molecular structure, biological function, drug purity and stability; bioequivalent in regard to pharmacokinetics and pharmacodynamics; and similar, without clinically meaningful differences, in regard to safety and immunogenicity.

UDENYCA™ was developed to deliver high quality supportive care and expand patient access to pegfilgrastim while helping to control healthcare costs. Inclusion in the NCCN Guidelines for Myeloid Growth factors will enhance awareness of the available pegfilgrastim growth factors and their utility.

Listed below are published data for the UDENYCA™ development program. UDENYCA™ was previously known as CHS-1701:

- Randomized, Single-Blind, Crossover Study to Assess the Pharmacokinetic and Pharmacodynamic Bioequivalence of CHS-1701 to Pegfilgrastim in Healthy Subjects (Abstract # 187286)
- Proposed Pegfilgrastim Biosimilar CHS-1701 Demonstrates Pharmacokinetic and Pharmacodynamic Similarity to Marketed Pegfilgrastim in a Rat Neutropenia Model and in Healthy Subjects (Abstract # EHA-2775)

European Public Assessment Report (EPAR) for UDENYCA™

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Abstract #187286 was presented at the American Society of Clinical Oncology (ASCO) meeting in June 2017. Abstract # EHA-2775 was presented at the European Hematology Association meeting in June 2017. The European Public Assessment Report (EPAR) is the public scientific assessment report of medicines authorized by the EMA. It was published on the EMA website following authorization approval.

In addition to the materials listed above, a UDENYCA™ Clinical Overview, produced by Coherus, in response to medical information requests about the UDENYCA Development Program, is provided. It gives a more detailed view of UDENYCA's Clinical Development Program.

The Summary Basis of Approval for UDENYCA™ is not included with this application for NCCN Guideline inclusion, as it has not yet been published on the FDA website; and a timeline for publication is not available.

If you have any questions regarding this application or the data provided in support of this application, please do not hesitate to contact me at the address below.

Sincerely,

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