

Food and Drug Administration Advisory Committee Member
Acknowledgment of Financial Interests

Name of Advisory Committee Member: Andrew Seidman, M.D.

Committee: Oncologic Drugs Advisory Committee (ODAC)

Meeting Date: July 13, 2017

I acknowledge that contingent upon public disclosure of the following financial interest related to the agenda item: During the afternoon the committee will discuss biologics license application (BLA) 761074 for MYL-1401O, a proposed biosimilar to Genentech Inc.'s HERCEPTIN (trastuzumab), submitted by Mylan GmbH. The proposed indications (uses) for this product are: (1) for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer (a) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; (b) with docetaxel and carboplatin; or (c) as a single agent following multi-modality anthracycline based therapy; (2) in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer; (3) as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease; and, (4) in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease. 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		
Speakers Bureau	(b) (4) (Competing Firm)	\$10,001 – \$25,000 per year
II. Other Imputed Interests		
Contracts/grants	(b) (4) (Competing Firm)	\$850,000 – \$900,000 total

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