In the news

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Drug approvals in gastroenterology and hepatology in 2024

2024 saw the approvals of several drugs by the FDA and the EMA related to gastroenterology and hepatology.

Of the 50 FDA novel approvals, 5 were related to gastroenterology and hepatology. Specifically, Ziihera (Ziihera, Jazz Pharmaceuticals; zanidatamab, a bispecific HER2-directed antibody) was granted accelerated approval for the treatment of unresectable or metastatic HER2-positive biliary tract cancer. Vyloy (Astellas Pharma; zolbetuximab, a claudin 18.2-directed cytolytic antibody) was approved in combination with chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma, and Livdelzi (Gilead; seladelpar, a PPARD agonist) for the treatment of primary biliary cholangitis. Rezdiffra (Madrigal; resmetirom, a thyroid hormone receptor β agonist) was granted fast-track status and was approved in combination with diet and exercise for the treatment of non-cirrhotic metabolic dysfunction-associated steatohepatitis (formerly known as nonalcoholic steatohepatitis) with moderate to advanced liver fibrosis (F2 to F3 stages). Finally, Tevimbra (BeiGene; tislelizumab, a programmed cell death protein 1 blocking antibody) was approved for treating unresectable or metastatic oesophageal squamous cell carcinoma.

In 2024, the FDA also approved biosimilar products to Stelara (Janssen; ustekinumab, a monoclonal antibody targeting IL-12 and IL-23) for the treatment of moderate to severely active Crohn's disease and ulcerative colitis, which included Steqeyma (Celltrion), Yesintek (Biocon Biologics), Imuldosa (Janssen), Otulfi (Fresenius Kabi and Formycon) and Pyzchiva (Sandoz). For the treatment of moderate to severely active Crohn's disease in adults and paediatric patients >6 years of age and of moderately to severely active ulcerative colitis in adult patients, the FDA approved the biosimilar to Humira (AbbVie; adalimumab, a monoclonal antibody targeting TNF), Simlandi (Telva and Alvotech). For treating HER2-overexpressing metastatic gastric or gastro-oesophageal junction adenocarcinoma, the FDA approved Hercessi (Accord), a biosimilar to Herceptin (Genentech; trastuzumab, a monoclonal antibody that binds HER2 receptors).

Two drug approvals were expanded to include new paediatric populations. Lutathera (Novartis), a radiolabelled somatostatin analogue, was first approved in 2018 for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumours. Now, the patient population is extended to paediatric patients >12 years of age. Livmarli (Mirium; maralixibat), an ileal bile acid transporter inhibitor, was approved in 2021 to treat cholestatic pruritus in children with Alagille syndrome 1 year of age and older. The patient population is now extended to children 12 months or older to treat cholestatic pruritus with progressive familial intrahepatic cholestasis.

The EMA and the European Commission also authorized Livmarli to treat Alagille syndrome. Other EMA authorizations, specifically in oncology, include Imjudo (AstraZeneca; tremelimumab, a monoclonal antibody targeting CTLA-4), Nexavar (Bayer; sorafenib, a tyrosine kinase inhibitor) and Sorafenib Accord (Accord; sorafenib) for the treatment of hepatocellular carcinoma. Fruzaqla (Takeda; fruquintinib, an anti-VEGF receptor), Stivarga (Bayer; regorafenib, a tyrosine kinase inhibitor) and Vegzelma (Celltrion Healthcare Hungary; bevacizumab, a monoclonal antibody targeting VEGF), among others, were authorized for the treatment of colorectal neoplasms.

For the treatment of moderately to severely active Crohn's disease, the EMA and the European Commission authorized biosimilar products to Stelara, such as Absimky (Accord; also for moderately to severely active ulcerative colitis), Otulfi (Fresenius Kabi Deutschland) and Pyzchiva (Samsung Bioepis NL).

> "approvals of several drugs by the FDA and the EMA"

Finally, in 2024, the EMA and the European Commission authorized 40 drugs for the treatment of type 2 diabetes mellitus, such as Ebymect (AstraZeneca; dapagliflozin (an SGLT2 inhibitor), metformin), Byetta (AstraZeneca; exenatide, a GLP1 receptor agonist), Victoza (Novo Nordisk; liraglutide, a GLP1 receptor agonist) and Eucreas (Novartis; vildagliptin (a dipeptidyl peptidase-4 inhibitor), metformin).

Eleni Kotsiliti

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