New Approvals

- **Emflaza™ (deflazacort):** The Food and Drug Administration (FDA) approved Marathon Pharmaceutical’s corticosteroid Emflaza for Duchenne muscular dystrophy (DMD) in patients aged 5 years and older. Emflaza is the first corticosteroid approved by the FDA for DMD and will be available as a tablet and an oral suspension. Other generic corticosteroids, such as prednisone, have been commonly used for DMD and are recommended in guidelines. Deflazacort has been available in other countries for decades and is currently available in Canada for approximately $1,000 – $1,200 per patient annually. Marathon originally announced an $89,000 list price per patient per year, but due to backlash for the high price, Marathon has decided to pause the launch.

- **Parsabiv™ (etelacacetide):** The FDA approved Amgen’s Parsabiv for the treatment secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. Parsabiv is given via intravenous injection three times per week at the end of hemodialysis treatment.

- **Gammaplex 10% (immune globulin intravenous [human], 10% liquid):** Bio Products Laboratory received approval for their immune globulin product Gammaplex 10% for replacement therapy in primary humoral immunodeficiency in adults. Gammaplex 10% is also indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) in adults.

- **Siliq™ (brodalumab):** The FDA approved Valeant’s Siliq for the treatment of moderate-to-severe plaque psoriasis. Siliq is injected subcutaneously twice monthly. Siliq is a monoclonal antibody that targets the IL-17 receptor similar in mechanism of action to Cosentyx® and Taltz®. However, only Siliq labeling includes a Boxed Warning because of the observed risk of suicidal ideation and behavior, including completed suicides, seen in patients treated with Siliq during clinical trials. Siliq is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Siliq REMS Program. Physicians and pharmacies will have to be certified to prescribe and dispense Siliq and patients will have to sign informed consent agreements before taking it.

New Indications

- **Opdivo® (nivolumab):** The FDA granted accelerated approval to Opdivo for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing chemotherapy. This indication is based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
February news

● “Drugs approved in recent years that can cure hepatitis C may have severe side effects, including liver failure, a new report suggests. The number of adverse events appears relatively small, and the findings are not conclusive. But experts said the report was a warning that should not be ignored. It involves nine widely used antiviral drugs that were heralded as a huge advance because they greatly increased cure rates, seemingly with few side effects.”

● “Have drugmakers misused a decades-old law designed to spur research into rare, neglected diseases? Sen. Chuck Grassley says he aims to find out. The frequent pharma critic says he’s investigating whether ‘unanticipated uses’ of the Orphan Drug Act have helped boost U.S. drug prices.”

● “The FDA has accepted and granted Priority Review to the NDA of glecaprevir/pibrentasvir for the treatment of genotypes 1-6 (GT1-6) chronic hepatitis C virus (HCV) infection.”

● “Amgen announced that evolocumab (Repatha®) had met both its primary composite endpoint (cardiovascular death, non-fatal MI, non-fatal stroke, hospitalization for unstable angina, or coronary revascularization) and the even more rigorous key secondary composite endpoint (cardiovascular death, non-fatal MI, or non-fatal stroke) in the FOURIER trial.”

References


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