# PULSE

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## Clinical Pharmacy Update

### FDA Approves Ponvory™ for Relapsing Multiple Sclerosis

On March 19, 2021, the U.S. Food and Drug Administration (FDA) approved Ponvory™ (ponesimod) oral tablets for the treatment of adults with relapsing forms of 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 may result in a variety of neurological symptoms such as numbness, tingling, mood changes, memory problems and paralysis. Relapsing MS involves periods of increased neurological symptoms followed by periods of complete or partial disease recovery. Approved treatments for MS can be used to slow the progression of disease, manage symptoms, and control relapses. Ponvory™ works by attaching to a type of white blood cell involved in the body's immune system, often called lymphocytes, which blocks them from entering the bloodstream. As a result, the blocked lymphocytes are unable to travel to the central nervous system and cause damage to the myelin sheath. This approval comes after analysis of a Phase 3 trial showed patients treated with once daily Ponvory™ experienced a greater reduction in annual relapse rate compared to Aubagio® (teriflunomide), another oral treatment for MS. Over the two-year study, 71% of patients treated with Ponvory™ reported no relapses compared to 61% in the group treated with Aubagio®. Ponvory™ was generally well tolerated and had similar adverse event rates to Aubagio® and placebo, with the most common adverse effects being respiratory infection, abnormal liver tests and high blood pressure. Ponvory™, which is now available on the market, will provide an additional treatment option for patients with relapsing MS.

## Drug Safety

### Nationwide Recall of Guanfacine ER Due to Contamination

On March 31, 2021, the FDA announced voluntary recall of guanfacine extended-release tablets by Apotex Corp. The recall was made following the discovery of trace amounts of quetiapine in one lot. Two other lots, which were manufactured around the same time as the contaminated lot, are also being recalled. All affected lots were distributed between December 22, 2020, and March 19, 2021. Guanfacine extended-release tablets are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Quetiapine is an antipsychotic medication indicated for the treatment of Schizophrenia, major depression, and Bipolar disorder. Administration of trace amounts of quetiapine may lead to lowering of blood pressure, sleepiness/sedation, dizziness or result in an allergic reaction. Patients who are elderly, pediatric, or pregnant may be more likely to experience low blood pressure or dizziness. Patients are advised to contact their health care provider if they have experienced any complications related to taking this drug. Apotex is arranging the return of all recalled product from all wholesalers, distributers and retailers and questions regarding the recall can be made directly to Apotex by phone or email. As of March 31, 2021, no adverse events related to the affected lots have been reported to Apotex. Adverse reactions or quality problems should be reported to the FDA's MedWatch Adverse Event Reporting Program.

## From the Pharmaceutical Industry

### J&J Vaccinations Halted After Rare Clotting Cases Emerge

On April 13, 2021, the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) issued a joint statement calling for a pause in the use of Johnson & Johnson's single-dose coronavirus vaccine in the U.S. while they study the emergence of a rare blood clotting disorder that developed in six American women between the ages of 18 and 48, each of which developed the illness within two weeks of vaccination. As of April 13, 2021, one woman has died and a second woman in Nebraska has been hospitalized in critical condition. Nearly 7 million people in the United States have received Johnson & Johnson shots so far, and about 9 million more doses have been shipped out to the states, according to data from the CDC. States have been quick to act on the recommendation, with Ohio, New York, Connecticut, Nebraska, and others advising healthcare providers in their respective states to discontinue giving the J&J vaccine for the time being. Data from specially held meetings of the CDC Advisory Committee on Immunization Practices will be used by the FDA to support their investigation. Prior to the completion of the investigation, the CDC and FDA are recommending a pause on the use of the vaccine. Healthcare providers have been asked to report any adverse events related to the COVID vaccine to the Vaccine Adverse Event Reporting System.

## FDA Approvals

### New FDA Drug Approvals

**Novel Drug Approval: Ponvory™ (ponesimod)**
Oral tablet approved for the treatment of relapsing forms of multiple sclerosis (MS) [3/18/21 – JANSSEN PHARMS]

**Novel Drug Approval: Zegalogue® (dasiglucagon)**
Autoinjector and prefilled syringe indicated for the treatment of severe hypoglycemia (low blood sugar) in pediatric and adult patients with diabetes age 6 years and above [3/22/21 – ZEALAND PHARMA AS]

## New Generics

### New Generic Medications Entering the Marketplace

*As of this issue, there have been no new generics to market.


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