# HEM/ONC News

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## ASCO Updates Guidelines on Use of Hematopoietic Colony-Stimulating Factors

The prophylactic use of hematopoietic colony-stimulating factors (CSFs) continues to be warranted in oncology patients with a 20% or higher risk of febrile neutropenia, according to updated practice guidelines from the American Society of Clinical Oncology (ASCO).

The new guidelines, which were published online by the *Journal of Clinical Oncology* on July 13th with Dr Thomas Smith as the first author, contain several changes from the previous guidelines, published in 2006. For example, they include tbo-filgrastim (Granix, Teva), which was approved by the US Food and Drug Administration (FDA) in 2012, and the biosimilar filgrastim-sndz (Zarxio, Sandoz), which was approved in March 2015. They state that prophylactic CSFs should be "considered" (rather than "given," as in the 2006 version) for older patients with diffuse aggressive lymphoma. They also contain new recommendations against the routine use of dose-dense chemotherapy in lymphoma, and in favor of high–dose-intensity chemotherapy in urothelial cancer.

Although primary prophylaxis with a CSF is warranted for patients with a 20% or higher risk of febrile neutropenia (the risk is based on factors related to the patient, the disease, and treatment), the guidelines state that "consideration should be given to alternative, equally effective, and safe chemotherapy regimens not requiring CSF support when available."

Because all 4 agents—filgrastim (Neupogen, Amgen), tbo-filgrastim, filgrastim-sndz, and pegfilgrastim (Neulasta, Amgen)—are effective in reducing the risk of febrile neutropenia, the guidelines state that the choice of agent may depend on factors such as convenience and cost.

## Trial of Nivolumab vs Everolimus in Renal Cell Cancer Stopped Early

Bristol-Myers Squibb announced on July 20th that the phase 3 CheckMate-025 trial, which studied patients with previously treated advanced or metastatic clear-cell renal cell carcinoma, was stopped early after the study met its primary endpoint. The study demonstrated better overall survival in patients receiving nivolumab (Opdivo, Bristol-Myers Squibb) than in those receiving everolimus (Afinitor, Novartis).

For the open-label study, 821 patients were randomly assigned to receive either nivolumab (3 mg/kg intravenously every 2 weeks) or everolimus (10 mg by mouth daily) until documented disease progression or unacceptable toxicity occurred. The primary endpoint was overall survival, and the secondary endpoints included objective response rate and progression-free survival. Now that the trial has been halted, eligible participants will have the option of switching to or continuing on nivolumab.

Nivolumab, a programmed death 1 inhibitor, is approved for use in certain patients with metastatic squamous non–small cell lung cancer or unresectable or metastatic melanoma. Potential adverse effects include immune-mediated pneumonitis, colitis, hepatitis, nephritis, hypothyroidism, and hyperthyroidism.

## ASCO Releases Guidelines on Use of Biomarkers in Patients With Metastatic Breast Cancer

An ASCO Expert Panel has released recommendations on when to use biomarker assay results to guide the selection of systemic therapy in patients with metastatic breast cancer. The evidence-based recommendations, which were written by Dr Catherine Van Poznak and colleagues, were published online by the *Journal of Clinical Oncology* on July 20th.

Based on data from 17 studies, the panelists recommended that patients with newly diagnosed metastases from primary breast cancer be offered a biopsy to confirm the disease process and to test estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) status. If the biomarker test results differ between the primary and metastatic tissue, the panelists suggested using results from metastatic tissue.

The panelists cautioned that changes in therapy should not be based solely on results of biomarker studies apart from ER, PR, and HER2 status, or solely on results of circulating biomarker tests.

Finally, the panelists did not recommend that CEA, CA 15-3, and CA 27-29 alone be used to monitor response to treatment.

The authors cautioned that the research on predictive biomarkers in metastatic breast cancer is limited by the lack of prospective confirmatory studies, and recommended that the medical community "lobby for and conduct high-quality biomarker research for women with advanced breast cancer."