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Clinical Update

FDA Approves New Topical Acne Treatment

On August 27, 2020, the U.S. Food and Drug Administration (FDA) approved Winlevi® (clascoterone 1% cream) for the treatment of acne vulgaris in patients 12 years and older. Acne is a skin condition characterized by excess oil production, clogged pores, bacteria growth and inflammation. Winlevi® is the first acne medication to target androgens (hormones) directly in the skin and works by limiting the effects that these hormones have on oil production and inflammation. Results from a clinical trial enrolling patients 9 years and older with facial acne vulgaris, showed that Winlevi® decreased the number and severity of both inflammatory and non-inflammatory lesions when compared to placebo, in patients aged 12 years and older, over a 12-week period. Mild local skin irritation and swelling were the most commonly observed side effects. The manufacturer expects that Winlevi® will be made available in the U.S. in early 2021.

Safety First

FDA Requiring Labeling Changes for Benzodiazepines

On September 23, 2020, the FDA released a Drug Safety Communication about a Boxed Warning update and new class-wide labeling requirements for benzodiazepines. The changes require the disclosure of the risk of abuse, misuse, addiction, physical dependence and withdrawal reactions to help improve the safe use of these medications. Benzodiazepines are commonly used medications and are approved treatment options for generalized anxiety disorder, insomnia, seizures, social phobia and panic disorder. Benzodiazepines are typically recommended to use for weeks to months at a time, but the dose, frequency and duration of treatment may vary on a case-by-case basis. A physical dependence to benzodiazepines can occur after just days to weeks of use. Discontinuing benzodiazepines abruptly can result in acute and potentially life-threatening withdrawal reactions. The FDA is also requiring changes to the "Warning and Precautions," "Drug Abuse and Dependence" and "Patient Counseling Information" sections of the prescribing information for all benzodiazepine products. Medication Guides given to patients will also be updated to reflect the new requirements. These measures are part of the FDA's ongoing effort to help health care providers better understand the risks associated with inappropriate use of controlled substances while enabling appropriate access to these products for medical use.

From the Industry

FDA Grants Breakthrough Therapy Status to Magrolimab

On September 15, 2020, Gilead announced that the FDA has given magrolimab a Breakthrough Therapy designation for treatment of Myelodysplastic Syndrome (MDS). MDS, often referred to as "bone marrow failure disorder," is a condition in which the body does not produce an adequate number of normal, healthy blood cells in the bone marrow. This rare blood cancer has an average survival rate of six years for lower-risk disease and 18 months for higher-risk disease. Magrolimab is a first-in-class anti-CD47 monoclonal antibody designed to stop cancer cells from going unnoticed by macrophages, a key part of the body's immune system. Data released from Phase 1b trials evaluated 68 patients with either untreated higher-risk MDS or with untreated Acute Myeloid Leukemia (AML) who were ineligible for intensive chemotherapy. All 68 patients received magrolimab infused intravenously (IV) either once weekly or every two weeks in combination with azacitidine. Results of the study showed 91% of MDS patients reached an objective response (OR) and 42% achieved a complete response (CR), while 64% of AML patients achieved an OR and 56% achieved a CR with or without blood cell counts returning to normal levels. Common adverse effects in this limited patient population included anemia, fatigue, low white blood cell count (neutropenia), low platelet count and infusion reactions. Magrolimab has been given an Orphan Drug designation by the FDA for MDS and AML, and has been given a Fast-Track designation for MDS, AML, diffuse large b-cell lymphoma (DLBCL) and follicular lymphoma.

FDA Approvals

Recent FDA Approvals

New Dosage Form: Xeljanz® (tofacitinib citrate)
Oral solution approved for the treatment of adult patients with active moderate to severe rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, or polyarticular course juvenile idiopathic arthritis.. [9/25/20 – Priority Review – PFIZER INC]

New Dosage Form: Alkindi® Sprinkle (hydrocortisone)
Oral granules, intended to be sprinkled over soft food, indicated as replacement therapy in pediatric patients with adrenocortical 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

Kuvan® (sapropterin dihydrochloride)
Indication: Hyperphenylalaninemia in patients with phenylketonuria (high levels of phenylalanine in the blood)
Dosage Form/Strength: 100MG, 500MG Powder; 100MG Tablet
Average Wholesale Price (AWP): Generic = $1,306 – $6,528* | Brand = $1,451 – $7,254*

*Dosage regimen is based on weight, therefore prices are per package (30 powder packets or 120 tablets)

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