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Clinical Update

FDA Approves New Treatment for Multiple Sclerosis

On March 26, 2020, Bristol Myers Squibb™ (BMS) published a press release announcing the U.S. Food and Drug Administration's (FDA) approval of Zeposia® (ozanimod) oral capsules indicated for adult patients with relapsing forms of multiple sclerosis (RMS). Multiple Sclerosis is a rare disease that occurs when the body unintentionally damages the protective coating around the nerves, hindering communication between the brain and the rest of the body. Zeposia® offers patients a new oral treatment option to effectively combat worsening of RMS symptoms, for which treatment response can often vary. Clinical trials showed that patients taking Zeposia® compared to Avonex®, another RMS therapy, saw a more significant reduction in the rate of annual relapse and the number of brain lesions at one- and two-year time points. BMS has also announced that they will delay the launch of Zeposia® due to the ongoing COVID-19 pandemic.

Safety First

FDA Warns of Possible Device Malfunction and User Errors for Epinephrine Auto-Injector Devices

On March 24, 2020, the FDA notified the public that branded EpiPen®, EpiPen Jr.®, and authorized generic versions of epinephrine auto-injector devices may experience delayed injection or be prevented from properly injecting due to device failure. The manufacturers of these devices have detailed these potential outcomes in a letter sent to healthcare professionals and included specific user errors that could prevent administration of the intended dose of epinephrine. The FDA advises that the devices be inspected by pharmacists prior to dispensing and patients prior to use. Pharmacists and/or patients should contact Mylan Customer Relations at 800-796-9526 to obtain a replacement if they find an issue.

From the Industry

Injectable Diabetes Medicine Shows Benefit in Cardiovascular Outcomes

On March 17, 2020, the *Journal of the American College of Cardiology* (JACC) published results of the LEADER clinical trial that evaluated the effects of liraglutide on cardiovascular (CV) events and mortality in patients with type 2 diabetes (T2D). Liraglutide, commonly known as Victoza®, belongs to a class of anti-diabetic medications known as GLP-1 receptor agonists, which are non-insulin injectables used in combination with diet and exercise to help treat diabetes. The study evaluated the time it took for patients with and without heart failure history (class I-IV) to experience heart-related death, nonfatal heart attack, or nonfatal stroke. Results of the study showed patients taking liraglutide experienced fewer major heart-related events when compared to those treated with placebo, 13% versus 14.9%. The author concluded that the results suggest that liraglutide should be considered a suitable treatment option for patients with T2D regardless of heart failure history.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Zeposia® (ozanimod)
Oral capsule for the treatment of relapsing multiple sclerosis in adult patients [3/25/2020 – CELGENE]

New Dosage Form: Triferic AVNU® (ferric pyrophosphate citrate)
Intravenous injection for the replacement of iron to maintain hemoglobin in adult patients with chronic kidney disease requiring hemodialysis [3/27/2020 – ROCKWELL MEDICAL INC]

New Generics

New Generics Entering the Marketplace

Daraprim® (pyrimethamine)
Indication: Parasitic infection
Dosage Form/Strength: 25MG oral tablet
Average Wholesale Price (AWP): Generic = $47,813 | Brand = $54,000

Zortress® (everolimus)
Indication: Organ transplant rejection prevention
Dosage Form/Strength: 0.25MG, 0.5MG, 0.75MG oral tablet
Average Wholesale Price (AWP): Generic = $1,903-2,537 | Brand = $2,003-2,676*
*Costs based on standard initial dosing

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