U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Mary Kwok, M.D.**

Committee: **Oncologic Drugs Advisory Committee**

Meeting Date: **September 22, 2022**

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 September 22, the committee will hear an update on new drug application (NDA) 214383, for Pepaxto (melphalan flufenamide) for injection, submitted by Oncopeptides A.B. This product was approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) for use in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. The confirmatory trial demonstrated a worse overall survival and failed to verify clinical benefit. 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 the product.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
contract/grant	Harpoon Therapeutics, competing firm	$250,000 – $300,000 to University of Washington School of Medicine
contract/grant	Celgene, competing firm	$200,000 – $250,000 to University of Washington
contract/grant	Nektar Therapeutics, competing firm	$300,000 – $350,000 to University of Washington
contract/grant	Janssen, competing firm	$250,000 – $300,000 to University of Washington

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/ 8/16/2022

Signature Date

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