Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Christopher Lieu, MD**

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 27, 2021, the committee will hear updates on BLA 761034/S-018, for Tecentriq (atezolizumab), submitted by Genentech, Inc., and indicated 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.

Genentech is a subsidiary of Roche. Ono Pharmaceuticals and Bristol-Myers Squibb (BMS) have a global patent licensing agreement with Roche for atezolizumab. 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; and (2) BLA 761034/S-001, trade name TECENTRIQ (atezolizumab), submitted by Genentech, Inc., and indicated for 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-024, trade name Keytruda (pembrolizumab), submitted by Merck Sharp & Dohme Corp., and indicated for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy; and 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)	$300,000 – $350,000 total received Additional $150,000 – $200,000 total anticipated from Merck
Contracts/grants	Employer's research funded by Merck, sponsor of Keytruda (pembrolizumab)	$375,000 – $425,000 total received. Additional $75,000 – $125,000 total anticipated from Merck
Contracts/grants	Employer's research funded by the National Cancer Institute (NCI). NCI has an agreement with Roche/Genentech, sponsor of Tecentriq (atezolizumab)	$25,000 – $75,000 per year from NCI

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/_____ _____4/6/2021_____

Signature Date