



Submitted by:  
Lorraine Dethlefsen, PharmD  
Celgene Corporation  
400 Connell Drive  
Berkeley Heights, NJ 07922  
Ph: 908-673-1651  
Email: ldethlefsen@celgene.com  
Date of Request: March 7, 2014

Dear NCCN Bladder Cancer Guidelines Panel:

On behalf of Celgene Corporation, we respectfully request that the NCCN Bladder Cancer Guidelines Panel review and consider the enclosed data for Abraxane<sup>®</sup> (albumin-bound paclitaxel) for the second-line treatment of metastatic bladder cancer.

**Specific changes:**

Consider the enclosed data on the use of albumin-bound paclitaxel for the treatment of metastatic bladder cancer and include albumin-bound paclitaxel as a preferred second-line therapy option in the NCCN Clinical Practice Guidelines in Oncology for Bladder Cancer.

**FDA Clearance:**

The FDA has not approved albumin-bound paclitaxel for the treatment of bladder 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 study of single agent albumin-bound paclitaxel 260 mg/m<sup>2</sup> every 3 weeks (Q3W) in 47 evaluable patients with platinum-refractory, second-line metastatic urothelial carcinoma was conducted. The primary endpoint was overall response rate (ORR). Of 47 patients evaluable for response, 1 (2%) achieved a complete response (CR) and 12 (26%) had a partial response (PR) resulting in an ORR of 28%; 10 (21%) had stable disease (SD) and 24 (51%) progressed. The median progression free survival (PFS) and overall survival (OS) were 6 months (95% confidence interval [CI] 3.9-8.5) and 10.8 months (95% CI 5.8-16.9), respectively. PFS at ≥8.4 months was 43%; 18-month OS was 25%. The most common Grade 3/4 adverse events were pain (23%), fatigue (10%), hypertension (6%), neuropathy (6%) and joint pain (4%). A total of 7 patients discontinued treatment due to AEs (n=6 Grade 2 or 3 neuropathy; n=1 Grade 2 AEs including fatigue). There were no treatment-related deaths.

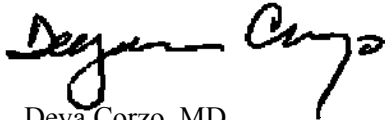
Ko YJ, Canil CM, Mukherjee SD, et al. Nanoparticle albumin-bound paclitaxel for second-line treatment of metastatic urothelial carcinoma: a single group, multicentre, phase 2 study [published online ahead of print, May 21, 2013]. *Lancet Oncology* 2013; doi:10.1016/S1470-2045(13)70162-1.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "Lorraine Dethlefsen".

Lorraine Dethlefsen, PharmD  
Senior Manager, Medical Information

A handwritten signature in cursive script, appearing to read "Deya Corzo".

Deya Corzo, MD  
Executive Director, Global Medical Affairs