2025 Current Fiscal Year Report: Oncologic Drugs Advisory Committee

Report Run Date: 09/05/2025 07:23:31 PM

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
2	0	0	0	2

Meetings and Dates

Purpose	Start	End

On the morning of May 20, 2025, the Committee discussed supplemental biologics license application (sBLA) 761309/S-001, for COLUMVI (glofitamab) injection, submitted by Genentech, Inc. The proposed indication (use) is in combination with gemcitabine and oxaliplatin for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) who are not candidates for autologous stem cell transplant (ASCT). On the afternoon of May 20, 2025, the Committee discussed sBLA 761145/S-029, for DARZALEX FASPRO (daratumumab and hyaluronidase) injection, for subcutaneous use, submitted by Janssen Biotech, Inc. The proposed indication (use) is as monotherapy for the treatment of adult patients with high-risk smoldering multiple myeloma (SMM). On the morning of May 21, 2025, the Committee discussed new drug application (NDA) 215793, for UGN-102 (mitomycin) intravesical solution, submitted by UroGen Pharma, Inc. The proposed indication (use) is for the treatment of adult patients with low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC). On the afternoon of May 21, 2025, the Committee discussed supplemental new drug application (sNDA) 211651/S-013, for TALZENNA (talazoparib) capsules, submitted by Pfizer Inc. The proposed indication (use) is in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC).	05/20/2025 - 05/21/2025
The Committee discussed BLA 761440, belantamab mafodotin submitted by GlaxoSmithKline LLC, for the treatment of adults with multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior line of therapy; and in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide.	07/17/2025 - 07/17/2025

Number of Committee Meetings Listed: 2

	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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$0.00	$0.00
18e. Total Costs	$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-25, the Committee held 2 meetings. Between May 20-21, 2025, the Oncologic Drugs Advisory Committee met to discuss the following: On the morning of May 20, 2025, the Committee discussed supplemental biologics license application (sBLA) 761309/S-001, for COLUMVI (glofitamab) injection, submitted by Genentech, Inc. The proposed indication (use) is in combination with gemcitabine and oxaliplatin for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) who are not candidates for autologous stem cell transplant (ASCT). The issues the Committee discussed focused on how the differential results observed in the Asian and Non-Asian regions impacted the overall interpretation of the STARGLO trial results and the generalizability to a U.S. patient population. The Committee members were in near unanimous agreement (8 Noes and 1 Yes) that

the STARGLO population and trial results are not applicable to the proposed U.S. patient population. Agency Action: The Agency is reviewing recommendations made at the meeting - On the afternoon of May 20, 2025, the Committee discussed sBLA 761145/S-029, for DARZALEX FASPRO (daratumumab and hyaluronidase) injection, for subcutaneous use, submitted by Janssen Biotech, Inc. The proposed indication (use) is as monotherapy for the treatment of adult patients with high-risk smoldering multiple myeloma (SMM). The issues the Committee discussed focused on the clinical meaningfulness of the efficacy endpoints assessed in the AQUILA trial, and the benefit-risk of daratumumab hyaluronidase for the intended high-risk (SMM) population. The majority of Committee members (6 Yeses and 2 Noes) agreed that the results from the AQUILA trial provided sufficient evidence to support a favorable benefit-risk profile for Dara SC for patients with high-risk SMM. Agency Action: The Agency is reviewing recommendations made at the meeting. - On the morning of May 21, 2025, the Committee discussed new drug application (NDA) 215793, for UGN-102 (mitomycin) intravesical solution, submitted by UroGen Pharma, Inc. The proposed indication (use) is for the treatment of adult patients with low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The issues the Committee discussed focused on whether randomized trialsshould be required in the future to assess the effectiveness oftherapies in LG-IR-NMIBC given the uncertainty regarding interpretation of study results. The Committee was split with a slight majority voting that the overall benefit-risk of UGN-102 was not favorable in patients with recurrent LG-IR-NMIBC (5 Noes and 4 Yeses). Agency Action: The Agency is reviewing

recommendations made at the meeting. - On the afternoon of May 21, 2025, the Committee discussed supplemental new drug application (sNDA) 211651/S-013, for TALZENNA (talazoparib) capsules, submitted by Pfizer Inc. The proposed indication (use) is in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC). The issues the Committee discussed focused on whether efficacy should be formally evaluated in a biomarkernegative population when the biomarker is predictive of response and the prevalence of the biomarker-negative group is high. The Committee members were in unanimous agreement (8 Noes, and 0 Yeses) that the results from the TALAPRO-2 trial were not sufficient to conclude a favorable benefit-risk profile for adding talazoparib to enzalutamide in patients with non-HRRm mCRPC. Agency Action: The Agency is reviewing recommendations made at the meeting. On July 17, 2025, the Committee discussed BLA 761440, belantamab mafodotin submitted by GlaxoSmithKline LLC, for the treatment of adults with multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior line of therapy; and in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide. The majority of Committee members (5 Noes, 3 Yeses) agreed that the overall benefit-risk of belantamab mafodotin in combination with bortezomib and dexamethasone was not favorable at the proposed dosage in the proposed patient population. The Committee was nearly in unanimous agreement (7 Noes, 1 Yes) that the overall benefit-risk of belantamab mafodotin in combination with pomalidomide and

dexamethasone was not favorable at he proposed dosage in the proposed patient population. Agency Action: The Agency is reviewing recommendations made at the meeting. It is expected that the Committee will meet 4-6 times during FY-26.

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-25.

21. Remarks
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.

Designated Federal Officer
Yvette Waples Acting Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation

Ball, Mark	05/21/2025	05/21/2025	Associate Research Physician (Associate Professor), Associate Program Director, Urologic Oncology Fellowship Urologic Oncology Branch, National Cancer Institute, NIH	Regular Government Employee (RGE) Member
Beringer, Paul	07/17/2025	07/17/2025	Professor of Clinical Pharmacy, Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, University of Southern California	Special Government Employee (SGE) Member
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	07/17/2025	Professor, Division of Translational Research and Applied Statistics, Department of Public Health Sciences, University of Virginia School of Medicine	Special Government Employee (SGE) Member
DeFlice, John	07/17/2025	07/17/2025	Patient Representative	Special Government Employee (SGE) Member

Frenkl, Tara	01/17/2024	10/31/2027	Senior Vice President, Head of Global Medical Strategy and Evidence Generation, Bayer Pharmaceuticals	Representative Member
Garraway, Isla	05/21/2025	05/21/2025	Staff Urologist and Principal Investigator, Veterans Affairs (VA) Greater Los Angeles Healthcare System; Professor and Director of Research, Department of Urology Member, Jonsson Comprehensive Cancer Center David Geffen School of Medicine at UCLA	Regular Government Employee (RGE) Member
Gradishar, William	08/28/2023	06/30/2027	Professor of Medicine/Betsy Bramsen Professor of Breast Oncology; Director, Maggie Daley Center for Women's Cancer Care Robert H. Lurie Comprehensive Cancer Center Feinberg School of Medicine at Northwestern University	Special Government Employee (SGE) Member
Graff, Julie	05/21/2025	05/21/2025	Staff Oncologist, VA Portland Health Care System; Professor of Medicine, Oregon Health & Science University	Regular Government Employee (RGE) Member
Johnston, Colette	05/21/2025	05/21/2025	Patient Representative	Special Government Employee (SGE) Member

Kungel, Terrence	05/21/2025	05/21/2025	Patient Representative	Special Government Employee (SGE) Member
Kunz, Pamela	09/29/2021	06/30/2025	Associate Professor of Medicine (Oncology), Division Chief, GI Oncology, Yale School of Medicine and Yale Cancer Center	Special Government Employee (SGE) Member
Lieu, Christopher	05/20/2025	05/20/2025	Professor of Medicine, Associate Director for Clinical Research, Co-Director, Gastrointestinal (GI) Medical Oncology, University of Colorado Cancer Center	Special Government Employee (SGE) Member
Madan, Ravi	09/29/2021	07/17/2025	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
Majkowski, Paul	05/20/2025	05/20/2025	Patient Representative	Special Government Employee (SGE) Member
McKean, Heidi	05/20/2025	05/21/2025	Director, GI Oncology Program, Community Oncologist, Avera Medical Oncology and Hematology	Special Government Employee (SGE) Member

Nooka, Ajay	05/20/2025	05/20/2025	Professor, Department of Hematology and Medical Oncology; Director, Myeloma Program, Associate Director of Clinical Research Winship Cancer Institute, Emory University School of Medicine	Special Government Employee (SGE) Member
Nowakowski, Grzegorz	07/17/2025	07/17/2025	Professor of Medicine and Oncology, Enterprise Deputy Director for Clinical Research Mayo Clinic Comprehensive Cancer Center; Chair, Lymphoid Malignancy Group; Vice-Chair, Division of Hematology, Mayo Clinic	Special Government Employee (SGE) Member
Powell, Joan	05/20/2025	05/20/2025	Patient Representative	Special Government Employee (SGE) Member
Spratt, Daniel	08/28/2023	06/30/2027	Assoc. Chief Scientific Officer, Univ Hospitals Cleveland Medical Ctr; Medical Director, Clinical Research Ctr, Vincent K Smith Chair of Radiation Oncology, UH Seidman Cancer Ctr; Chair and Professor, Dept of Radiation Oncology, Case Western Reserve Univ	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: 21

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?

208

Number of Recommendations Comments

The Committee made 208 recommendations from FY-03 through FY-25.

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