From: APhA's Pharmacy Today

Date sent 12/23/2015 05:12:30 am

Subject: December 23, 2015: FDA approves orphan drug to treat PAH

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Pharmacy Today

DECEMBER 23, 2015

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FDA approves orphan drug to treat PAH
FDA News Release (12/22/15)

FDA has approved selexipag (Uptravi—Actelion Pharmaceuticals US) for the treatment of pulmonary arterial hypertension (PAH) in adults. The new drug is an oral IP prostacyclin receptor agonist, which acts by relaxing muscles in the walls of blood vessels to dilate blood vessels and reduce the elevated pressure in the vessels supplying blood to the lungs. A long-term clinical trial involving more than 1,100 individuals with PAH found selexipag was effective in reducing... Read More

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DRUGS & DISEASES

FDA approves lesinurad to treat high blood uric acid levels associated with gout
FDA News Release (12/22/15)

FDA on Tuesday approved lesinurad (Zurampic—AstraZeneca Pharmaceuticals) to treat high levels of uric acid in the blood (hyperuricemia) associated with gout, when used in combination with a xanthine oxidase inhibitor (XOI), a type of drug approved to reduce the production of uric acid in the body. "Controlling hyperuricemia is critical to the long-term treatment of gout," said Badrul Chowdhury, MD, director of the Division of Pulmonary, Allergy and Rheumatology Products in FDA's Center for Drug Evaluation and Research. "[Lesinurad] provides a new treatment option for the millions of people who may develop gout over their lifetimes." The drug works by helping the kidney excrete uric acid. It does this by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney. FDA is also requiring a postmarketing study to further evaluate the renal and cardiovascular safety of the drug.

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Effectiveness of analgesics for patients being treated for lung condition
Journal of the American Medical Association (12/22/15) Vol. 314, No. 24, P. 2641 Rahman, Najib M.; Pepperell, Justin; Rehal, Sunita; et al.

Researchers conducted a Phase III trial to assess the effect of chest-tube size and analgesia (NSAIDs vs opiates) on pain and efficacy related to pleurodesis in patients with malignant pleural effusion. The study included patients requiring pleurodesis in 16 U.K. hospitals. Of 206 patients undergoing thoracoscopy, they received a 24F chest tube, and were randomized to receive either opiates or NSAIDs. The 114 not undergoing thoracoscopy were randomized to one of four groups: 24F chest tube and opioids; 24F chest tube and NSAIDs; 12F chest tube and opioids; or 12F chest tube and NSAIDs. Pain scores in the opiate group compared with the NSAID group were not significantly different, but patients in the NSAID group required more rescue analgesia. Pain scores were lower among participants in the 12F chest tube group compared with the 24F group. The 12F chest tubes compared with 24F chest tubes were associated with higher pleurodesis failure and more complications during insertion. NSAID use showed noninferior rates of pleurodesis efficacy at 3 months.

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FDA probing latest E.coli outbreak linked to Chipotle
Reuters (12/22/15)

FDA said on Tuesday it is investigating the more recent outbreak of a rare strain of E.coli linked to Chipotle Mexican Grill. FDA said it is working with CDC and state and local officials. CDC said on Monday it was investigating five new cases of E.coli infections, one each in Kansas and North Dakota and three in Oklahoma. Chipotle has been linked to a previous E.coli outbreak that has sickened 53 people in nine states with a different strain since late October. The latest reports take the number of people sickened by E.coli outbreaks linked to Chipotle to 58 and the states affected to 12. FDA said on Tuesday the evidence available suggests that a common meal item or ingredient served at Chipotle's restaurants in several states is a likely source of both the outbreaks.

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Why a drug to prevent HIV infection is in low demand
Wall Street Journal (12/21/15) Reddy, Sumathi

Public-health officials are trying to encourage more people to take the preexposure prophylaxis (PrEP) drug emtricitabine–tenofovir disoproxil fumarate (Truvada—Gilead), which could help prevent HIV infection among high-risk individuals. PrEP is a daily medication that was approved by FDA in 2012. Although CDC reports that about 50,000 people in the United States become infected with HIV annually, fewer than 22,000 are estimated to have taken PrEP, according to a recent report. PrEP can reduce the risk of HIV infection through sexual transmission by as much as 92%, and by about 70% through I.V. drug use. Still, only about 66% of primary-care doctors know about the medication. Some organizations are concerned that promotion of the drug could encourage risky behavior, but at least one study has found that use of the drug was associated with unchanged or lower risky behavior. PrEP can cost between $8,000 and $14,000 a year, but it is covered by most private insurers and by many state Medicaid programs.

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Bevacizumab for newly diagnosed pleural mesothelioma
The Lancet (12/21/2015) Zalcman, Gerard; Mazieres, Julien; Margery, Jacques; et al.

Adding bevacizumab to pemetrexed plus cisplatin can increase overall survival (OS) in patients with malignant pleural mesothelioma, according to a new study. The randomized phase III trial assessed the effects of adding bevacizumab

to standard care in 448 patients. The data showed that patients who took pemetrexed plus cisplatin with bevacizumab had a significantly higher overall survival rate, with a median of 18.8 months survival compared with 16.1 months for standard care alone. "Addition of bevacizumab to pemetrexed plus cisplatin significantly improved OS in malignant pleural mesothelioma at the cost of expected manageable toxic effects, therefore it should be considered as a suitable treatment for the disease," researchers for the French Cooperative Thoracic Intergroup concluded.

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PRACTICE & TRENDS

Turing launches search for successor to ex-CEO Martin Shkreli
Wall Street Journal (12/23/15) Stynes, Tess

Turing Pharmaceuticals AG has launched a search for a permanent successor to its former chief executive, Martin Shkreli, who resigned Friday amid allegations of fraud during his time as a hedge-fund manager. The drugmaker also said it was streamlining its operations, including a workforce reduction, and plans to expand its board to include new, independent members. Chairman and interim CEO Ron Tilles said Tuesday that the "staff changes put us in the best position to continue executing on our long-term plan." "Though this has been a period of leadership transition for Turing, I am confident that the fundamental business model remains strong," said Tilles.

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Express Scripts releases better-than-expected 2016 forecast
Associated Press (12/23/15)

Express Scripts Holding, the largest U.S. PBM, on Tuesday gave stronger-than-expected earnings guidance for next year. The PBM said it expects to earn $6.08 to $6.28 a share next year, while analysts had forecast $6.04 a share in earnings. Express Scripts reaffirmed its expectation for adjusted claims, a measure that takes into account monthly prescriptions filled in community pharmacies and 90-day fills through the company’s mail-order business—of 1.26 billion to 1.3 billion. The company heads into 2016 facing a transition. Express Scripts announced in September that CEO George Paz will retire in May and be replaced by Tim Wentworth, company president. Paz will remain company chairman. He has served as Express Scripts chief executive for more than a decade.

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GlaxoSmithKline to buy raft of HIV drugs in development
New York Times (12/18/15) Bray, Chad

British drugmaker GlaxoSmithKline announced Friday that it will purchase a pipeline of HIV drugs that Bristol-Myers Squibb is currently developing. The agreement involves two deals that could be worth up to $1.46 billion. GlaxoSmithKline intends to pay $317 million for the late-stage drugs, and it would make an additional payment of up to $518 million depending on the drugs' sales and development. The pharmaceutical firm also will pay $33 million for early-stage HIV treatments in development by Bristol-Myers, with additional payments based on future performance. These deals could boost the drug pipeline of ViiV Healthcare, a specialist HIV company owned by GlaxoSmithKline, Pfizer, and Shionogi. The two separate deals are expected to be finalized in the first half of 2016, subject to regulatory approval.

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LAWS, REGS & RULINGS

CMS demands scrutiny of opioids, antipsychotics in Medicaid
Modern Healthcare (12/22/15) Dickson, Virgil

CMS in November issued a notice that it plans to implement new quality measures to better track the use of opioids and antipsychotics by patients in Medicaid and the Children's Health Insurance Program (CHIP). The measures are a response to an epidemic of opioid abuse among adults, and high rates of off-label prescriptions of antipsychotics to children and adolescents. Starting no later than December 2016, Medicaid programs will be required to track the use of high-dose opioids acquired from four or more providers and pharmacies by program beneficiaries who are free of cancer. The American Pharmacists Association said that these measures could reveal patterns of opioid misuse. CHIP would have to track the percentage of minors who are prescribed two or more antipsychotic medications at the same time.

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Critics say Orphan Drug Act is abused

New York Times (12/23/15) Tavernise, Sabrina

Tension is growing over the rising prices of drugs in the United States. Some companies have been harshly criticized for abruptly raising the prices of medicines after acquiring them — without having taken the risks involved in research and development. The Orphan Drug Act was passed by Congress in 1983 to stimulate the development of drugs for rare diseases that would otherwise not be profitable, offering fast-track approval, tax breaks, and 7 years of market monopoly. But the law has been abused, critics say, with drug companies "salami slicing" more common diseases into small categories, or repurposing older drugs that have been in general use for many years but never had FDA approval, or were approved for different treatments. "The Orphan Drug Act has been turned on its head in recent years," said Henry Waxman, the former Democratic congressman who sponsored the law. "It has created a special status for orphan diseases that offer large potentials for making generous profits."

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FDA lifts clinical hold on Advaxis' cancer compounds
Reuters (12/16/15) Nathan, Vidya L.

FDA has lifted a clinical hold on three experimental therapies developed by Advaxis, the company announced. The hold was implemented in October after the death of a participant in a mid-stage trial of axalimogene filolisbac. The company said the patient had died from progression of cervical cancer and that use of the drug was unrelated. Advaxis will resume its studies but agreed to risk mitigation measures that include a revised study design and improved patient surveillance.

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