U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Philip C. Hoffman, MD (Chairperson)**

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

Meeting Date: **April 27-29, 2021**

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

On April 27th, 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 Pharmaceutical 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 ≥ 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.

On April 28th, the committee will hear updates on BLA 125514/S-017, trade name Keytruda (pembrolizumab), submitted by Merck Sharp & Dohme Corp. (Merck), and indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

On April 29th, the committee will hear updates on BLA 125514/S-042, trade name Keytruda (pembrolizumab), submitted by Merck Sharp & Dohme Corp. (Merck), and indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

These applications were approved under 21 CFR 601.40 (subpart E, accelerated approval regulations) with confirmatory trial(s) that have not verified clinical benefit. These 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 for each product including whether the indications should remain on the market while additional trial(s) are conducted.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
Contracts/grants	Employer's research funded by Merck, sponsor of Keytruda (pembrolizumab)	$0 – 50,000 per year
Contracts/grants	Employer's research funded by Merck, sponsor of Keytruda (pembrolizumab)	$0 – 50,000 per year
Contracts/grants	Employer's research funded by Merck, sponsor of Keytruda (pembrolizumab)	$150,000 – $200,000 received; $0 – 50,000 anticipated

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/_____ _____4/1/2021_____

Signature Date