



Submitted by:
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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.

1. Takiuchi H, Sasaki Y, Nishina T, et al. ABI-007 in the treatment of unresectable or recurrent gastric cancer refractory to fluoropyrimidine containing regimen: Updated data from the multicenter Phase II study [poster]. *Poster presented at: 2012 Gastrointestinal Cancers Symposium (ASCO) 2012a*; January 19-21; San Francisco, CA; USA.

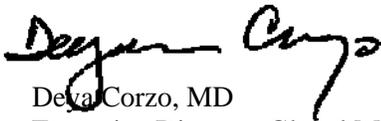
2. Takiuchi H, Sasaki Y, Nishina T, et al. ABI-007 in the treatment of unresectable or recurrent gastric cancer refractory to fluoropyrimidine-containing regimen: Updated data from the multicenter Phase II study [abstract]. *Proceedings of the 2012 Gastrointestinal Cancers Symposium (ASCO) 2012b*; January 19-21; San Francisco, CA; USA: Abstract #090.

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

Sincerely,



Lorraine Dethlefsen, PharmD
Senior Manager, Medical Information



Deval Corzo, MD
Executive Director, Global Medical Affairs