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Clinical Update

FDA Approves First Treatment for COVID-19

On October 22, 2020, the U.S. Food and Drug Administration (FDA) approved Veklury® (remdesivir) for the treatment of coronavirus disease 2019 (COVID-19), an illness caused by the SARS-CoV-2 virus that that can range in severity from mild/moderate to sometimes fatal disease. This approval was for hospitalized patients 12 years and older weighing at least 88 pounds. Veklury®, an intravenous (IV) injection that is given once a day for up to 10 days, works by inhibiting the activity of an enzyme that the virus needs to replicate. Data from three key clinical trials were analyzed to support the approval of Veklury®. The Adaptive COVID-19 Treatment Trial (ACTT-1) indicated that patients treated with Veklury® had a statistically significant lower median time to recovery when compared to placebo (10 days vs. 15 days), and the odds of clinical improvement at day 15 were also significantly higher in the Veklury® group. Overall mortality rates seen in the trial at day 15 were 6.7% in the Veklury® group compared to 11.9% in the placebo group. Data from two other trials, which explored the safety and efficacy of a 5-day treatment course vs. 10-day treatment course, provided further support for the approval. This approval comes after an initial Emergency Use Authorization (EUA), issued on May 1, 2020, as part of the FDA's Coronavirus Treatment Acceleration Program (CTAP), which has been updated following this approval, and allows continued use of Veklury® in hospitalized pediatric patients weighing between 7.7 and 88 pounds. Approval of Veklury® denotes an important step in addressing the ongoing COVID-19 pandemic, offering a treatment option that has been shown to decrease duration of symptoms and overall mortality in those infected with the virus.

Safety First

Sunstar Americas Inc. Issues Voluntary Recall of Paroex® Chlorhexidine Oral Rinse

On October 27, 2020, the FDA published a company announcement regarding a voluntary recall of Paroex® Chlorhexidine Gluconate Oral Rinse USP, 0.12%. Paroex®, indicated for use as part of a treatment regimen for gingivitis, and is distributed to pharmacies, dental offices and schools, as well as pharmaceutical wholesalers and distributors. Sunstar Americas Inc. (SAI) has recalled all products expiring between June 30 and September 30, 2022, as they may be contaminated with the bacteria Burkholderia lata. Although no adverse events have been reported, the use of contaminated products may result in infections requiring treatment with antibiotics. In high-risk patients (i.e., immunocompromised patients), the contaminants may cause more life-threatening infections, such as pneumonia and bacteremia, an infection of the bloodstream. Anyone who may have used these recalled products and/or wants to report any complications associated with these products may do so via the FDA's MedWatch Adverse Event Reporting Program. SAI is in the process of notifying customers of the recall and organizing for the return of potentially contaminated products. It is advised that use and dispensing of these products be stopped immediately.

From the Industry

Novel Cream Studied as Treatment for Rosacea

On September 3, 2020 the results of the "Rosazel" trial showed potential for a novel cream being studied as a treatment option for patients diagnosed with rosacea. Rosacea is a common chronic inflammatory skin disease often characterized by flushing, facial redness and bumps, which can spread across several areas of the face and even to the chest and back. Individuals with rosacea may also develop acne and inflammatory lesions. Although the exact cause of rosacea is unknown, it is suspected that patients with rosacea have altered metabolism of an important antioxidant, glutathione (GSH), which has been shown to help combat cellular = inflammation. While current treatment options work to decrease signs and symptoms of the disease by targeting and restricting blood vessels, the novel cream being studied aims to target inflammation by increasing intracellular GSH. In the "Rosazel" trial, the cream studied contained a combination of GSH C4 (0.1%), a modified GSH molecule that has been shown to remain more readily available in the body longer than naturally occurring GSH, as well as beta Glycyrrhetic (0.5%) and azelaic acids (10%), with an SPF of 30. Patients in the study were evaluated at baseline, 4 weeks and 8 weeks. Results showed a 63% reduction in inflammatory lesion count from baseline to the 8-week mark, with tolerability comparable to other topical treatments for rosacea. This combination cream may provide patients suffering from rosacea with a new treatment option.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Veklury® (remdesivir)
Intravenous injection approved for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization in patients 12 years and older, weighing at least 88 pounds [10/22/20 – Fast Track; Material Threat Medical Countermeasure Priority Review Voucher; Priority Review – GILEAD SCIENCES INC]

New Indication: Eysuvis™ (loteprednol etabonate)
Ophthalmic suspension approved for the treatment of signs and symptoms of dry eye disease for up to two weeks [10/26/20 – KALA PHARMS INC]insufficiency, a disease in which the body does not produce enough steroid hormones. [9/29/20 – Orphan Drug – DIURNAL LTD]

New Generics

New Generics Entering the Marketplace

Truvada® (emtricitabine/tenofovir disoproxil fumarate)
Indication: HIV-1 Infection and HIV-1 Pre-Exposure Prophylaxis (PrEP)
Dosage Form/Strength: 200-300 MG Film-Coated Oral Tablet
Average Wholesale Price (AWP): Generic = $2,100 | Brand = $2,211

Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
Indication: HIV-1 Infection
Dosage Form/Strength: 600-200-300 MG Film-Coated Oral Tablet
Average Wholesale Price (AWP): Generic = $3,414 | Brand =$3,594

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