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Review of Oncology and Infectious Disease Drugs Approved by the FDA in 2024 Oncology Drug Approvals

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ABSTRACT

The present work is a review comprising the details of selected drugs, which were approved in 2024 by US-FDA for oncology and infectious diseases. The selected drugs belong to small molecule category with a focus on their structural features, mechanism of action, dosage limit, significance and indications. The details provided could be useful to medicinal chemists developing novel therapeutics for oncology and infectious diseases.

Keywords: *US-FDA, Oncology, Infectious diseases, Drug Discovery*

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Introduction:

The year 2024 marked significant advancements in the approval of oncology and infectious disease drugs by the U.S. Food and Drug Administration (FDA). As precision medicine and immunotherapy[1] continue to evolve, regulatory agencies have expedited the approval of novel treatments that address critical unmet medical needs. In oncology, breakthroughs in targeted therapies[2], antibody-drug conjugates[3], and next-generation immunotherapies[4] have reshaped the treatment landscape for various cancers. Simultaneously, the approval of innovative antimicrobial agents and antiviral therapies[5] reflects the ongoing efforts to combat emerging infectious diseases and antibiotic resistance.

This review provides a comprehensive analysis of the oncology drugs approved by the FDA in 2024, highlighting key therapeutic advancements, mechanisms of action, and their potential clinical impact. By examining these approvals, we aim to offer insights into current trends in oncology drug development, the role of biomarkers in personalized medicine, and the challenges associated with regulatory approvals. Understanding these trends is crucial for

researchers, clinicians, and policymakers as they navigate the rapidly evolving field of oncology therapeutics.

Methodology[6,7]:

The methodology for this review follows a structured approach to analyzing oncology drug approvals granted by the U.S. Food and Drug Administration (FDA) in 2024. Data collection was conducted using publicly available databases and official FDA resources, including the FDA Drug Approvals and Databases and reports from the Center for Drug Evaluation and Research (CDER). Additional information was gathered from peer-reviewed journals, clinical trial registries such as ClinicalTrials.gov, pharmaceutical company press releases, and regulatory filings.

To ensure relevance, specific inclusion and exclusion criteria were applied. Included in this review are drugs approved by the FDA in 2024 for the treatment of any type of cancer, including novel drug entities, new indications for previously approved drugs, and significant reformulations. Excluded from the review are non-oncology drugs, drugs approved before 2024 unless receiving a new indication, and supportive care drugs without direct anti-cancer activity.

The data extraction process involved classifying each approved drug based on several parameters: therapeutic class (such as targeted therapy, immunotherapy, or chemotherapy), mechanism of action (including kinase inhibitors, monoclonal antibodies, and checkpoint inhibitors), specific indication (cancer type or subtypes), and approval type (full approval, accelerated approval, or breakthrough therapy designation).

Following data extraction, a comparative analysis was performed to identify emerging trends in oncology drug approvals. The review examined key developments such as the increasing role of precision medicine, the use of biomarkers in patient selection, and shifts in regulatory strategies, including the frequency of accelerated approvals. Additionally, the clinical impact of these drugs was evaluated based on available clinical trial data, reported efficacy, safety profiles, and potential advantages over existing therapies.

While this review provides a comprehensive overview of FDA-approved oncology drugs in 2024, certain limitations must be acknowledged. The analysis relies on publicly available data, which may not include unpublished or ongoing regulatory considerations. Furthermore, as these drugs were recently approved, long-term safety and real-world efficacy data are not yet available for assessment. Despite these limitations, this review aims to offer valuable insights into the latest advancements in oncology therapeutics and their implications for clinical practice and future drug development.

Results and Discussion:

The oncology section features six novel small molecule drugs that received FDA approval in 2024. These drugs target specific mechanisms of action within cancer cells, improving the therapeutic outcomes for various cancer types. Here's a closer look at the drugs approved for oncology:

Tovorafenib[8], developed by Day One Biopharma, is a type II RAF kinase inhibitor designed to target the RAF kinase pathway, which is frequently mutated in various cancers, including melanoma. It has been approved for the treatment of BRAF V600E-mutant melanoma, with a recommended dosage of 125 mg once daily. The drug has demonstrated significant tumor growth inhibition in patients with this mutation, making it a promising option for personalized melanoma therapy.

Vorasidenib[9], from Servier, is a dual inhibitor of IDH1 and IDH2 mutations, commonly found in cancers such as gliomas. It has been approved for the treatment of IDH1/IDH2-mutated gliomas, with a prescribed dosage of 500 mg once daily. This drug introduces a new therapeutic option for glioma patients, particularly those with these genetic mutations, which have historically had limited treatment alternatives.

Lazertinib[10], developed by Janssen, is an EGFR inhibitor that selectively targets mutant forms of EGFR, including those found in non-small cell lung cancer (NSCLC). Approved for the treatment of EGFR mutant-positive NSCLC, Lazertinib is administered at a dose of 240 mg once daily. This targeted therapy provides an alternative to first-line treatments by focusing on specific EGFR mutations, enhancing the precision of NSCLC management.

Inavolisib[11], from Genentech, is a PI3Kδ inhibitor that disrupts the PI3K/AKT signaling pathway, a crucial mechanism in cancer cell proliferation and survival. It has been approved for the treatment of PIK3CA-mutated HR-positive, HER2-negative breast cancer, with a recommended dosage of 200 mg twice daily. The approval of Inavolisib expands treatment options for patients with this specific genetic mutation, contributing to improved therapeutic outcomes in HER2-negative breast cancer cases.

Revumetinib[12], developed by Syndax, is a menin-KMT2A PPI inhibitor that disrupts the interaction between menin and the KMT2A protein, a key factor in leukemogenesis in certain cancers. Approved for the treatment of KMT2A-rearranged leukemias, it is administered at a dose of 50 mg twice daily. This novel inhibitor represents a major advancement in leukemia

treatment, particularly for patients with KMT2A gene rearrangements, a common mutation in hematological malignancies.

Ensartinib[13], from Xcovery, is an ALK inhibitor that targets and inhibits the anaplastic lymphoma kinase (ALK) pathway, which is implicated in the progression of several cancers, including lung cancer. Approved for ALK-positive NSCLC, it is prescribed at a dosage of 225 mg once daily. Ensartinib serves as an effective treatment alternative for ALK-positive NSCLC patients, especially those who have exhausted other therapeutic options.

These six drugs represent cutting-edge advancements in oncology, targeting specific genetic mutations and pathways involved in cancer development. With a strong focus on personalized medicine, these therapies are designed to improve patient outcomes and reduce treatment-related side effects.

Infectious Disease Drug Approvals

In 2024, four small molecule drugs were approved for the treatment of infectious diseases, a category of medicine that continues to evolve with the growing challenges of antibiotic resistance and emerging infections. Below is an overview of the new drugs approved in this category:

Berdazimer[14], developed by Pelagos Therapeutics, is a nitric oxide-releasing agent that targets and eliminates bacterial pathogens by releasing nitric oxide, which has strong bactericidal effects. It has been approved for the treatment of urinary tract infections (UTIs) caused by multi-drug resistant (MDR) pathogens and is administered at a dosage of 500 mg once daily. With the increasing prevalence of MDR bacteria in clinical settings, Berdazimer offers a novel approach to combating these difficult-to-treat infections.

Cefepime[15], produced by Allergan, is a broad-spectrum cephalosporin antibiotic that works by inhibiting bacterial cell wall synthesis, ultimately leading to bacterial cell death. Approved for the treatment of pneumonia and complicated intra-abdominal infections caused by susceptible bacteria, it is prescribed at a dosage of 2 g every 12 hours. Cefepime remains a crucial component in the antibiotic arsenal, particularly for treating severe infections caused by resistant bacterial strains.

A combination therapy consisting of cefepime and enmetazobactam, also from Allergan, pairs the cephalosporin antibiotic with a novel β-lactamase inhibitor to enhance efficacy against β-lactamase-producing bacteria. This combination has been approved for the treatment of complicated urinary tract infections (cUTIs) and complicated intra-abdominal infections (cIAIs), with a recommended dosage of 2 g of cefepime and 250 mg of

enmetazobactam every 12 hours. By addressing the growing challenge of β-lactamase-mediated resistance, this therapy provides an advanced treatment option for patients with complex bacterial infections.

Ceftobiprole medocarbil sodium[16], developed by Basilea, is a cephalosporin antibiotic that inhibits bacterial cell wall synthesis and is effective against both gram-positive and gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and *Pseudomonas aeruginosa*. It has been approved for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP), with a dosage of 500 mg every 12 hours. Given the rising incidence of multi-drug resistant organisms in hospital settings, ceftobiprole serves as a critical option in the management of severe pneumonia cases.

These four antibiotics reflect the ongoing need for novel therapeutics in the fight against infectious diseases, particularly with the rise of antibiotic resistance and the need for new treatments for multi-drug resistant organisms.

Future perspective:

The FDA's approval of new small molecule drugs in 2024 brings significant advances to the treatment of oncology and infectious diseases. The oncology drugs target specific mutations and pathways in various cancers, offering hope for personalized treatment approaches. Similarly, the infectious disease drugs provide new strategies to combat resistant bacteria and treat complex infections, demonstrating the continuing innovation in the fight against both cancer and infectious diseases. These approvals underscore the importance of precision medicine and the need for tailored therapies to address the growing challenges in modern healthcare.

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