U.S. FOOD & DRUG ADMINISTRATION

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**

Meeting Date: **November 16, 2023**

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 November 16, 2023, the committee will receive updates on the accelerated approval program in oncology and two new drug applications (NDAs) approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) that have not met their agreed-upon milestones for completion of confirmatory trial(s). Confirmatory trials are post-marketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. These updates will provide information on the status of all accelerated approvals granted in oncology, including products with delayed confirmatory trials, and the status of confirmatory trials for the specific NDAs to be discussed, including any ongoing and planned trials. The two products to be discussed are: (1) Folotyn (pralatrexate), NDA 022468 submitted by Acrotech Biopharma Inc, indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), and (2) Beleodaq (belinostat), NDA 206256 submitted by Acrotech Biopharma Inc, indicated for the treatment of patients with relapsed or refractory PTCL. Based on the updates provided, the committee will have a general discussion about delayed confirmatory trials as well as a focused discussion on next steps for the two products, Folotyn (pralatrexate) and Beleodaq (belinostat), approved for PTCL. The overall goal will be the continued optimization of the accelerated approval process with a focus on decreasing the amount of time to verify (or fail to verify) clinical benefit while continuing to provide early availability of promising oncology products.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
Contracts/grants	Employer's research funded by competing firms/competing entities: • National Cancer Institute (NCI)/National Institutes of Health (NIH) • Effector	 • $500,000 – $700,000 per year • $0 – $50,000 per year

U.S. Food & Drug Administration
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	• Seattle Genetics • Shanghai Hai He • Celgene • Daiichi Sankyo • Actuate Therapeutics • Aptose • (b) (4)	• $100,000 – $300,000 per year • $50,000 – $100,000 per year • $0 – $50,000 per year • $0 – $50,000 per year • $300,000 – $500,000 per year • $0 – $50,000 per year • $ (b) (4) 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

10/26/2023 — Date