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

DATE: December 20, 2021

TO: Russell Fortney
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 Member: **Ashley Rosko, M.D.**

Committee: Oncologic Drugs Advisory Committee

Meeting date: February 10, 2022

Description of the Particular Matter to Which the Waiver Applies:

Ashley Rosko, M.D., is a standing 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 the use in the treatment of cancer and make appropriate recommendations to the Commissioner of Food and Drugs.

On February 10th, the committee will discuss biologics license application (BLA) 761222, for sintilimab injection, submitted by Innovent Biologics (Suzhou) Co., Ltd. The proposed indication (use) for this product is in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of patients with Stage IIIB, IIIC, or Stage IV non-squamous non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. The topic of the meeting is a particular matter involving specific parties.

Type, Nature, and Magnitude of the Financial Interests:

Dr. Rosko's employing institution, the Ohio State University (OSU), is participating in the study titled *A Phase 1b/2a Pilot Study to Evaluate the Safety and Tolerability of Autologous T-Cells Expressing Enhanced TCRs (T Cell Receptors) Specific for NY-ESO-1/LAGE-1a (GSK3377794) Alone, or in Combination With Pembrolizumab in HLA-A2+ Participants With NY-ESO-1- or*

LAGE-1a-Positive Advanced or Recurrent Non-Small Cell Lung Cancer, NCT03709706, sponsored by GlaxoSmithKline, a competing firm. This study population overlaps with the indication coming before the advisory committee. The study began on February 4, 2020 and is projected to end is May 30, 2025. Dr. Rosko has not been involved in the study and will not be involved in the future.

The Ohio State University anticipates receiving between $0 and $50,000 per year, from GlaxoSmithKline, for its participation in this study. Dr. Rosko does not receive any personal remuneration or salary support from this funding.

Dr. Rosko's employer is also anticipating participation in the study titled (b) (4) , sponsored by (b) (4) , a competing firm. This study population overlaps with the indication coming before the advisory committee. The study has not opened at OSU yet. Dr. Rosko has not been involved in the study and will not be involved in the future.

Since Dr. Rosko does not have direct involvement with this study, she is not aware of the funding amount being provided to OSU from (b) (4) for its participation in this study. Further, Dr. Rosko does not receive any personal remuneration or salary support from the funding.

Basis for Granting the Waiver:

Dr. Ashley Rosko has unique qualifications and specialized expertise needed for this particular matter.

Dr. Ashley Rosko is Associate Professor of Internal Medicine, in the Division of Hematology, at the Ohio State University, and Medical Director of the Oncogeriatrics Program at the Ohio State University Comprehensive Cancer Center - The James. She also serves as Co-Director of the Cancer and Aging Resiliency Clinic at The James, a multidisciplinary care clinic for aging adults with cancer. Dr. Rosko earned her medical degree from the Wright State University Boonshoft School of Medicine and completed her residency and fellowship in hematology/oncology at the University Hospitals Case Medical Center in Cleveland, Ohio.

As a member of the Cancer Control Program, Dr. Rosko's research focuses on cancer and aging, translational geriatric research efforts, bone marrow transplantation and outcomes in older adults with multiple myeloma. Her research is focused on biologic age — rather than chronological age — to better understand a patient's ability to tolerate aggressive cancer therapies. Dr. Rosko's research in identifying frailty in older adults with blood cancer is currently funded by a NCI K23 Mentored Career Development Award in addition to other grants like the Paul Calabresi Scholar Award, the Alliance NCI NCORP Cancer Control Program YIA and the National Comprehensive Cancer Network (NCCN) YIA. Dr. Rosko's work has been published in several medical journals, including Journal of Geriatric Oncology, Clinical Cancer Research, and Journal of Clinical Oncology. Dr. Rosko is the founding member of the ASH Scientific Symposium on Hematology and Aging, an editorial board member for Journal of Geriatric Oncology, and a member of the NCCN Older Adult Oncology standing panel.

According to the review division responsible for the review of the application at issue for this meeting, it is particularly important to include Dr. Rosko in the upcoming ODAC meeting. Dr. Rosko's specific experience in geriatric oncology and in clinical trial conduct will be particularly useful to the particular matter given the demographics of the NSCLC population in the U.S. (median age at diagnosis is 70 years) and the issues inherent in clinical development in a single country outside the U.S.

The particular matter is sensitive.

The particular matter is considered to be sensitive. The FDA Division responsible for review of this product does expect the matter coming before the committee to garner public interest and (non-trade) press interest. This is the first product for lung cancer seeking approval based on clinical data obtained completely outside of the U.S from a single country or limited geographic region.

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

Lung cancer is the leading cause of cancer-related mortality in the United States. There are two primary types of lung cancer, known as non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Named initially for how the cancer cells look under the microscope, these account for 230,000 newly diagnosed cases of lung cancer in the U.S. each year. The 5-year relative survival rate from 2010 to 2016 for patients with lung cancer was 21%.

The vast majority (85%) of lung cancers fall into the category of NSCLC, of which 70% are classified as non-squamous NSCLC. NSCLC progresses more slowly than SCLC, however 40% of NSCLCs will have distant metastases by the time it is diagnosed. Early diagnosis offers the best prognosis for NSCLC. However, NSCLC and other lung cancers can be difficult to diagnose because these cancers often have symptoms that are mistaken for common illnesses or from the effects of long-term smoking.

Treatment for NSCLC depends on whether the cancer has spread to other areas of the body, the overall health and age of the patient, and the presence of certain proteins that make treatments more effective. If NSCLC is detected early, surgery to remove the affected tissue or tumor is the treatment of choice. Other treatments include radiation therapy, chemotherapy, targeted therapy, and immunotherapy. The product at issue for the February 10th meeting is Innovent Biologics' sintilimab, an anti-PD-1 monoclonal antibody, in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of patients with Stage IIIB, IIIC, or Stage IV non-squamous non-small cell lung cancer with no epidermal growth factor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. In the interest of public health, it is important that the Agency has available the unique expertise that Dr. Rosko 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. Ashley Rosko's expertise in this matter.

The expertise of multiple different medical oncologists who specialize in different areas of oncology is essential to ensure that a cross-section of U.S. academic oncology is represented given the broad implications an approval of this marketing application would have across the field. There is a large number of similar programs, e.g., marketing applications for anti-PD-(L)1 antibodies based on data from a single foreign country or limited geographic regions, currently either under development or under review at the FDA across multiple oncology divisions and given this expansive potential impact, multiple medical oncologists are necessary. Dr. Rosko's expertise in medical oncology, clinical trial conduct, and anti-PD-(L)1 therapies in general is central to the particular matter which involves an anti-PD-(L)1 antibody and its ex-U.S. development plan. Dr. Rosko will provide her expert opinion on the development of anti-PD-(L)1 antibodies for the first-line treatment of NSCLC, the current treatment landscape for NSCLC, and the conduct of multinational clinical trials for oncology patients.

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

Certification:

___✓___ 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.

Russell Fortney -S Digitally signed by Russell Fortney -S Date: 2022.01.24 09:48:10 -05'00'

Russell Fortney
Director, Advisory Committee Oversight and Management Staff
Office of the Chief Scientist

January 24, 2022
Date