



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: March 15, 2024

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

On March 15, 2024, during the morning session, the committee will discuss supplemental biologics license application (sBLA) 125746.74 for Carvykti (ciltacabtagene autoleucel), suspension for intravenous infusion, submitted by Janssen Biotech, Inc. The proposed indication for this product is for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor, and an immunomodulatory agent, and are refractory to lenalidomide. The Committee will have a general discussion focused on the overall survival data in the Study MMY3002 (CARTITUDE-4) and the risk and benefit of ciltacabtagene autoleucel in the intended population.

During the afternoon session, the Committee will discuss sBLA 125736.218 for Abecma (idecabtagene vicleucel), suspension for intravenous infusion, submitted by Celgene Corp., a Bristol-Myers Squibb Co. The proposed indication is for the treatment of adult patients with relapsed or refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The Committee will have a general discussion focused on the overall survival data in the Study MM-003 (KarMMA-3) and the risk and benefit of idcabtagene vicleucel in the intended population. The topics of the meeting are particular matters involving specific parties.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
Consulting	(b) (4) the matter/competing firm: (b) (4)	Under negotiation

