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Clinical Update

BioNTech Reports Potential Breakthrough with MS Vaccine Development

BioNTech, the same company that developed a COVID-19 vaccine in partnership with Pfizer, is now hoping to apply the same novel messenger ribonucleic acid (mRNA) technology used for the COVID-19 vaccine to create a vaccine for multiple sclerosis (MS). MS is an autoimmune disorder in which a person's immune system attacks the outermost insulating layer that protects nerve cells in the brain and spinal cord, also known as myelin sheath. This damage results in a variety of neurological symptoms such as numbness, tingling, mood changes, memory problems and paralysis. There are many disease-modifying medications for MS on the market today that are effective in improving quality of life but can consequently leave patients with weakened immune systems. BioNTech is leading research to investigate how an mRNA vaccine may work for MS. Most conventional vaccines contain a weakened or inactivated disease-causing organism (i.e., viruses, bacteria) that helps the body produce an active immune response when encountering the organism in the future. Conversely, mRNA vaccines contain genetic material which functions as a "blueprint" for cells to produce a response targeted at the myelin-destructing cells without inducing systemic immune suppression the way many traditional MS medications would. Mouse models of MS showed that administration of an mRNA vaccine helped control symptoms and prevented progression of disease in sick animals. Trial of the vaccine has not yet progressed to humans.

Safety First

Fresenius Kabi Issues Voluntary Recall of Ketorolac Injection

On January 8, 2021, the U.S. Food and Drug Administration (FDA) announced the voluntary recall of a single lot of ketorolac tromethamine injection by the manufacturer, Fresenius Kabi. Ketorolac, a nonsteroidal anti-inflammatory drug (NSAID), is used for short-term pain management. The recall stems from the discovery of particulate matter in reserve sample vials. The risks of particulate matter entering the blood stream include local irritation of blood vessels, injection site swelling, inflammation, infection and formation of life-threatening blood clots. Information regarding the recalled lot, produced and sold in 2019, can be found on the FDA's website. Fresenius Kabi is notifying distributors to remove any affected product from stock. Distributors should inform their customers of the recall and direct them to discontinue use of the affected lot. Anyone who has experienced problems related to using this medication should contact their physician or health care provider. No adverse events have been reported to the FDA's MedWatch Adverse Event Reporting program thus far.

From the Industry

Regeneron Inks Coronavirus Antibody Supply Deal Worth up to $2.6B

On January 12, 2021, Regeneron announced a new agreement with the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD) to provide another 1.25 million doses of its COVID-19 antibody cocktail, casirivimab and imdevimab. The cocktail was given an FDA emergency use authorization (EUA) for COVID-19 patients with mild to moderate cases who are at high risk of progressing to severe disease. Regeneron has already agreed to supply doses to treat approximately 300,000 people, bringing the total purchases to more than1.5 million doses. The U.S. government will be responsible for coordinating the allocation and distribution of the medication at no cost to patients, although health care facilities may charge fees related to administration. The current authorized dose for emergency use in non-hospitalized patients is a one-time 2,400 mg infusion (1,200 mg casirivimab and 1,200 mg imdevimab), and Regeneron is also evaluating the safety and efficacy of a lower 1,200 mg infusion (600 mg casirivimab and 600 mg imdevimab). Clinical trials have shown that patients who have been treated with the antibody cocktail experienced significant reductions in virus levels and required fewer overall medical visits.

FDA Approvals

Recent FDA Approvals

Novel Drug Approval: Verquvo™ (vericiguat)
Oral tablet approved for reducing the risk of cardiovascular death and heart failure (HF) hospitalization in adults with symptomatic chronic HF with an ejection fraction less than 45%, following a hospitalization for HF or exacerbation requiring outpatient IV diuretics [1/19/21 – Priority Review – MERCK SHARPE DOHME]

New Generics

New Generics Entering the Marketplace

Amitiza® (lubiprostone)
Indication: Treatment of chronic idiopathic constipation, opioid-induced constipation (OIC) in adults with chronic, non-cancer related pain, and irritable bowel syndrome with constipation (IBS-C) in women 18 years and older.
Dosage Form/Strength: 8 and 24 MCG Oral capsules
Average Wholesale Price (AWP): Generic = $401 | Brand = $445

Naprelan® (naproxen)
Indication: Nonsteroidal Anti-Inflammatory Drug (NSAID)
Dosage Form/Strength: 750 MG ER Oral tablets
Average Wholesale Price (AWP):
Generic = $740 | Brand = $831

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