



Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: **Kristen Ciombor, M.D., MSCI**

Committee: **Oncologic Drugs Advisory Committee**

Meeting Date: **February 9, 2023**

I acknowledge that contingent upon public disclosure of the following financial interest related to the agenda item described below, I may be considered for participation in the advisory committee meeting.

On February 9, 2023, the committee will discuss investigational new drug application (IND) 157775, for dostarlimab-gxly for injection, submitted by GlaxoSmithKline LLC. The proposed indication (use) for this product is as a single agent for the treatment of patients with locally advanced, treatment-naïve mismatch repair deficiency/microsatellite instability-high rectal cancer. FDA would like to obtain the committee's input on the following: (1) the adequacy of the proposed trial(s) to evaluate the benefits and risks of dostarlimab for the proposed indication, including trial design, study population, clinical endpoint, and patient followup; and (2) the adequacy of the proposed data package to permit an assessment of the benefits and risks of dostarlimab for the proposed indication.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
None		
II. Other Imputed Interests		
contract/grant	Employer's research funded by the National Cancer Institute	\$0 - 8,000 per patient to Vanderbilt University. At the writing of this waiver, Vanderbilt University has accrued (b) (4).

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

_____/01/23/2023_____
Date