Welcome to the *2023 PAYERS' GUIDE TO FDA UPDATES*: *Latest Approvals, Upcoming Decisions*

American Health & Drug Benefits is pleased to bring you the *2023 PAYERS' GUIDE TO FDA UPDATES: Latest Approvals, Upcoming Decisions*.

One objective of this *Guide* is to offer payers, providers, and other healthcare stakeholders an expert perspective on the challenges that the US healthcare system will face in 2023 and beyond. An article by Gary M. Owens, MD, provides his views on the many issues that are expected to significantly affect payers, such as rising healthcare costs driven by a postpandemic demand for services related to COVID-19 and other illnesses; increased pressure to raise prices; the growth of specialty drugs; cost impact of the Inflation Reduction Act for payers managing Medicare members; and the medical and cost consequences occurring with the spread of medical misinformation and the politicization of scientific findings.

The *Guide* also includes in-depth profiles on some important new US Food and Drug Administration (FDA) approvals from October 2022 to August 2023. In October 2022, tremelimumab-actl (IMJUDO) plus durvalumab (IMFINZI) was approved for the treatment of adult patients with unresectable hepatocellular carcinoma (HCC), and in November, the dual therapy was approved for the treatment of adults with non–small cell lung cancer (NSCLC) in combination with platinum-based chemotherapy. The approval of this immunotherapy regimen introduced a new, generally well-tolerated treatment option for patients with HCC or NSCLC.

A second profile delves into 2 newly approved FDA treatments for geographic atrophy (GA), an advanced form of age-related macular degeneration (AMD). GA causes progressive vision loss, resulting in permanent deterioration of vision. In fact, approximately 25% of cases of legal blindness in the United States can be attributed to GA, emphasizing the critical need for effective therapies because previously, no treatments had been approved to prevent onset or inhibit progression of GA. In February 2023, the FDA approved the use of pegcetacoplan injection (SYFOVRE) for the treatment of GA secondary to AMD, and in August 2023, the FDA approved avacincaptad pegol intravitreal solution (IZERVAY), also for the treatment of GA secondary to AMD.

Another objective of the *Guide* is to offer payers, providers, and other healthcare stakeholders a useful overview of new drugs approved by the FDA from October 2022 to August 2023. This entry represents a complete listing of all new molecular entities and new biologic license applications, and it provides all the new indications, new combinations, new dosages, new formulations, and new patient populations approved in the United States during that period.

In addition to the FDA approvals, the *Guide* provides a listing of what is in the FDA pipeline from October through December 2023, a forward-looking listing that allows payers, providers, and other healthcare stakeholders to anticipate what is likely coming in terms of approvals.

New technologies continue to feature high in today's drug development, with the ongoing introduction of new and improved biologic therapies, immunotherapies, and targeted therapies, while simultaneously making use of new testing and screening technologies to match the right patient with the right treatment.

The trend of accelerating the drug approval process continues, as evidenced by the many drugs approved under an expedited review pathway. Of the 21 approvals during January to August 4, 2023, 15 received fast track/accelerated/priority designation. Applying these various expedited review tracks to the drug approval process continues to show the FDA's commitment to innovation by encouraging pharmaceutical companies to focus their research and development on novel life-saving medications and, perhaps more important, giving patients earlier access to essential therapies.

Additional updates of new drugs and new indications will be posted online at **www.AHDBonline.com**, together with the full *Guide*.

We hope you find this publication a useful tool for applying up-to-date information on new pharmaceuticals to benefit design decisions and patient care.

EDITOR'S NOTE: The FDA continues to make changes to the prescribing information of many drugs on an ongoing basis. Every effort has been made to update the information in each drug update and any other sections of this publication based on each drug's prescribing information up to August 4, 2023. The Publisher is not responsible for any inaccuracies stemming from changes, new approvals, or company updates that became available after that date. Readers are advised to review the prescribing information for any future updates and revisions.