Request for NCCN Guidelines Panel to consider review of albumin-bound paclitaxel (ABRAXANE®) data for use in first-line advanced pancreatic cancer in combination with gemcitabine

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NCCN Guidelines Panel: Pancreatic Cancer

Request for NCCN Guidelines Panel to consider review of data for a specific indication:

Abraxis requests that the NCCN Guidelines Panel review the data for albumin-bound paclitaxel in combination with gemcitabine for the treatment of first-line advanced pancreatic cancer with a dosing schedule of albumin-bound paclitaxel 125 mg/m² and gemcitabine 1000 mg/m² given weekly for 3 weeks followed by a week of rest.

Specific changes recommended within the NCCN Guidelines:

We recommend that the Albumin-Bound Paclitaxel Monograph reflect the use of albumin-bound paclitaxel in combination with gemcitabine for the treatment of first-line advanced pancreatic cancer with a dosing schedule of albumin-bound paclitaxel 125 mg/m² and gemcitabine 1000 mg/m² given weekly for 3 weeks followed by a week of rest.

Statement of whether the submitted use is or is not FDA approved for that indication:

The submitted use is not FDA approved. On September 3, 2009, the FDA granted orphan-drug designation to albumin-bound paclitaxel in combination with gemcitabine for the treatment of patients with metastatic adenocarcinoma of the pancreas (designation request #09-2910).¹

Rationale for recommended change:

In a phase I/II study, preliminary antitumor results suggest that albumin-bound paclitaxel in combination with gemcitabine is active and well tolerated in patients with advanced pancreatic cancer, demonstrating a rapid decrease in serum CA19-9, clinically higher response rate, and a clinically meaningful increase in progression-free survival (>120%) and overall survival (>70 %) when compared to historical use of gemcitabine monotherapy.² ³
Citation of literature support and complete articles supporting recommended change. Please see attachments including with the original email for copies of complete articles.

1. FDA, Orphan Products Development. Re: Designation request #09-2910. 2009; Sep 3.