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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 platinum-sensitive recurrent ovarian, primary peritoneal or fallopian tube cancer.

Specific Changes: Consider the recently presented data on Avastin in combination with carboplatin and gemcitabine in the treatment of platinum-sensitive recurrent ovarian, primary peritoneal or fallopian tube cancer for your updating purposes.

FDA Clearance: FDA has not 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: Results were recently presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois in June 2011. OCEANS is a Phase III, multicenter open-label trial comparing carboplatin and gemcitabine to carboplatin and gemcitabine in combination with Avastin followed by maintenance Avastin in patients with platinum-sensitive recurrent ovarian cancer.¹

Aghajanian et al. reported a statistically significant improvement in the primary endpoint, progression-free survival (PFS). An interim overall survival (OS), a secondary endpoint, was also reported but the data is immature at this time. The safety profile was consistent with previous reports of Avastin and there were no new safety signals.

Phase II and Phase III data on the use of Avastin in relapsed or recurrent ovarian cancer and front-line ovarian cancer, respectively, have previously been reported.²⁻¹⁶

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

- Avastin Prescribing Information

Cited References


3. Perren T, Swart AM, Pfisterer J, et al. ICON 7: A Phase III gynaecologic cancer interGroup (GCIG) trial of adding bevacizumab to standard chemotherapy in women with newly diagnosed epithelial ovarian, primary peritoneal or fallopian tube cancer. Presented at the 35th European Society for Medical Oncology in Milan, Italy; October 8-12, 2010. ESMO Oral Presentation.


13. Burger RA, Brady MF, Bookman MA, et al. Safety and subgroup efficacy analyses in GOG-0218, a Phase III trial of bevacizumab in the primary treatment of advanced epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer: a gynecologic oncology group study. Presented at the 35th European Society for Medical Oncology in Milan, Italy; October 8-12, 2010. ESMO Poster #978PD.

