2025 Current Fiscal Year Report: Oncologic Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Oncologic Drugs Advisory Committee	35

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	09/01/2024	09/01/2026	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
0	0	0	0	0

Meetings and Dates

No Meetings

	Current FY	Next FY

18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$0.00
18d. Total	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions. Members will be invited to

serve for overlapping terms of up to four years. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

20c. How frequent and relevant are the Committee Meetings?

In FY-24, the Committee held eight meetings. On October 4, 2023, the Committee discussed new drug application (NDA) 215500, for eflornithine tablets, submitted by USWM, LLC (doing business as US WorldMeds). The proposed indication (use) for this product is to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma (HRNB) who have completed multiagent, multimodality therapy. The majority of the committee members (14 Yeses, 6 Noes, and 0 Abstention) agreed that the Applicant provided sufficient evidence to conclude that DFMO improves event-free survival in patients with high-risk neuroblastoma; however, there were questions for clarity around if this was intended to mean substantial evidence and deferred to FDA on that aspect. On December 13, 2023, the Food and Drug Administration approved eflornithine tablets (IWILFIN, USWM) to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated

at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. On October 5, 2023, the Committee discussed supplemental new drug application (sNDA) 214665/S-005, for LUMAKRAS (sotorasib) tablets, submitted by Amgen Inc., for the proposed treatment of adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy. This supplement proposes to convert the NDA to full approval based on the confirmatory study, CodeBreaK 200. The Committee considered the results of the CodeBreaK 200 study and discussed the benefit-risk profile of LUMAKRAS. A majority of the Committee (10 Noes, 2 Yeses, 0 Abstention) agreed that the primary endpoint, PFS per BICR cannot be reliably interpreted in CodeBreak200. Agency Action: The Agency is currently evaluating recommendations made during the meeting. On November 16, 2023, the Committee received updates on the accelerated approval program in oncology and two new drug applications (NDAs) approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) that have not met their agreed-upon milestones for completion of confirmatory trial(s). Confirmatory trials are postmarketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. These updates provided information on the status of all accelerated approvals granted in oncology, including products with delayed confirmatory trials, and the status of confirmatory trials for the specific NDAs to be discussed, including any ongoing and planned trials. Action: The Agency is currently evaluating recommendations made during the meeting. On March 14, 2024, the Committee

discussed 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 majority of the Committee (12 Yeses, 2 Noes, 0 Abstain) agreed that imetelstat's benefits outweigh its risks for the treatment of transfusion dependent anemia in adult patients with International Prognosis Scoring System low- to intermediate-1 risk MDS who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents. On June 6, 2024, the Food and Drug Administration approved imetelstat for injection (RYTELO, Geron Corp.) for the treatment of adult patients with low-to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA). On March 15, 2024, during the morning session, the Committee discussed 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 had 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. The Committee unanimously (11 Yeses, 0 Noes, 0 Abstention) agreed that the risk-benefit assessment was favorable. Committee members acknowledged the risk of early death could be related to an inadequate bridging regimen, which was not optimized. On April 5, 2024, the Food and Drug Administration approved CARVYKTI (ciltacabtagene autoleucel), suspension for intravenous infusion (Janssen Biotech) 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. During the afternoon session, the Committee discussed 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 had a general discussion focused on the overall survival data in the Study MM-003 (KarMMa-3) and the risk and benefit of idecabtagene vicleucel in the intended population. The majority of the panel (8 Yeses, 3 Noes, 0 Abstention) agreed that the risk-benefit assessment for idecabtagene vicleucel for the proposed indication was favorable. On April 4, 2024, the Food and Drug Administration approved ABECMA (idecabtagene vicleucel), suspension for intravenous infusion (Celgene Corp., a Bristol-Myers Squibb Co.) 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. On April 12, 2024, the Committee discussed 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 Committee unanimously (12 Yeses, 0 Noes, 0 Abstention) agreed that the evidence does support the use of MRD as an accelerated approval endpoint in MM clinical trials. The Agency is currently evaluating recommendations made during the meeting. On July 25, 2024, the Committee discussed supplemental biologics license application (sBLA) 761069/S-043, for IMFINZI (durvalumab) injection, submitted by AstraZeneca UK Limited. The proposed indication (use) is IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, for the treatment of adult patients with resectable (tumors 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. The Committee was also asked to discuss whether drug sponsors should be required to adequately justify treatment of patients both before and after surgery for resectable NSCLC prior to an approval that would include both neoadjuvant and adjuvant therapy. The Committee unanimously (11 Yeses, 0 Noes, 0 Abstention) agreed that FDA should require that new trial design proposals for perioperative regimens for resectable NSCLC include adequate within trial assessment of contribution of treatment phase. On August 15, 2024, the Food and Drug Administration approved

IMFINZI (durvalumab) injection (AstraZeneca UK Limited) for use in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, for the treatment of adult patients with resectable (tumors = 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. On September 26, 2024, during the morning session, the Committee discussed the use of immune checkpoint inhibitors in patients with unresectable or metastatic gastric and gastroesophageal junction adenocarcinoma. The current labeling for approved checkpoint inhibitors in this indication reflect broad approvals in the intent to treat patient populations agnostic of programmed death cell ligand-1 (PD-L1) expression. Cumulative data has shown that PD-L1 expression appears to be a predictive biomarker of treatment efficacy in this patient population; however, clinical trials have used different approaches to assess PD-L1 expression and different thresholds to define PD-L1 positivity. FDA received the Committee's opinion on the: - adequacy of PD-L1 expression as a predictive biomarker for patient selection in this patient population, - differing risk-benefit assessments in different subpopulations defined by PD-L1 expression, and - adequacy of the cumulative data to restrict the approvals of immune checkpoint inhibitors based on PD-L1 expression. The Committee discussed the existing supplemental biologics license applications (sBLA) which were approved for patients with previously untreated HER2-negative unresectable or metastatic gastric or gastroesophageal adenocarcinoma: - sBLA 125554/S-091 for OPDIVO (nivolumab) injection,

submitted by Bristol Myers-Squibb Co. and - sBLA 125514/S-143 for KEYTRUDA (pembrolizumab) injection, submitted by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. The Committee also discussed BLA 761417 for tislelizumab injection, submitted by BeiGene USA, Inc., for the same proposed indication. The majority of the Committee voted (2 Yeses, 10 Noes, 1 Abstention) that the risk benefit is not favorable for the use of PD-1 inhibitors in first line advanced HER2 negative microsatellite stable gastric/GEJ adenocarcinoma in patients with PD-L1 expression < 1. The Agency is currently evaluating recommendations made during the meeting. During the afternoon session, the Committee discussed the use of immune checkpoint inhibitors in patients with metastatic or unresectable esophageal squamous cell carcinoma. The current labeling for approved checkpoint inhibitors in this indication reflect broad approvals in the intent to treat patient populations agnostic of programmed death cell ligand-1 (PD-L1) expression. Cumulative data has shown that PD-L1 expression appears to be a predictive biomarker of treatment efficacy in this patient population; however, clinical trials have used different approaches to assess PD-L1 expression and different thresholds to define PD-L1 positivity. FDA received the Committee’s opinion on the: - adequacy of PD-L1 expression as a predictive biomarker for patient selection in this patient population, - differing risk-benefit assessments in different subpopulations defined by PD-L1 expression, and - adequacy of the cumulative data to restrict the approvals of immune checkpoint inhibitors based on PD-L1 expression. The Committee discussed the existing sBLAs which were approved for patients with previously untreated unresectable or metastatic esophageal

squamous cell carcinoma: - sBLA 125514/S-096 for KEYTRUDA (pembrolizumab) injection, submitted by Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. - sBLAs 125554/S-105 and S-106 for OPDIVO (nivolumab) injection, submitted by Bristol Myers-Squibb Co.; and - sBLA 125377/S-122 for YERVOY (ipilimumab) injection, submitted by Bristol Myers-Squibb Co. The Committee also discussed the new BLA 761380 for tislelizumab, submitted by BeiGene USA, Inc., for the same proposed indication. The majority of the Committee voted (1 Yes, 11 Noes, 1 Abstentions) that the risk: benefit assessment in not favorable for the use of anti-PD-1 antibodies in first line unresectable or metastatic esophageal squamous cell carcinoma with PD-L1 expression <1. The Agency is currently evaluating recommendations made during the meeting. It is expected that the Committee will meet 4-6 times during FY-25.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Members of the Committee are drawn from academia, research and/or clinical practice. Their advice and input lends credibility to FDA regulatory decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientist on a full-time basis at a maximum rate of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?
The Committee held no closed meetings during FY-24.

21. Remarks
There were no reports required for this Committee in FY-24. On May 22, 2024, the Pediatric

Subcommittee of the Oncologic Drugs Advisory Committee met regarding the Amendments made by section 504 of the 2017 FDA Reauthorization Act to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) required, for original applications submitted on or after August 18, 2020, pediatric investigations of certain targeted cancer drugs with new active ingredients, based on molecular mechanism of action rather than clinical indication. The subcommittee discussed perspectives relating to implementation of this legislation and its impact on pediatric cancer drug development to date. The Agency is currently evaluating recommendations made during the meeting. Although the current charter states that the Committee shall hold meetings approximately 4-6 times a year, this is only an estimation based on data from previous years. As the FDA convenes advisory committees regarding based on the needs of the Agency, it should not be construed as an exact figure. The meeting minutes for the 09/26/2024 meeting are currently being reviewed and will be posted to the committee website as soon as they become available.

Designated Federal Officer

Yvette Waples Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Choueiri, Toni	08/28/2023	06/30/2027	Director, Lank Center for Genitourinary Oncology, Professor, Harvard Medical School, Dana-Farber Cancer Institute	Special Government Employee (SGE) Member
Conaway, Mark	07/01/2021	06/30/2025	Professor, Division of Translational Research and Applied Statistics, Department of Public Health Sciences, University of Virginia	Special Government Employee (SGE) Member

Frenkl, Tara	01/17/2024	10/31/2027	Senior Vice President, Head of Oncology Development, Bayer Pharmaceuticals	Representative Member
Gradishar, William	08/28/2023	06/30/2027	Professor of Medicine/Betsy Bramsen Professor of Breast Oncology, Chief, Hematology/Oncology, Robert H. Lurie Comprehensive Center, Feinberg School of Medicine at Northwestern University	Special Government Employee (SGE) Member
Kunz, Pamela	09/29/2021	06/30/2025	Associate Professor of Medicine (Oncology), Division Chief, GI Oncology; Vice Chief, Diversity Equity and Inclusion, Medical Oncology, Yale School of Medicine and Yale Cancer Center	Special Government Employee (SGE) Member
Madan, Ravi	09/29/2021	06/30/2025	Senior Clinician, Head, Prostate Cancer Clinical Research Section, Genitourinary Malignancies Branch, Center for Cancer Research, National Cancer Institute, National Institutes of Health	Regular Government Employee (RGE) Member
Spratt, Daniel	08/28/2023	06/30/2027	Vincent K Smith Chair, Department of Radiation Oncology, Professor of Radiation Oncology and Urology, UH Seidman Cancer Center, Case Western University	Special Government Employee (SGE) Member
Vasan, Neil	07/01/2022	06/30/2026	Assistant Professor, Division of Hematology & Oncology, Department of Medicine, Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center	Special Government Employee (SGE) Member

Number of Committee Members Listed: 8

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Oncologic Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

The utilization of the Oncologic Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

203

Number of Recommendations Comments

The Committee made 203 recommendations from FY-03 through FY-24.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

84%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ✓ No ☐ Not Applicable ☐

Agency Feedback Comments
When appropriate, information is made available to the public. Actions related to guidance documents or other general matters or issues are available publicly when implemented https://www.fda.gov/advisory-committees

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	✓
Reallocated resources	✓
Issued new regulation	✓
Proposed legislation	✓
Approved grants or other payments	☐
Other	✓

Action Comments
FDA approves or chooses not to approve an investigational new medical products.

Is the Committee engaged in the review of applications for grants?
No

Grant Review Comments
N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A