2024 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	2024

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	09/01/2022	09/01/2024	

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. The Office of Oncology Drug Products also uses committee members as subject matter experts, on an as needed basis.

20b. How does the Committee balance its membership?

Members are selected from academic and practice settings and include practitioners knowledgeable in the field of general oncology,

pediatric oncology, hematological oncology, immunology oncology, biostatistics, and other related professions. The Committee includes one technically qualified voting member who is identified with consumer interests. The Committee may also include one non-voting member who is identified with industry interests.

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

The Committee met four times in FY-23. On October 28, 2022, the Committee discussed biologics license application 761176, for 131I-omburtamab solution for injection, submitted by Y-mAbs Therapeutics, Inc. The proposed indication (use) for this product is for the treatment of central nervous system/leptomeningeal (CNS/LM) metastases in pediatric patients with neuroblastoma following standard multimodality treatment for CNS disease. The issues that the Committee discussed included whether data provided by the Applicant isolate the treatment effect of 131I-omburtamab from the effects of multimodality therapy for CNS/LM relapse or if additional data are needed. There was one voting question, and the Committee unanimously (0 Yeses, 16 Noes) agreed that the Applicant did not provide sufficient evidence to conclude that 131I-omburtamab improves overall survival. Agency Action: The Agency is currently evaluating recommendations made during the meeting. On February 9, 2023, the Committee discussed investigational new drug application (IND) 157775, for dostarlimab-gxly for injection, submitted by GlaxoSmithKline LLC. The proposed indication (use) for this product is as a single agent for the treatment of patients with locally advanced, treatment-naïve mismatch repair deficiency/microsatellite instability- high rectal

cancer. FDA obtained the committee's input on the following: (1) the adequacy of the proposed trial(s) to evaluate the benefits and risks of dostarlimab for the proposed indication, including trial design, study population, clinical endpoint, and patient followup; and (2) the adequacy of the proposed data package to permit an assessment of the benefits and risks of dostarlimab for the proposed indication. The Committee had four discussion questions regarding 1) the adequacy of proposed single-arm trials to evaluate the efficacy and safety of dostarlimab, including the long-term benefits and risks of treatment , 2) the adequacy of the proposed clinical endpoints, to characterize and verify the benefit of dostarlimab including the proposed timing of analyses, 3) the study population with Stage II/III LARC dMMR/MSI-H for a non-operative management approach, 4) the potential impact of the variability in care, expertise, etc., across multi-disciplinary study staff and across study sites on study conduct and ultimately on outcomes. There was one voting question, and a majority of the Committee (8 Yeses, 5 Noes) agreed that the data from the proposed single arm trials is sufficient to characterize the benefits and risks of dostarlimab in the curative intent setting for patients with dMMR/MSI-H LARC. Agency Action: The Agency is currently evaluating recommendations made during the meeting. On March 9, 2023, the Committee discussed supplemental biologics license application (BLA) 761121/S-008, for POLIVY (polatuzumab vedotin-piiq) for injection, submitted by Genentech, Inc. The proposed indication (use) for this product is in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL). This product was approved under 21

CFR 601.41 (subpart E, accelerated approval regulations) for use in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, after at least two prior therapies. Confirmatory studies are post-marketing studies to verify and describe the clinical benefit of a product after it receives accelerated approval. The new proposed indication is based on the confirmatory study, POLARIX (Study GO39942), conducted to fulfill post-marketing requirement 3630-1 detailed in the June 10, 2019, approval letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761121Orig1s000ltr.pdf. Based on the results of the POLARIX study, the committee will discuss the benefit-risk profile of POLIVY in patients with previously untreated DLBCL. The issues that the Committee discussed included based on results of POLARIX trial to consider the benefit-risk profile of polatuzumab vedotin-piiq in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the proposed patient population with large B-cell lymphoma (LBCL), including patients with DLBCL NOS, and specifically the overall survival results to consider whether additional follow-up data from POLARIX should be required to inform the benefit-risk of polatuzumab vedotin-piiq in patients with LBCL in the frontline setting. There was one voting question, and a majority of the Committee (11 Yeses, 2 Noes) agreed that polatuzumab vedotin-piiq has a favorable benefit-risk profile in patients with previously untreated LBCL, including DLBCL NOS given the results of the POLARIX trial. Agency Action: On April 19, 2023, the Agency approved polatuzumab vedotin-piiq (Polivy, Genentech, Inc.) with a rituximab product, cyclophosphamide, doxorubicin, and prednisone

(R-CHP) for adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of 2 or greater. On April 28, 2023, the Committee discussed supplemental new drug application (sNDA) 208558/S–025, for LYNPARZA (olaparib) tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) for this product is in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC). The issue that the Committee discussed included whether to restrict the indication to patients whose tumors have a BRAC mutation. There was one voting question, and a majority of the Committee (11 Yeses, 1 No, 1 Abstention) agreed that the proposed indication for olaparib in combination with abiraterone for initial treatment of mCRPC should be restricted to patients whose tumors have a BRCA mutation. Agency Action: The Agency approved olaparib (Lynparza, AstraZeneca Pharmaceuticals LP) with abiraterone and prednisone (or prednisolone) for adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved companion diagnostic test. It is expected that the Committee will meet 4-6 times during FY-24.

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-23.

21. Remarks

There were no reports required for this Committee in FY-23. On June 16, 2023, the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee discussed considerations related to dosage optimization of new drug and biological products for pediatric patients with cancer. Dosage optimization is an integral aspect of oncology drug development and is important to maximizing the safety, efficacy, and tolerability of new drugs for pediatric cancers. Unique considerations associated with dosage selection and optimization in pediatric oncology include variability in pharmacokinetic and pharmacodynamic parameters by age and size, the need for age-appropriate formulations, potential for toxicities associated with long-term use, and the rarity of pediatric cancers. Representatives from the European Medicines Agency, the pediatric oncology investigator community, and the pharmaceutical industry were also invited to present. The issues that the Committee discussed included 1) the unique considerations associated with dosage optimization in pediatric oncology, 2) the potential challenges to identify an optimized dosage for new drugs and biological products for pediatric cancers and potential strategies to address these challenges, 3) the considerations the timing of dosage selection in adults impacts the timing of

trial initiation and dosage optimization in pediatric patients with cancers, and 4) the considerations for dosage optimization in pediatric oncology clinical trials investigating combination therapies. Agency Action: The Agency is reviewing recommendations made at the meeting.

Designated Federal Officer

She-Chia C. Jankowski Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Advani, Ranjana	12/08/2020	06/30/2024	Saul Rosenberg Professor of Lymphoma Division of Oncology, Stanford University School of Medicine	Special Government Employee (SGE) Member
Cheng, Jonathan	11/01/2019	10/31/2023	Senior Vice President, Head of Oncology Development Global Drug Development, Bristol-Myers Squibb	Representative 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
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

Lieu, Christopher	12/08/2020	06/30/2024	Associate Professor of Medicine; Associate Co-Director for Clinical Research; Director, Gastrointestinal Medical Oncology, University of Colorado 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
Mitchell, David	10/22/2019	06/30/2024	CONSUMER REPRESENTATIVE; President, Patients for Affordable Drugs	Special Government Employee (SGE) Member
Nieva, Jorge	06/15/2021	06/30/2024	Associate Professor of Clinical Medicine Section Head, Solid Tumors, University of Southern California Norris Comprehensive Cancer Cente, Keck School of Medicine of USC	Special Government Employee (SGE) Member
Pappo, Alberto	06/04/2015	06/30/2024	Member, St. Jude Faculty; Director, Solid Tumor Division; Co-Leader, Developmental Biology & Solid Tumor Program; Alvin Mauer Endowed Chair, St. Jude Children's Research Hospital	Special Government Employee (SGE) Member
Rosko, Ashley	06/15/2021	06/30/2024	Associate Professor, Division of Hematology; Medical Director Oncogeriatric, The Ohio State University Comprehensive Cancer Center	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: 11

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?

193

Number of Recommendations Comments

The Committee made 193 recommendations from FY-03 through FY-23.

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 product.

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