APhA DrugInfoLine®

November 2018

Cardiology

Advising on this article: Eric MacLaughlin

November 5, 2018

A bleak picture of aspirin for primary prevention in older adults

Key Point

Three publications in the New England Journal of Medicine from the ASPREE trial showed that daily use of low-dose aspirin in healthy, community-dwelling older people without documented cardiovascular (CV) disease, dementia, or physical disability did not prolong disability-free survival, did not reduce the risk of CV disease (CVD), and was associated with a higher risk of all-cause mortality and major hemorrhage compared with placebo.

Source URL:

http://www.aphadruginfoline.com/cardiology/bleak-picture-aspirin-primary-prevention-older-adults

Respiratory

Advising on this article: Roy A. Pleasants, II

November 5, 2018

A personalized approach to COPD management is needed

Key Point

A small decline in lung function with no change in the rate of exacerbations was observed in patients with infrequent exacerbations and moderate to severe chronic obstructive pulmonary disease (COPD) who had been on long-term triple therapy and were subsequently de-escalated to dual therapy, according to data published in the American Journal of Respiratory and Critical Care Medicine.

Source URL:

http://www.aphadruginfoline.com/respiratory/personalized-approach-copd-management-needed

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
November 1, 2018	
Pembrolizumab ***(Keytruda—Merck)*** **In combination with chemotherapy, drug approved for first-line treatment of metastatic squamous NSCLC**	FDA approved a new indication for pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non–small cell lung cancer (NSCLC). Approval was based on a randomized, multicenter, double-blind, placebo-controlled trial in 559 patients with metastatic squamous NSCLC, regardless of PD-L1 tumor expression status, who had not previously received systemic therapy for metastatic disease. Patients were randomized (1:1) to pembrolizumab 200 mg or placebo in combination with carboplatin, along with either paclitaxel every 3 weeks or nab-paclitaxel weekly on a 3-week cycle for four cycles, followed by pembrolizumab or placebo. Patients continued pembrolizumab or placebo until disease progression, unacceptable toxicity, or a maximum of 24 months. The trial demonstrated statistically significant improvements in patients receiving pembrolizumab plus chemotherapy compared with those randomized to placebo plus chemotherapy. The most common adverse reactions in at least 20% of patients who received pembrolizumab were fatigue/asthenia, nausea, constipation, diarrhea, vomiting, pyrexia, decreased appetite, rash, cough, dyspnea, alopecia, and peripheral neuropathy. The recommended pembrolizumab dose for metastatic squamous NSCLC is 200 mg intravenously every 3 weeks, prior to chemotherapy when given on the same day, until disease progression, unacceptable toxicity, or 24 months after initiation.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/combination-chemotherapy-drug-approved-first-line-treatment-metastatic

New Drug Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
November 1, 2018	
Adalimumab-adaz ***(Hyrimoz—Sandoz)*** **Sandoz receives FDA approval for adalimumab biosimilar**	Sandoz announced FDA approval of adalimumab-adaz (Hyrimoz), a biosimilar to adalimumab (Humira), for treatment of rheumatoid arthritis, juvenile idiopathic arthritis in patients aged 4 years and older, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis. The drug, a tumor necrosis factor inhibitor administered subcutaneously by injection, is the third FDA-approved biosimilar to adalimumab. Approval was based on a randomized, double-blind, three-arm, parallel biosimilarity study that confirmed the pharmacokinetics, immunogenicity, and safety of adalimumab-adaz. The study met the primary endpoint, demonstrating bioequivalence for all primary pharmacokinetic parameters. A confirmatory efficacy and safety biosimilarity study demonstrated therapeutic equivalence in the sensitive indication of patients with moderate to severe chronic plaque-type psoriasis, with a similar safety and immunogenicity profile to the reference biologic. The most common adverse reactions (incidence > 10%) were infections (e.g., upper respiratory, sinusitis), injection-site reactions, headache, and rash.

Source URL:

http://www.aphadruginfoline.com/new-drug-approvals/sandoz-receives-fda-approval-adalimumab-biosimilar

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
November 1, 2018	
Irbesartan	FDA is alerting patients and health professionals to ScieGen's voluntary recall of certain lots of irbesartan, an angiotensin II receptor blocker (ARB), because they contain *N*-nitrosodiethylamine (NDEA), a known animal and suspected human carcinogen. FDA laboratory testing confirmed NDEA in some lots of ScieGen's irbesartan. ScieGen's irbesartan products are labeled as Westminster Pharmaceuticals and Golden State Medical Supply (GSMS). See the list of irbesartan products under recall. This is the first nonvalsartan drug product the agency has found to contain the NDEA impurity. In addition, Aurobindo, which manufactures the active pharmaceutical ingredient (API) for ScieGen's irbesartan products, is recalling all unexpired lots of its irbesartan API supplied to the U.S. market with NDEA. FDA and Aurobindo laboratory testing confirmed NDEA in certain lots of the Aurobindo's irbesartan API. FDA reminds patients taking any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. Not all ARBs contain NDEA or *N*-nitrosodimethylamine (NDMA), so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition. To date, ScieGen is the only manufacturer of irbesartan drug products found to contain NDEA. FDA continues to test all ARBs for the presence of impurities and has publicly posted two methods for manufacturers and regulatory agencies around the world to test their ARBs for the unexpected NDMA and NDEA impurities. The combined headspace method and the combined direct injection method can detect and quantify NDMA and NDEA simultaneously in ARB API and finished drug products. FDA continues to work with API and drug manufacturers

(No trade names—ScieGen)

Some lots of irbesartan recalled because they contain NDEA carcinogen

to ensure their products are not at risk for NDMA or NDEA formation.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/some-lots-irbesartan-recalled-because-they-contain-ndea-carcinogen

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
November 1, 2018	
Irbesartan ***(No trade names—Aurobindo)*** **Aurobindo recalls 22 batches of drug substance because of NDEA impurity**	Aurobindo Pharma is voluntarily recalling 22 batches of irbesartan drug substance because they contain *N*-nitrosodiethylamine (NDEA). NDEA, which occurs naturally in certain foods, drinking water, air pollution, and industrial processes, has been classified as a probable human carcinogen by the International Agency for Research on Cancer. These 22 batches of irbesartan drug substance were supplied to ScieGen Pharmaceuticals to manufacture the finished irbesartan drug product. Aurobindo has notified ScieGen of the recall and is arranging for the return of all available irbesartan drug substance. Aurobindo Pharma Limited has further advised Sciegen to contact its distributors and retailers to return irbesartan drug product and finished irbesartan tablets that have been identified by Aurobindo. Patients should contact their pharmacist or physician for advise on an alternative treatment before returning their medication. Patients who are on irbesartan should continue taking their medication, as the risk of harm to a patient's health may be higher if treatment is stopped immediately without an alternative treatment.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/aurobindo-recalls-22-batches-drug-substance-because-ndea-impurity