Dear NCCN Gastric Cancer Guidelines Panel:

On behalf of Celgene Corporation, we respectfully request that the NCCN Gastric Cancer Guidelines Panel review and consider the enclosed data for Abraxane® (albumin-bound paclitaxel) for the treatment of gastric cancer.

**Specific changes:**
Consider the enclosed data on the use of albumin-bound paclitaxel for the treatment of unresectable or recurrent gastric cancer and include albumin-bound paclitaxel as a preferred therapy option in the NCCN Clinical Practice Guidelines in Oncology for Gastric Cancer.

**FDA Clearance:**
The FDA has not approved albumin-bound paclitaxel for the treatment of gastric cancer. Please refer to the enclosed prescribing information for the FDA-approved indications as well as safety information.

**Rationale for recommended change:** A Phase II, multi-center, single arm study evaluated the use of albumin-bound paclitaxel as monotherapy in 55 patients with unresectable or recurrent gastric cancer after failure of 1 prior therapy that included a fluoropyrimidine. The primary efficacy endpoint was best overall response rate (ORR) by an independent review committee. Albumin-bound paclitaxel was administered at 260 mg/m² on day 1 of 21-day cycles. The median number of cycles administered was 4 (range, 1-18). Fifty four patients were evaluable for response. The ORR was 27.8% (95% confidence interval [CI] 16.5-41.6); 1 patient achieved a confirmed complete response and 14 patients (26%) achieved a partial response. Disease control rate (stable disease or better) was achieved in 32 patients (59.3%). Median PFS was 2.9 months (95% CI 2.4-3.6) and median OS was 9.2 months (95% CI 6.9-11.4). The most common Grade 3/4 adverse events included neutropenia (49.1%), peripheral sensory neuropathy (23.6%), leukopenia (20%), anemia (18.2%), and lymphopenia (16.4%).

These data were presented at the 2012 American Society of Clinical Oncology Gastrointestinal Cancer Symposium (ASCO GI) and served as the basis for the approval of albumin-bound paclitaxel for gastric cancer in Japan.


Thank you for your consideration and we look forward to your reply concerning our request.

Sincerely,

[Signature]
Lorraine Dethlefsen, PharmD
Senior Manager, Medical Information

[Signature]
Deya Corzo, MD
Executive Director, Global Medical Affairs