Dr. Nooka will not be participating in the meeting noted in the waiver. This waiver is null and void.

Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: March 5, 2024

TO: Rachel Bressler
Acting Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

FROM: Byron Marshall
Director, Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

Name of Advisory Temporary Voting Member: **Ajay Nooka, MD, MPH**

Committee: Oncologic Drugs Advisory Committee

Meeting date: April 12, 2024

Description of the Particular Matter to Which the Waiver Applies:

Dr. Ajay Nooka is a temporary voting member of the Oncologic Drugs Advisory Committee (ODAC). The Committee's function is to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and make appropriate recommendations to the Commissioner of Food and Drugs.

On April 12, 2024, the Committee will discuss the use of minimal residual disease (MRD) as an endpoint in multiple myeloma clinical trials including considerations regarding timing of assessment, patient populations, and trial design for future studies that intend to use MRD to support accelerated approval of a new product or a new indication. The topic of the meeting is a particular matter of general applicability.

Type, Nature, and Magnitude of the Financial Interest(s):

Dr. Nooka is a Professor of Hematology and Medical Oncology, and serves as Director of the Myeloma Program at the Winship Cancer Institute of Emory University.

Dr. Nooka's employing institution, Emory University, is participating in a study titled: *A Phase 2, Multicohort Open-Label Study of JNJ-68284528, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against BCMA in Subjects With Multiple Myeloma (CARTITUDE-2)*[NCT04133636], sponsored by Janssen Pharmaceuticals, an affected firm. This is a study of

JNJ-68284528, an affected product, for the treatment of MM with MRD as the primary endpoint, related to the topic before the advisory committee. The study began in October 2019 with an anticipated end date of November 2028. Dr. Nooka is Co-Principal Investigator for this study. Emory University anticipates receiving between $50,000 and $100,000 per year from Janssen Pharmaceuticals. Dr. Nooka does not receive salary support or personal remuneration from this funding.

In addition, Dr. Nooka has an ongoing agreement with (b) (4) for his role in a trial of (b) (4), an affected product, in (b) (4) as a primary endpoint. He serves as (b) (4) The study began in (b) (4) and is anticipated to end in (b) (4). Dr. Nooka receives between $0 and $5,000 per year from (b) (4) as honoraria for his role.

Basis for Granting the Waiver:

Dr. Ajay Nooka has unique qualifications and specialized expertise needed for this particular matter.

Dr. Nooka attended medical school at the Andhra Medical College in Visakhapatnam, India. He earned his master's degree in public health at the University of Texas School of Public Health. He then went on to complete his residency at the Canton Medical Education Foundation of the Northeastern Ohio Universities College of Medicine. He completed his fellowship in Hematology and Oncology at the Emory University School of Medicine.

Dr. Nooka is a board-certified hematologist specializing in the treatment of patients with multiple myeloma with over 13 years as an Attending Physician at the Emory Clinic and Emory University Hospital. He is also board-certified in Internal Medicine and Medical Oncology. Dr. Nooka is a clinical member of the Cancer Prevention and Control Research Program at Winship Cancer Institute of Emory University. He also serves on the steering committee of the Multiple Myeloma Research Consortium. His research interests include integrating genomic and clinical data on a uniform platform; interpreting data in a meaningful way to risk-stratify myeloma; and evaluating newer myeloma therapeutic strategies aimed at prolonging survival in myeloma patients. He also focuses on cancer epidemiology. Dr. Nooka's extensive experience with clinical trials and treatment experience in multiple myeloma are needed for a productive discussion on the issue coming before the Committee.

The particular matter is sensitive.

The particular matter is considered to be sensitive, as the FDA Division responsible for the issue coming before the Committee expects the meeting is likely to receive significant public interest, (non-trade) press interest, and may be considered highly controversial.

Dr. Ajay Nooka's expertise in this particular matter is necessary in the interest of public health.

Multiple myeloma (MM) is a systemic malignancy of plasma cells that typically involves multiple sites within the bone marrow. Multiple myeloma constitutes 1.8% of all new cancer cases and 2.1% of all cancer deaths yearly in the United States, with an incidence of 4.5 to 6 per 100,000 annually. According to the American Cancer Society, the estimated number of new cases of MM in the United States in 2024 is 35,780 while the estimated number of deaths is 12,540.

The outcome of patients with MM has vastly improved over the last decade with the approval of novel agents with different mechanisms of action. Despite improved outcomes, MM remains an incurable disease with a need for new therapies. Overall response rate with durability has been used as an early or intermediate endpoint to support accelerated approval for treatment of patients with multiple myeloma. However, high overall response rates associated with recent treatments have prompted research in early efficacy endpoints to speed up drug development. Currently available data seem to suggest that the depth of response in terms of minimal residual disease (MRD) correlates with clinical outcome. The agency has also begun to see an increase in interest in the use of MRD as an early endpoint to facilitate clinical development of products intended to treat patients with MM.

In the interest of public health, it is important that the Agency has available the expertise that Dr. Nooka will provide for the discussion of the particular matter coming before the Committee.

Any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Ajay Nooka's expertise in this matter.

Dr. Nooka serves as Principal Investigator for more than 40 clinical trials in multiple myeloma. Dr. Nooka's expertise in the treatment landscape of MM as well as clinical trial experience are needed in the discussion regarding the appropriateness of the use of MRD as an earlier endpoint to support accelerated approval for the therapies used to treat patients with MM.

Accordingly, I recommend that you grant Dr. Ajay Nooka, a temporary voting member of the Oncologic Drugs Advisory Committee, a waiver from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

___X___ The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

_____ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

Michael F. Ortwerth -S Digitally signed by Michael F. Ortwerth -S Date: 2024.03.22 12:59:52 -04'00' *for*

Rachel Bressler
Acting Director
Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

03/22/2024
Date