

Food and Drug Administration Advisory Committee Member
Acknowledgment of Financial Interests

Name of Advisory Committee Member: Deborah Schrag, M.D.

Committee: Oncologic Drugs Advisory Committee Meeting (ODAC)

Meeting Date: July 13, 2017

I acknowledge that contingent upon public disclosure of the following financial interest related to the agenda item:

On July 13, 2017, the committee will discuss biologics license application (BLA) 761028 for ABP 215, a proposed biosimilar to Genentech/Roche’s AVASTIN (bevacizumab), submitted by Amgen Inc. The proposed indications/uses for this product are: (1) For the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy; (2) in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line ABP 215-containing regimen; (3) for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer in combination with carboplatin and paclitaxel; (4) for the treatment of glioblastoma with progressive disease in adult patients following prior therapy as a single agent; (5) for the treatment of metastatic renal cell carcinoma in combination with interferon alfa; and (6) in combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix. The topic of this meeting is a particular matter involving specific parties.

I may be considered for participation in the advisory committee meeting described above.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
Investment	(b) (4) Healthcare Sector Fund	current aggregate value of the fund is \$50,000 – \$150,000

I hereby request that FDA make this information publicly available on my behalf if the agency grants a waiver allowing me to participate in the meeting described above. I understand that without public disclosure of these interests, I will not participate in the advisory committee meeting described above.

_____/S/
Signature

June 21, 2017
Date