



Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Gita Thanarajasingam, M.D.**

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

Meeting Date: **October 28, 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 described above.

On October 28th, the committee will discuss new drug application (NDA) 214383, Pepaxto melphalan flufenamide) for injection submitted by Oncopeptides AB, approved under 21 CFR 314.500 (subpart H, accelerated approval regulations), 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 committee will hear an update where the confirmatory trial demonstrated a worse overall survival in the melphalan flufenamide treatment arm compared to the control arm. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. Based on the update provided, the committee will have a general discussion focused on next steps for the product 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	Employer's research funded by Amgen, a competing firm, related to a competing product and indication.	\$100,000 – \$500,000 per year

Contracts/grants	Employer's research funded by Trillium, a competing firm, related to a competing product and indication.	\$100,000 - \$500,000 per year
Contracts/grants	Employer's research funded by Cyteir, a competing firm, related to a competing product and indication.	\$100,000 - \$500,000 per year

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

____10/8/2021_____
Date