

Submitted by:

Jenny Nugent, PharmD, Scientist
Medical Communications, Medical Affairs
Genentech, Inc.
1 DNA Way, South San Francisco, CA 94080
Phone: (650) 467-5089
Email mc-mc-d@gene.com
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NCCN Guidelines Panel: Ovarian Cancer

On behalf of Genentech, I respectfully request the NCCN Ovarian Cancer Guideline Panel to review the enclosed data for the use of Avastin® (Bevacizumab) in the treatment of patients with previously untreated, advanced epithelial ovarian, primary peritoneal or fallopian tube cancer.

Specific Changes: Consider two recent publications of two pivotal, Phase III studies involving the study of Avastin in patients with previously untreated, advanced epithelial ovarian, primary peritoneal or fallopian tube cancer for your updating purposes. Both of these studies were previously presented at medical congresses, and the results are now available in full journal publications.

FDA Clearance: FDA has not been approved Avastin for the treatment of ovarian cancer. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale: Two pivotal studies, GOG-218 and ICON-7, were recently published in the New England Journal of Medicine. GOG-218 is a Phase III, international, multicenter, placebo-controlled, randomized, double-blind study and ICON7 is a Phase III, multicenter open-label Gynaecologic Cancer InterGroup (GCIG) trial.^{1,2} Both trials studied different regimens of Avastin in combination with carboplatin and paclitaxel compared to carboplatin and paclitaxel alone and included a maintenance regimen with Avastin.

The following enclosures are included for your review (copyright-paid where applicable):

- Burger RA, Brady MF, Bookman MA, et al. Incorporation of bevacizumab in the primary treatment of ovarian cancer. N Engl J Med 2011;365:2473-2483.
- Perren TJ, Swart AM, Pfisterer J, et al. A Phase 3 trial of bevacizumab in ovarian cancer. N Engl J Med 2011;365:2484-2496.
- Avastin Prescribing Information

Cited References

1. Burger RA, Brady MF, Bookman MA, et al. Incorporation of bevacizumab in the primary treatment of ovarian cancer. N Engl J Med 2011;365:2473-2483.
2. Perren TJ, Swart AM, Pfisterer J, et al. A Phase 3 trial of bevacizumab in ovarian cancer. N Engl J Med 2011;365:2484-2496.