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Advances in Oncology Drug Development

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Several drugs in development could achieve blockbuster status over the next decade



Oncology is the growth engine of the pharma industry. The oncology drug market totaled $193 billion in sales in 2021 and is estimated to reach $300 billion by 2028. Fueling the growth of this dynamic marketplace is the unrelenting pace of drug development, especially in the immuno-oncology arena and combinatorial approaches comprising immune checkpoint inhibitors in particular.

In 2022, the FDA approved 10 new oncology drugs – and countless label expansions, broadening the indications of many marketed novel therapies – including acclaimed antibody-drug conjugates (ADC), bispecific therapies, and therapies targeted to specific molecular markers. The diversity and sophisticated nature of 2022-approved oncology drugs exemplifies the exciting period of discovery and advancement we are in.

We witnessed three first-in-class bispecific therapy approvals: most recently, Lunsumio (mosunetuzumab; Genentech), a first-in-class CD20xCD3 T-cell engaging antibody for follicular lymphoma; Kimmtrak (tebentafusp; Immunocore), a gp100xCD3 protein for uveal melanoma; and Tecvayli (teclistamab; Janssen), a BCMAxCD3 antibody for multiple myeloma. In addition, Elahere (mirvetuximab soravtansine; ImmunoGen), a novel antifolate receptor ADC, is the first FDA-approved treatment for platinum-resistant ovarian cancer.

Another much-awaited biologic to reach the market is Imjudo (tremelimumab; AstraZeneca), a CTLA-4 inhibitor in combination with PD-L1 inhibitor Imfinzi (durvalumab) for hepatocellular carcinoma. Other noteworthy ‘firsts’ include Pluvicto (lutetium Lu177 vipivotide tetraxetan; Novartis), a radioligand therapy for PSMA-positive metastatic castrate-resistant prostate cancer

and Opdualag (a fixed dose combination of nivolumab and relatlimab; Bristol Myers Squibb), a dual-targeted PD-1 and LAG-3 inhibitor for malignant melanoma.

In addition, several novel therapies targeted to niche patient segments received the FDA nod: Krazati (adagrasib; Mirati) for KRAS G12C-mutated non-small-cell lung cancer (NSCLC), Rezlidhia (olutasidenib; Rigel) for acute myeloid leukemia patients with a susceptible IDH1 mutation, and Lytgobi (futibatinib; Taiho) for intrahepatic cholangiocarcinoma patients harboring FGFR2 gene fusions or other rearrangements.

So, what can we expect for 2023? Likely another long list of new oncology drug approvals comprising biologic and small-molecule therapies with an array of novel mechanisms and combination approaches, plus numerous label expansions.

Despite the oncology landscape being characterised by increased fragmentation and narrower patient populations, driven by the development and selective use of therapies targeted to molecular markers (e.g., *ROS1, ALK, KRAS G12C* in NSCLC), the era of the blockbuster is not over. Several drugs in development could achieve blockbuster status over the next decade. Drugs to watch are capivasertib (AstraZeneca), an oral small-molecule pan-AKT inhibitor therapy that has the potential to secure 2023 approval in HR-positive, HER2-negative breast cancer irrespective of biomarker status. For 2022-approved Tecvayli, success in ongoing Phase III trials could propel it to achieve sales of more than $1.5 billion through use in combination with other treatments and in earlier disease settings.

With the promise of continued oncology drug development in 2023 and beyond, if one thing is certain, it is that this development will drive rapid evolution of the oncology treatment landscape and dynamic markets.

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