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

DATE: February 7, 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 Committee Meeting Temporary Member: **Anthony Hunter, M.D.**

Committee: Oncologic Drugs Advisory Committee

Meeting date: March 14, 2024

Description of the Particular Matter to Which the Waiver Applies:

Anthony Hunter, M.D. is a temporary voting member of the Oncologic Drugs Advisory Committee (ODAC). The committee's function is to review and evaluate available 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 March 14, 2024, the Committee will discuss new drug application (NDA) 217779 for imetelstat for injection, submitted by Geron Corporation. The proposed indication for this product is for the treatment of transfusion-dependent anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents. The topic of the meeting is a particular matter involving specific parties.

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

Dr. Hunter is an Assistant Professor in the Department of Hematology and Medical Oncology at Emory University School of Medicine and serves as the Medical Director at the Rollins Immediate Care Center in Winship Cancer Institute of Emory University.

Dr. Hunter's employer, Emory University, is participating in the study titled: *A Phase 1b/2 Study Evaluating the Safety and Efficacy of Canakinumab With Darbepoetin Alfa in Patients With Lower-Risk Myelodysplastic Syndromes (MDS) Who Have Failed Erythropoietin Stimulating Agents (ESA)* [NCT04798339], sponsored by Novartis, a competing firm. The study began in May 2023 with an anticipated end date of (b) (4). Dr. Hunter is a Site Principal Investigator for the study.

At the writing of the waiver, the study has (b) (4) Emory University is targeting to enroll up to (b) (4) patients and will receive between $0 and $50,000 per year from Novartis. Dr. Hunter does not receive any salary support or personal remuneration from this funding.

In addition, Emory University is participating in the study titled: *A Phase 1, Open-Label, Dose-Escalation With Expansion Study of SX-682 Alone and in Combination With Oral or Intravenous Decitabine in Subjects With Myelodysplastic Syndrome* [NCT04245397], sponsored by Syntrix Biosystems, a potential competing firm. The study began in December 2022 with an anticipated end date of (b) (4). Dr. Hunter is a Site Principal Investigator for the study.

Emory University is targeting the enrollment of up to (b) (4) patients and will receive between $0 and $50,000 per year from Syntrix Biosystems. Dr. Hunter will receive between $0 and $5,000 per year in salary support from this funding.

Basis for Granting the Waiver:

Dr. Anthony Hunter has unique qualifications and specialized expertise needed for this particular matter.

Dr. Hunter received his Medical Degree from the Medical College of Wisconsin in Milwaukee, Wisconsin. He completed his residency in internal medicine at Emory University School of Medicine in Atlanta, Georgia. He completed a fellowship in hematology and medical oncology at H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida.

Dr. Hunter is a hematologist, specializing in treating patients with leukemia and other myeloid malignancies including myeloproliferative neoplasms, myelodysplastic syndromes, myelodysplastic/myeloproliferative neoplasms and systemic mastocytosis.

Dr. Hunter's research interests revolve around comprehending the molecular drivers of myeloid malignancies to improve prognostication and develop novel treatment strategies. He actively participates in clinical trials evaluating novel therapies in the treatment of myeloproliferative neoplasms, myelodysplastic syndromes, and myelodysplastic/myeloproliferative neoplasms. Additionally, Dr. Hunter serves as a co-investigator of a large international effort to develop a novel prognostic system for chronic myelomonocytic leukemia.

The particular matter is not sensitive.

This meeting topic is not considered to be sensitive as the FDA Division responsible for review

of this product does not expect that the meeting is likely to receive significant public interest, (non-trade) press interest, nor is it considered highly controversial.

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

Myelodysplastic syndrome (MDS) is a blood cancer characterized by abnormal production of blood cells in the bone marrow, with anemia (a condition where the body lacks enough red blood cells to carry oxygen effectively) being the most common symptom.

In the United States, 20,000 new cases of MDS are reported annually, establishing it as one of the most prevalent blood cancers. The epidemiological assessment of MDS presents challenges due to evolving classification systems; however, the estimated overall incidence in the United States is approximately 4 per 100,000 and increases with age.

Current treatment options for lower-risk MDS (LR-MDS) primarily focus on managing symptoms like anemia. The treatment options for symptomatic LR-MDS include the following: erythropoiesis-stimulating agent, lenalidomide, luspatercept, hypomethylating agents, or immunosuppressive therapy.

Allogeneic hematopoietic cell transplantation (HCT) is the treatment with the highest potential to cure MDS. However, because of factors such as advanced age, comorbid conditions, lack of adequately matched donors, and/or patient preferences, only a small subset of patients with MDS qualify for this intervention.

Imetelstat is a first-in-class telomerase inhibitor. It selectively kills the malignant stem and progenitor cells in the bone marrow that are the source of disease in blood cancers.

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

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

The committee will discuss imetelstat for the treatment of transfusion-dependent anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents. Multiple MDS experts with clinical experiences in treating MDS patients are needed for the meeting.

Dr. Hunter is uniquely qualified by having the specialized knowledge and research experiences in evaluating novel therapies in myeloid malignancies. Dr. Hunter's expertise in myeloid malignancies will be instrumental in understanding the issues around safety, efficacy, and risk and benefit evaluation of imetelstat. Furthermore, Dr. Hunter's professional proficiency in designing and executing clinical trials for novel therapeutics in myeloid neoplasms, combined with his extensive experience in treating these patients, will be invaluable to a robust and productive discussion of the issue coming before the committee.

Accordingly, I recommend that you grant Dr. Anthony Hunter, 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):

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_____ Denied – The individual may not participate.

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

Date