64-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0008]

Advisory Committee; Oncologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Oncologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Oncologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the September 1, 2028, expiration date.

DATES: Authority for the Oncologic Drugs Advisory Committee will expire on September 1, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993-0002, (301) 796-8220, ACOMSSubmissions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65, 21 CFR 14.40, and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Oncologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates 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.

The Committee shall consist of a core of at least thirteen voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. 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.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1)

expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the Committee and the variety in the types of issues that it will consider, or other reason determined appropriate in accordance with legal and regulatory requirements. 21 CFR §14.22(d).

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Members appointed to an advisory committee serve for the duration of the committee, or until their terms expire, they resign, or they are removed from membership by the Commissioner or designee. Committee members' terms may be ended prior to their date of expiration, for reasons determined to be good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by established procedures, or violation of other applicable rules and regulations.

The Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (Pediatric Subcommittee) is a permanent subcommittee of the Oncologic Drugs Advisory Committee described in Section 15 of the Best Pharmaceuticals for Children Act, Pub. L. 107-109. The Pediatric Subcommittee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers and provides advice on new and emerging therapeutic alternatives for children with cancer. Its functions include evaluating and, to the extent practicable, prioritizing new and emerging

pediatric cancer therapies; providing recommendations and guidance to help ensure timely access to promising new cancer therapies; and advising on ways to improve consistency in the availability of new therapeutic agents.

The Pediatric Subcommittee shall consist of up to 11 voting members appointed by the Secretary of Health and Human Services from the membership of the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee. As needed for the scientific and ethical consideration of pediatric cancer topics, the Pediatric Subcommittee may include or request participation from pediatric oncology specialists, including specialists from the National Cancer Institute, statisticians, representatives of pediatric cancer patients or patient-family organizations, representatives of the nursing community, representatives of the pharmaceutical industry, pediatric pharmacologists, and other scientific experts. Relevant expertise includes pediatric oncology, general oncology, hematologic oncology, immunologic oncology, clinical pharmacology, biostatistics, pediatric therapeutics, patient and family perspectives, and related scientific and ethical expertise.

Further information regarding the most recent charter and other information can be found at https://www.fda.gov/advisory-committees/oncologic-drugs-advisory-committee/oncologic-drugs-advisory-committee-charter or by contacting the Advisory Committee Oversight and Management Staff (see FOR FURTHER INFORMATION CONTACT). Because the committee's name and description of duties remain unchanged, 21 CFR 14.100 will not be amended.

RENEWAL REQUIREMENTS AND JUSTIFICATION: The Commissioner has determined that renewal of the Oncologic Drugs Advisory Committee is in the public interest. This determination is based on the Committee’s essential role in providing independent expert advice on the safety and effectiveness of marketed and investigational human drug

products for use in the treatment of cancer, the continued need for specialized expertise in this therapeutic area, and the Committee's demonstrated value in supporting FDA's regulatory mission. The following information supports this determination in accordance with applicable legal and regulatory requirements.

Public Interest Determination

Pursuant to 41 CFR § 102-3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the General Services Administration's Committee Management Secretariat (the Secretariat) and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 CFR § 102-3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee.

Information on the following factors for the committee is provided to the Secretariat to demonstrate that renewing the committee is in the public interest:

1. Annual budget

   Annual budget and expected costs: $286,942

   a. Federal personnel on a full-time equivalent (FTE) basis

      The estimated person years of Federal staff support is .40 at an estimated annual cost of $70,265.

   b. Other Federal internal costs

      The anticipated total value in USD of other internal costs, such as cost associated with IT supplies for meeting is $73,958.

   c. Proposed payments to members

      The estimated annual payment to members is $39,090.

d. Proposed number of members

The anticipated number of members is thirteen.

e. Reimbursable costs

The estimated annual reimbursable costs, including travel and related expenses for members, is $41,159.

2. If applicable, the total dollar value of grants expected to be recommended during the fiscal year

N/A

3. Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership

Ensuring Necessary Expertise:

Members must have background, education, and experience commensurate with the committee's function of advising FDA on the existing and relevant evidence of benefits and risks of marketed and investigational human drug products for use in the treatment of cancer and related specialties. Scientific and technical competence is critical. Nominees should be acknowledged experts with demonstrated skills in critical evaluation of data and effective communication. As outlined in the committee charter, the membership should include authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions, as well as needed consumer and industry representation. FDA also follows the requirements in section 505(n)(3) regarding membership of drug product advisory committees. (21 U.S.C. 355(n)(3)). Additionally, as outlined in the committee charter, relevant expertise for members of the pediatric subcommittee includes pediatric oncology, general oncology, hematologic oncology, immunologic oncology, clinical pharmacology, biostatistics, pediatric therapeutics, nursing, industry perspectives, patient and family perspectives, and related scientific and ethical expertise.

Ensuring Fair Balance:

Appointments are made without discrimination. The committee is reviewed in totality for balance, characterized by inclusion of necessary knowledge, insight, and scientific perspective from the relevant community or expertise area. Nominations are sought from all geographic locations within the United States and its territories, and from diverse sources including professional and scientific societies, academia, government agencies, industry and trade associations, consumer and patient organizations, and current Agency staff.

4. List of all other Federal advisory committees of the agency

   FDA maintains the following Federal advisory committees:

   - Anesthetic and Analgesic Drug Products Advisory Committee
   - Antimicrobial Drugs Advisory Committee
   - Blood Products Advisory Committee
   - Cardiovascular and Renal Drugs Advisory Committee
   - Cellular Tissue and Gene Therapies Advisory Committee
   - Dermatologic and Ophthalmic Drugs Advisory Committee
   - Device Good Manufacturing Practice Advisory Committee
   - Digital Health Advisory Committee
   - Drug Safety and Risk Management Advisory Committee
   - Endocrinologic and Metabolic Drugs Advisory Committee
   - Genetic Metabolic Disease Advisory Committee
   - Medical Devices Advisory Committee

- National Mammography Quality Assurance Advisory Committee (Administratively Inactive)
- Nonprescription Drugs Advisory Committee
- Obstetrics, Reproductive and Urologic Drugs Advisory Committee
- Pediatric Advisory Committee
- Peripheral and Central Nervous System Advisory Committee
- Pharmacy Compounding Advisory Committee
- Psychopharmacologic Drugs Advisory Committee
- Pulmonary-Allergy Drugs Advisory Committee
- Risk Communication Advisory Committee (Administratively Inactive)
- Science Board to the Food and Drug Administration
- Technical Electronic Product Radiation Safety Standards Committee
- Tobacco Products Scientific Advisory Committee
- Vaccines and Related Biological Products Advisory Committee

5. Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source The Oncologic Drugs Advisory Committee provides independent expert advice to FDA on the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer.

   The topics considered by the Oncologic Drugs Advisory Committee require specialized expertise in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and related specialties that is not within the primary scope of other FDA advisory committees. Potential topics that may need committee input

include products related to the topics outlined in Section (6) below. These and other issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue

   Summary of previous Accomplishments:

   In the last two years, ODAC met three times:

   On April 30, 2026, the Oncologic Drugs Advisory Committee met to discuss the following: On the morning of April 30, 2026, the Committee discussed new drug application (NDA) 220359, for camizestrant tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) is in combination with a CDK4/6 inhibitor (palbociclib, ribociclib or abemaciclib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon emergence of ESR1 mutation during first-line endocrine-based therapy, based on an FDA approved test. Agency Action: The Agency is reviewing recommendations made at the meeting.

   On the afternoon of April 30, 2026, the Committee discussed supplemental new drug application (sNDA) 218197/S-004, for Truqap (capivasertib) tablets, submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) is in combination with abiraterone for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) that is PTEN-deficient as detected by an FDA-approved test. Agency Action: The Agency is reviewing recommendations made at the meeting.

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 trials should be required in the future to assess the effectiveness of therapies 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 the proposed dosage in the proposed patient population. Agency Action: The Agency is reviewing recommendations made at the meeting

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business

   Reasons for Continuation:

   The committee plays a critical role in enabling FDA to meet the requirements of sections 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. Without the Oncologic Drugs Advisory Committee, FDA's ability to obtain external expert input on issues related to the approval and regulation of the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer would be significantly limited.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal **Advisory Committee** Act as amended (5 U.S.C. 1001 et seq.). For general information related to FDA advisory committees, please visit us at http://www.fda.gov/AdvisoryCommittees/default.htm.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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