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® (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/m² 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.

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

Sincerely,

Lorraine Dethlefsen, PharmD
Senior Manager, Medical Information

Deya Corzo, MD
Executive Director, Global Medical Affairs