



Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Harold Burstein, MD, PhD**

Committee: **Oncologic Drugs Advisory Committee (ODAC)**

Meeting Date: **April 27, 2021**

I acknowledge that contingent upon public disclosure of the following financial interests related to the agenda item described below, I may be considered for participation in the advisory committee meeting.

On April 27, the committee will hear updates on biologics license application (BLA) 761034/S-018, for Tecentriq (atezolizumab), submitted by Genentech, Inc., a subsidiary of Roche. Ono Pharmaceuticals and Bristol-Myers Squibb (BMS) have a global patent licensing agreement with Roche for the atezolizumab. The committee will review Tecentriq (atezolizumab) in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering $\geq 1\%$ of the tumor area), as determined by an FDA-approved test. Abraxane (nab-paclitaxel) is marketed by Abraxis Bioscience, a subsidiary of Celgene; Celgene and Abraxis Bioscience are subsidiaries of BMS.

This application was approved under 21 CFR 601.40 (subpart E, accelerated approval regulations) with confirmatory trial(s) that have not verified clinical benefit. The updates will provide information on: (1) the status and results of confirmatory clinical studies for a given indication; and (2) any ongoing and planned trials. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. Based on the updates provided, the committee will have a general discussion focused on next steps including whether the indication should remain on the market while additional trial(s) are conducted.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
Contracts/grants	Alliance for Clinical Trials in Oncology (Alliance) funded by National Cancer Institute (NCI) and Genentech (sponsor of Tecentriq (atezolizumab))	\$2.5 million - \$3.5 million per year

Contracts/grants	Alliance for Clinical Trials in Oncology (Alliance) funded by National Cancer Institute (NCI) and Abraxis (sponsor of Abraxane (nab-paclitaxel))	\$950,000 – \$1.5 million per year
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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

_____/4/2/2021_____
Date