Dear NCCN Melanoma Guidelines Panel:

On behalf of Celgene Corporation, we respectfully request that the NCCN Melanoma Guidelines Panel review and consider the enclosed data for Abraxane (albumin-bound paclitaxel) for the treatment of metastatic melanoma.

Specific changes:
Consider the recently presented data on the use of albumin-bound paclitaxel for the treatment of metastatic melanoma and include albumin-bound paclitaxel as a therapy option in the NCCN Clinical Practice Guidelines in Oncology for Melanoma.

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

Rationale for recommended change: Results from the CA033 Phase III study were recently presented by Hersh et al. at the Society for Melanoma Research (SMR) Meeting on November 8-11, 2012. This multicenter, open-labeled study was conducted to compare the efficacy and safety of albumin-bound paclitaxel to dacarbazine in the treatment of chemonaive patients with metastatic melanoma. The primary efficacy endpoint was progression free survival (PFS). The results of this trial demonstrated significantly longer median PFS for albumin-bound paclitaxel (4.8 months) compared to dacarbazine (2.5 months) \( (P=.044; \text{hazard ratio [HR]} \ .792; 95.1\% \text{confidence interval [CI]}: .631-.992) \).

The most common treatment-related adverse events (TRAEs) \( \geq \) Grade 3 reported in \( \geq 5\% \) of patients in the albumin-bound paclitaxel arm were peripheral neuropathy (25%), neutropenia (20%), leukopenia (12%), lymphocytopenia (8%), fatigue (8%), and alopecia (5%). The most common \( \geq \) Grade 3 TRAEs reported in \( \geq 5\% \) of patients in the dacarbazine arm were lymphocytopenia (11%), neutropenia (10%), and leukopenia (7%), thrombocytopenia (6%), and anemia (5%).

Additionally, the following publications, posters and presentations demonstrating the efficacy and safety of albumin-bound paclitaxel either as single-agent or in combination are submitted in support of the proposed change:


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

Sincerely,

Lorraine Dethlefsen, PharmD
Senior Manager, Medical Information – Solid Tumors

Victoria Manax, MD
Senior Director, Medical Affairs Disease Lead – Solid Tumors