



**Food and Drug Administration Advisory Committee Member
Acknowledgment of Financial Interests**

Name of Advisory Committee Member: **Andy Chen, M.D.**

Committee: **Oncologic Drugs Advisory Committee**

Meeting Date: **September 23, 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 23, the committee will hear an update on new drug application (NDA) 211155 for Copiktra (duvelisib) capsule, submitted by Secura Bio, Inc. This product was approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use in the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma after at least two prior therapies. The update includes the final overall survival data from the DUO trial (IPI-145-07) submitted in response to post-marketing requirement 3494-3 detailed in the [September 24, 2018 approval letter](#). Based on the updated overall survival along with the safety data with duvelisib, the committee will discuss a current assessment of benefit-risk.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
contract/grant	TG Therapeutics, competing firm	\$0 – \$50,000 per year to OHSU
contract/grant	Fate Therapeutics, competing firm	\$0 – \$10,000 per year to OHSU

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

_____/8/15/2022_____
Date