On behalf of Genentech, Inc, I respectfully request the NCCN Ovarian Cancer Guideline Panel to review the enclosed recent key Avastin® (bevacizumab) presentations from the 2013 European Cancer Congress (ECC). Presentations that have copyright consent are enclosed for your review.

- **ICON7 Trial**: Front-line treatment of ovarian cancer

  Oza AM, Perren TJ, Swart AM, et al. ICON7: final overall survival results in the GCIG Phase III randomized trial of bevacizumab in women with newly diagnosed ovarian cancer. Presented at the European Cancer Congress in Amsterdam, Netherlands; September 27-October 1, 2013. ECC Oral Presentation.


- **AURELIA Trial**: Platinum-resistant ovarian cancer

  Witteveen P, Lortholary A, Fehm T, et al. Final overall survival results from AURELIA, an open-label randomised phase III trial of chemotherapy with or without bevacizumab for platinum-resistant recurrent ovarian cancer. Presented at the European Cancer Congress in Amsterdam, Netherlands; September 27-October 1, 2013. ECC Oral Presentation.

**Specific Changes**: No specific changes are requested. Please consider the recently presented key Avastin data for your updating purposes.

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

**Rationale**: The ICON7¹ and AURELIA² trial results were previously published and submitted. Final overall survival (OS) results were presented at the European Cancer Congress in October, 2013.

**ICON7 Trial**

- At a median follow up of 49 months, the final analysis of OS, a secondary endpoint, showed no significant difference in patients treated with Avastin + chemotherapy compared with those treated with chemotherapy alone (HR=0.99, 95% CI 0.85-1.14; p=0.85). No new safety concerns were observed with long-term follow up.

**AURELIA Trial**

- Overall survival was a secondary endpoint. After a median follow up of 27.4 months, the final OS analysis showed a median OS of 16.6 months in the Avastin + chemotherapy arm and
13.3 months in the chemotherapy alone arm (HR=0.85; 95% CI 0.66-1.08; p=0.174). The study was not powered to detect a statistically significant difference in OS.

- In the updated safety results, Grade ≥3 adverse events that occurred more frequently in the Avastin arm compared with the chemotherapy alone arm included hypertension, proteinuria, gastrointestinal (GI) perforation, fistula/abscess formation, wound-healing complication, arterial thromboembolic events, and reversible posterior leukoencephalopathy syndrome.

Additional Phase III trials have been conducted to evaluate Avastin in patients with ovarian cancer. ³⁵

Respectfully submitted,

Supplemental References


