New indications

- **Viekira XR™ (ombitasvir, paritaprevir, ritonavir, dasabuvir):** AbbVie’s Viekira XR was recently approved for the treatment of patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection. Viekira XR is a once-daily, extended-release co-formulation of the active ingredients in Viekira Pak® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets).

- **Dysport® (abobotulinumtoxinA):** The Food and Drug Administration (FDA) has approved Ipsen Biopharmaceuticals’ Dysport for the treatment of lower limb spasticity in pediatric patients ages 2 years and older. Dysport was previously approved for the treatment of adults with cervical dystonia and the treatment of upper limb spasticity in adult patients.

- **Keytruda® (pembrolizumab):** The FDA has approved Merck’s Keytruda for use in the treatment of head and neck cancer by the FDA. Keytruda was previously approved for use in melanoma and non-small cell lung cancer.

August news

- “Natco Pharma Ltd. has announced the final approval of its abbreviated new drug application filed with the FDA for 30 mg, 45 mg, and 75 mg oseltamivir phosphate oral capsules—a generic version of Genentech’s Tamiflu®. Natco and its marketing partner Alvogen, Inc., are the first generic-drug companies to receive this approval. In December 2015, Natco and Alvogen settled a patent infringement suit with Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd., and Genentech, Inc. Under the terms of the settlement, Alvogen will be able to market the oseltamivir phosphate capsules before the expiration of the pediatric exclusivity period listed in the FDA’s Orange Book, which is February 23, 2017.”

- “In a dramatic seesaw effect today, Bristol-Myers Squibb (BMS) watched its share price plunge 20% while competitor Merck & Co.’s soared 10% after BMS said its cancer wonder drug Opdivo® had failed to meet goals for use as a first-line treatment for lung cancer. Opdivo and Merck’s Keytruda have been battling for market share in a variety of cancer forms, but the first-line use in lung cancer, which kills more people in the U.S. than any other cancer, is seen as very important for the immuno-oncology drugs, with the possibility of adding billions of dollars in annual sales. It is seen as so important by investors that the news swept away nearly $25 billion in market value for New York-based BMS in premarket trading before pressure on its shares eased.”
“Portola has been dealt a blow after its anticoagulation reversal drug AndexXa was rejected by the US Food and Drug Administration. The group was seeking approval for the use of its first-in-class drug in patients treated with a direct (apixaban, rivaroxaban, or edoxaban) or indirect (enoxaparin) Factor Xa inhibitor when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. The file included data from the Phase III ANNEXA-A trial, which showed that AndexXa (andexanet alfa) rapidly reversed the anticoagulant effect of Pfizer/Bristol-Myers Squibb’s Eliquis® (apixaban) by 93.5 percent, and sustained a high level of efficacy across the two-hour infusion period. However, the FDA has sent the firm a Complete Response Letter in which it asks for more information, primarily related to manufacturing.”

“Sanofi spent $245 million on a priority review voucher to beat Novo Nordisk to market with a diabetes med pairing a basal insulin with a GLP-1. But the FDA had other ideas. After that fast-track review, the agency pushed Sanofi’s Lantus-plus-lixisenatide combo off till November at the least. The FDA asked Sanofi for more data on the dual-drug delivery pen—a device that triggered debate during an FDA advisory panel review in May.”

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