PULSE

Your source for the latest industry trends and drug information news.

Pharmacy Benefit Dimensions®

March 1, 2020 Volume 2 | Issue 5

Clinical Updates

FDA approves first treatment for children with peanut allergy

On Jan. 31, 2020, the U.S. Food and Drug Administration (FDA) approved Palforzia™ (Peanut Allergen Powder) as the first treatment to reduce allergic reactions caused by peanut exposure in patients 4 to 17 years old. Allergic reactions to peanuts vary in presentation and can be life threatening. The medication works by providing gradual exposure to small amounts of peanut allergen over time. In clinical trials, 67% of patients on Palforzia™ were able to tolerate exposure to peanut proteins compared to only 4% of patients receiving a placebo. Contingent with the approval by the FDA, Palforzia™ was assigned a mandatory REMS program with the goal of reducing the risk of a severe allergic reaction caused by the medication. The program requires that initial doses and each subsequent dose increase occur in a health care setting equipped to monitor patients and manage allergic reactions, if necessary. The program also requires patients to be informed to avoid dietary peanuts as well as carry injectable epinephrine with them at all times.

Safety First

FDA requests withdrawal of weight-loss medication from U.S. market

On Feb. 13, 2020, the FDA issued a Drug Safety Communication to patients and health care professionals regarding the weight-loss medicines as Belviq®/Belviq® XR (lorcaserin). The communication details the request made by the FDA for the manufacturer, Eisai Inc., to remove the medicines from the market due to results from a safety clinical trial that showed an increased occurrence of cancer. This follows a January 2020 communication in which the FDA alerted the public about a possible risk of cancer associated with the medicines based on preliminary analysis of clinical trial data. The FDA has advised patients to stop taking lorcaserin and to discuss alternative therapies with their health care providers. The FDA has also advised health professionals to stop prescribing and dispensing the medication to their patients. The manufacturer has subsequently submitted a request to voluntarily withdraw the drug from the market.

From the Industry

Rinvoq™ meets endpoints for psoriatic arthritis in phase 3 trial

On Feb. 5, 2020, AbbVie, Inc. announced that Rinvoq™ (upadicitinib) achieved the clinical endpoints targeted in its phase 3 study in patients with psoriatic arthritis (PsA). PsA is a type of inflammatory arthritis that can result in significant joint pain, stiffness, and swelling. Currently, Rinvoq™ is only approved to treat rheumatoid arthritis (RA). In the phase 3 study, Rinvoq™ was found to significantly improve joint symptoms and decrease progression of the condition (confirmed by imaging) when compared to a placebo. In addition, a higher dose of Rinvoq™ also demonstrated superiority to Humira® (adalimumab). The safety of the medication was consistent with prior trials and no new safety risks were discovered. If approved, Rinvoq™ will offer a new oral treatment option for patients affected by PsA.

Recent FDA Approvals

New Formulation: Pemfexy™ (pemetrexed)
Intravenous solution for the treatment of a subset of lung cancer, known as non-squamous non-small cell lung cancer (NSCLC) in adult patients [2/8/2020 – EAGLE PHARMS]

Novel Drug Approval: Pizensy™ (lactitol)
Oral solution for the treatment of chronic idiopathic constipation (CIC) in adult patients [2/12/2020 – BRAINTREE LABS]

New Dosage Form: Twirla™ (levonorgestrel; ethinyl estradiol)
Transdermal patch used for contraception in women of reproductive potential [2/14/2020 – AGILE THERAPEUTICS INC]

New Generics Entering the Marketplace*

***As of this issue, there were no new generics entering the marketplace. However, there are several projected launches we are monitoring, including:**

Taytulla® (ethinyl estradiol; norethindrone acetate)
Indication: Contraception
Dosage Form/Strength: 1 mg/20mcg tablet
Projected Launch Date: March 2020

Zortress® (everolimus)
Indication: Immunosuppressant
Dosage Form/Strength: 0.25, 0.5, and 0.75 mg tablets
Projected Launch Date: March 2020

Humalog® Mix 75/25™ Kwikpen™ (insulin lispro)
Indication: Diabetes
Dosage Form/Strength: 75%/25% injectable
Projected Launch Date: April 2020

Chief Author: Kevin Lavery, PharmD
Editor: Dana Ranallo, PharmD