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

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Date of Request: February 8, 2010

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.