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NCCN Guidelines Panel: Supportive Care

On behalf of Amgen, Inc., I respectfully request the NCCN Supportive Care Guideline Panel to review the enclosed data for inclusion of the Neulasta® (pegfilgrastim) Delivery Kit/On-body Injector for Neulasta (NDK/OBI) as an alternative delivery option for growth factor support in patients receiving myelosuppressive chemotherapy with a clinically significant risk of febrile neutropenia (FN). The OBI is designed to be applied to appropriate patients on the same day as chemotherapy, and complete subcutaneous delivery of pegfilgrastim approximately 27 hours after application, in accordance with current guidelines and its FDA-approved labeling (see attached). This allows patients another option to receive pegfilgrastim that may not require a visit to their healthcare provider on the following day.

Specific Changes: Recommend including a sub-bullet under “Pegfilgrastim (category 1) (For prophylactic use only)” on MGF-E slide 1 of 2 of the “Myeloid Growth Factors” section of the NCCN Guidelines. The sub-bullet would read: “Dosing forms of pegfilgrastim include both the pre-filled syringe for manual use and the Neulasta Delivery Kit, including the On-body Injector for Neulasta”.

Also, on current page MS-10 of the Myeloid Growth Factor Guidelines, under “Dosage and Administration”, subsection “Pegfilgrastim”, we’d ask that you include a paragraph detailing the pharmacokinetics study published by Yang *et al.* in *Cancer Chemother Pharmacol* 2015 Apr 17, as below:

“Yang et al. published data on the pharmacokinetics and safety of pegfilgrastim administered either by the On-body Injector for Neulasta or manual injection. These data demonstrated that the pharmacokinetics and safety were comparable between the two subcutaneous delivery methods.”

FDA Clearance: The Neulasta Delivery Kit, including the On-body Injector for Neulasta, received FDA approval as a supplemental biologic license application to Neulasta on December 23, 2014.

Rationale: Given the comparable pharmacokinetics and safety of pegfilgrastim delivery by this new delivery option, and the potential benefit to patients, we believe inclusion of the OBI as a pegfilgrastim delivery option in guidelines is warranted.

In support of the proposed change, we provide an article documenting the comparable safety and pharmacokinetic equivalence of pegfilgrastim delivery via the On-body Injector for Neulasta which was pivotal to FDA-approval of this delivery option. We have also included two publications and an abstract demonstrating the negative effects of administering Neulasta on the same day as chemotherapy administration, which could potentially be avoided by utilizing the On-body Injector for Neulasta.

Yang et al. Comparison of pharmacokinetic and safety of pegfilgrastim administered by two delivery methods: on-body injector and manual injection with a prefilled syringe. *Cancer Chemother Pharmacol* Epub 2015 Apr 17.

Cheng et al. Rates of febrile neutropenia with pegfilgrastim on same day versus next day of CHOP with or without rituximab. *Anticancer Drugs* 2014 Sep;25(8):964-9.

Burriss et al. Pegfilgrastim on the same day versus next day of chemotherapy in patients with breast cancer, non-small-cell lung cancer, ovarian cancer, and Non-Hodgkin's lymphoma: Results of four multicenter, double-blind, randomized phase II studies. *J Oncol Prac* 2010 May;6(3):133-40.

Weycker et al. Risk of febrile neutropenia (FN) in cancer patients (pts) receiving myelosuppressive chemotherapy and pegfilgrastim prophylaxis (PEG-P): does day of administration matter? Abstract, Accepted for ASCO 2015.

Most Sincerely,

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Amgen, Inc.