

Current Pharma News

1. Cancer mortality continues steady decline, driven by progress against lung cancer

Date: January 8, 2020

Source: American Cancer Society

Summary: The cancer death rate declined by 29 percent from 1991 to 2017, including a 2.2 percent drop from 2016 to 2017, the largest single-year drop in cancer mortality ever reported, according to the American Cancer Society's annual report on cancer rates and trends.

2. Long work hours at the office linked to both regular and hidden high blood pressure

Date: December 19, 2019

Source: American Heart Association

Summary: Office workers who logged 49-plus hours on the job weekly were 70% more likely to have a hidden form of high blood pressure called masked hypertension, compared to people who work less than 35 hours per week. Masked hypertension is high blood pressure that doesn't appear during a regular blood pressure test at a medical visit and thus, often goes undetected.

3. Home hospital reduces costs, improves care

Date: December 16, 2019

Source: Brigham and Women's Hospital

Summary: The results of the investigators' randomized controlled trial with more patients strengthens the evidence, showing that home hospital care reduced cost, utilization, and readmissions while increasing physical activity compared with usual hospital care.

4. More than 1 in 3 low- and middle-income countries face both extremes of malnutrition

Date: December 16, 2019

Source: University of North Carolina at Chapel Hill

Summary: Being undernourished or overweight are no longer separate public health issues. A new article details how more than one in three low- and middle-

income countries face both extremes of malnutrition - a reality driven by the modern food system.

5. Excessive antibiotic prescriptions for children in low-, middle-income countries

Date: December 14, 2019

Source: Harvard T.H. Chan School of Public Health

Summary: Between 2007 and 2017, children in eight low- and middle-income countries received, on average, 25 antibiotic prescriptions from birth through age 5 up to five times higher than the already high levels observed in high-income settings. The number of antibiotic prescriptions for young children ranged from one per year for children in Senegal to 12 per year for children in Uganda.

6. Focus on food security and sustainability

Date: December 11, 2019

Source: University of Bonn

Summary: The numbers of malnourished people is increasing worldwide. More than two billion people suffer from lack of micronutrients. Infant mortality rates are unacceptably high. Against this background, there is a need for the global pooling of research efforts, more research funding and an international body for food security and agriculture that will prepare policy decisions.

7. Regional trends in overdose deaths reveal multiple opioid epidemics

Date: December 10, 2019

Source: Iowa State University

Summary: The United States in the grip of several simultaneously occurring opioid epidemics, rather than just a single crisis. The epidemics came to light after the researchers analyzed county-level data on drug overdose deaths. The study highlights the importance of different policy responses to the epidemics rather than a single set of policies.

8. Dramatic health benefits following air pollution reduction

Date: December 6, 2019

Source: American Thoracic Society

Summary: Reductions in air pollution yielded fast and dramatic impacts on health-outcomes, as well as decreases in all cause of morbidity, according to new findings.

9. BPA levels in humans dramatically underestimated, study finds

Date: December 5, 2019

Source: Washington State University

Summary: Researchers have developed a more accurate method of measuring bisphenol A (BPA) levels in humans and found that exposure to the endocrine-disrupting chemical is far higher than previously assumed. The study provides the first evidence that the measurements relied upon regulatory agencies, including the US Food and Drug Administration, are flawed, underestimating exposure levels by as much as 44 times.

References: www.sciencedaily.com

Information collected by:

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New Drug Approvals

1. Ayvakit (avapritinib)

Company: Blueprint Medicines Corporation

Date of Approval: January 9, 2020

Treatment for: Gastrointestinal Stromal Tumor

Ayvakit (avapritinib) is a potent and highly selective KIT and PDGFR α inhibitor for the treatment of PDGFR α Exon 18 mutant gastrointestinal stromal tumors (GIST) and fourth-line GIST.

2. Caplyta (lumateperone) Capsules

Company: Intra-Cellular Therapies, Inc.

Date of Approval: December 23, 2019

Treatment for: Schizophrenia

Caplyta (lumateperone) is first-in-class antipsychotic for the treatment of schizophrenia.

3. Ubrelvy (ubrogepant) Tablets

Company: Allergan plc

Date of Approval: December 23, 2019

Treatment for: Migraine

Ubrelvy (ubrogepant) is a potent, orally-administered CGRP receptor antagonist for the acute treatment of migraine.

4. Enhertu (fam-trastuzumab deruxtecan-nxki) Injection

Company: AstraZeneca and Daiichi Sankyo Company, Limited

Date of Approval: December 20, 2019

Treatment for: Breast Cancer

Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

5. Dayvigo (lemborexant) Tablets

Company: Eisai Inc.

Date of Approval: December 20, 2019

Treatment for: Insomnia

Dayvigo (lemborexant) is dual orexin receptor antagonist (DORA) for the treatment of insomnia.

6. Conjupri (levamlodipine maleate) Tablets

Company: CSPC Pharmaceutical Group Limited

Date of Approval: December 19, 2019

Treatment for: Hypertension

Conjupri (levamlodipine maleate) is a calcium channel blocker indicated for the treatment of hypertension.

7. Ervebo (ebola zaire vaccine, live) Injection - formerly V920

Company: Merck

Date of Approval: December 19, 2019

Treatment for: Prevention of Ebola Zaire Disease

Ervebo (ebola zaire vaccine, live) is a vaccine indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 18 years of age and older.

8. Arazlo (tazarotene) Lotion

Company: Bausch Health Companies Inc.

Date of Approval: December 18, 2019

Treatment for: Acne

Arazlo (tazarotene) is a lotion formulation of the approved retinoid tazarotene for the topical treatment of acne vulgaris in patients 9 years of age and older.

9. Padcev (enfortumab vedotin-efyv) for Injection

Company: Astellas and Seattle Genetics

Date of Approval: December 18, 2019

Treatment for: Urothelial Carcinoma

Padcev (enfortumab vedotin-efyv) is a Nectin-4 targeted antibody-drug conjugate (ADC) for the treatment of patients with locally advanced or metastatic urothelial cancer.

10. Nouress (cysteine hydrochloride) Injection

Company: Avadel Pharmaceuticals plc

Date of Approval: December 13, 2019

Nouress (cysteine hydrochloride) is a sulfur-containing amino acid indicated for use as an additive to amino acids solutions to meet nutritional requirements of neonates requiring total parenteral nutrition.

11. Vyondys 53 (golodirsen) Injection**Company:** Sarepta Therapeutics**Date of Approval:** December 12, 2019**Treatment for:** Duchenne Muscular Dystrophy

Vyondys 53 (golodirsen) is a phosphordiamidate morpholino oligimer for the treatment of Duchenne muscular dystrophy (DMD) in patients with a confirmed mutation amenable to exon 53 skipping.

12. EluRyng (ethinyl estradiol and etonogestrel) Vaginal Ring**Company:** Amneal Pharmaceuticals LLC**Date of Approval:** December 11, 2019**Treatment for:** Contraception

EluRyng (ethinyl estradiol/etonogestrel vaginal ring) is an estrogen/progestin combination hormonal contraceptive (CHC) indicated for use by women to prevent pregnancy.

13. Avsola (infliximab-axxq) Injection**Company:** Amgen Inc.**Date of Approval:** December 6, 2019**Treatment for:** Crohn's disease, Maintenance, Ulcerative Colitis, Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis

Avsola (infliximab-axxq) is a tumor necrosis factor (TNF) blocker biosimilar to Remicade indicated for the treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis.

14. RediTrex (methotrexate) Injection**Company:** Cumberland Pharmaceuticals Inc.**Date of Approval:** November 27, 2019**Treatment for:** Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriasis

RediTrex (methotrexate) is a folate analog metabolic inhibitor indicated for the management of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), and psoriasis.

15. Oxbryta (voxelotor) Tablets**Company:** Global Blood Therapeutics, Inc.**Date of Approval:** November 25, 2019**Treatment for:** Sickle Cell Anemia

Oxbryta (voxelotor) is an oral, HbS (sickle hemoglobin) polymerization inhibitor for the treatment of patients with sickle cell disease (SCD).

16. Exservan (riluzole) Oral Film**Company:** Aquestive Therapeutics, Inc.**Date of Approval:** November 22, 2019**Treatment for:** Amyotrophic Lateral Sclerosis

Exservan (riluzole) an oral film formulation of the approved glutamate Inhibitor riluzole for the treatment of patients with amyotrophic lateral sclerosis (ALS) patients who have difficulty swallowing.

17. Xcopri (cenobamate) Tablets**Company:** SK Life Science, Inc.**Date of Approval:** November 21, 2019**Treatment for:** Seizures

Xcopri (cenobamate) is an antiepileptic drug for the treatment of partial-onset seizures in adult patients.

18. Givlaari (givosiran) Injection**Company:** Alnylam Pharmaceuticals, Inc.**Date of Approval:** November 20, 2019**Treatment for:** Acute Hepatic Porphyria

Givlaari (givosiran) is an aminolevulinate synthase 1-directed small interfering RNA (siRNA) indicated for the treatment of adults with acute hepatic porphyria (AHP).

19. Adakveo (crizanlizumab-tmca) Injection**Company:** Novartis Pharmaceuticals Corporation**Date of Approval:** November 15, 2019**Treatment for:** Prevention of Vaso-Occlusive Crises (VOCs) in Sickle Cell Disease

Adakveo (crizanlizumab-tmca) is a P-selectin inhibitor for the prevention of vaso-occlusive crises (VOCs) in patients with sickle cell disease (SCD).

20. Abrilada (adalimumab-afzb) Injection**Company:** Pfizer Inc.**Date of Approval:** November 15, 2019**Treatment for:** Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's disease, maintenance, Ulcerative Colitis, Plaque Psoriasis

Abrilada (adalimumab-afzb) is a tumor necrosis factor (TNF) blocker biosimilar to Humira indicated for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease

(CD), ulcerative colitis (UC), and plaque psoriasis (Ps).

References: www.drugs.com

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New Indications & Dosage Forms For Existing Drugs

1. Lynparza (olaparib) Tablets

New Indication Approved: December 27, 2019

Date of Original Approval: December 19, 2014

Lynparza (olaparib) is a first-in-class oral poly ADP ribose polymerase (PARP) inhibitor indicated for the treatment of ovarian cancer, breast cancer and pancreatic cancer.

2. Fiasp (insulin aspart) Injection

Patient Population Altered: December 19, 2019

Date of Original Approval: September 29, 2017

Fiasp (insulin aspart) is a rapid-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus. Fiasp is a newer formulation of NovoLog, in which the addition of niacinamide (vitamin B3) helps to increase the speed of initial insulin absorption.

3. Xtandi (enzalutamide) Capsules

New Indication Approved: December 16, 2019

Date of Original Approval: August 31, 2012

Xtandi (enzalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with castration-resistant prostate cancer, and metastatic castration-sensitive prostate cancer.

4. Vascepa (icosapent ethyl) Capsules

New Indication Approved: December 13, 2019

Date of Original Approval: July 26, 2012

Vascepa (icosapent ethyl) is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, and as an adjunct to statin therapy to reduce the risk of cardiovascular events.

5. Xeljanz (tofacitinib) Tablets

New Indication Approved: December 12, 2019

Date of Original Approval: November 6, 2012

Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor for the treatment of adult patients with moderately to severely active rheumatoid arthritis,

active psoriatic arthritis, and moderately to severely active ulcerative colitis.

6. Tecentriq (atezolizumab) Injection

New Indication Approved: December 3, 2019

Date of Original Approval: May 18, 2016

Tecentriq (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for use in the treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), and small cell lung cancer (SCLC).

7. Calquence (acalabrutinib) Capsules

New Indication Approved: November 21, 2019

Date of Original Approval: October 31, 2017

Calquence (acalabrutinib) is a highly selective, potent, Bruton tyrosine kinase (BTK) inhibitor for the treatment of mantle cell lymphoma (MCL), and chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma.

8. Fluzone Quadrivalent (influenza virus vaccine, inactivated) Suspension for Intramuscular Injection

New Formulation Approved: November 4, 2019

Date of Original Approval: June 7, 2013

Fluzone Quadrivalent is an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

9. Liletta (levonorgestrel) Intrauterine Device

New Dosage Regimen: October 25, 2019

Date of Original Approval: February 26, 2015

Liletta (levonorgestrel) is a hormonal intrauterine device (IUD) for use by women to prevent pregnancy for up to six years.

10. Baxdela (delafloxacin) Tablets and Injection

New Indication Approved: October 24, 2019

Date of Original Approval: June 19, 2017

Baxdela (delafloxacin) is a fluoroquinolone antibacterial indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) caused by designated susceptible bacteria.

11. Zejula (miraparib) Capsules

New Indication Approved: October 23, 2019

Date of Original Approval: March 27, 2017

Zejula (miraparib) is an oral, poly ADP-ribose polymerase (PARP) inhibitor for the treatment of patients with ovarian, fallopian tube, or primary peritoneal cancer.

12. Cinvanti (aprepitant) Injection

New Dosage Regimen: October 21, 2019

Date of Original Approval: November 9, 2017

Cinvanti (aprepitant) is a polysorbate 80 free, intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK₁) receptor antagonist indicated for the prevention of chemotherapy-induced nausea and vomiting (CINV).

13. Stelara (ustekinumab) Injection

New Indication Approved: October 18, 2019

Date of Original Approval: September 25, 2009

Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis.

14. Botox (onabotulinumtoxinA) Injection

Patient Population Altered: October 18, 2019

Date of Original Approval: December 9, 1991

Botox (onabotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- treatment of urinary incontinence due to detrusor overactivity associated with a neurologic

condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication

- prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer)
- treatment of upper and lower limb spasticity in adult patients
- treatment of upper limb spasticity in pediatric patients 2 to 17 years of age
- treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- treatment of blepharospasm associated with dystonia in patients 12 years of age and older
- treatment of **strabismus** in patients 12 years of age and older.

15. Farxiga (dapagliflozin) Tablets

New Indication Approved: October 18, 2019

Date of Original Approval: January 8, 2014

Farxiga (dapagliflozin) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

16. Ultomiris (ravulizumab-cwvz) Injection

New Indication Approved: October 18, 2019

Date of Original Approval: December 21, 2018

Ultomiris (ravulizumab-cwvz) is a long-acting C5 complement inhibitor for:

- The treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
- The treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).

17. Xofluza (baloxavir marboxil) Tablets**Patient Population Altered:** October 16, 2019**Date of Original Approval:** October 24, 2018

Xofluza (baloxavir marboxil) is a polymerase acidic (PA) endonuclease inhibitor for the treatment of influenza (the flu) in people 12 years of age and older who have had flu symptoms for no more than 48 hours and who are otherwise healthy, or at high risk of developing flu-related complications.

18. Xarelto (rivaroxaban) Tablets**New Indication Approved:** October 11, 2019**Date of Original Approval:** July 1, 2011

Xarelto (rivaroxaban) is a factor Xa inhibitor indicated:

- to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
- for the treatment of deep vein thrombosis (DVT)
- for the treatment of pulmonary embolism (PE)
- for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months
- for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
- for the prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
- in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

19. Descovy (emtricitabine and tenofovir alafenamide) Tablets**New Indication Approved:** October 3, 2019**Date of Original Approval:** April 4, 2016

Descovy (emtricitabine and tenofovir alafenamide) is a nucleoside analog HIV-1 reverse transcriptase inhibitor (NRTI) and nucleotide reverse transcriptase inhibitor (NtRTI) fixed-dose combination for the treatment of HIV-1 infection, and for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

20. Fasenra (benralizumab) Injection**New Dosage Form Approved:** October 3, 2019**Date of Original Approval:** November 14, 2017

Fasenra (benralizumab) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody indicated for the treatment of patients with severe eosinophilic asthma.

21. Entresto (sacubitril and valsartan) Tablets**Patient Population Altered:** October 1, 2019**Date of Original Approval:** July 7, 2015

Entresto (sacubitril and valsartan) is a neprilysin inhibitor and angiotensin II receptor blocker combination indicated:

- to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.
- for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

References: www.drugs.com

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Herbal Medicine News Update

1. Tea drinkers live longer

Date: January 9, 2020

Source: European Society of Cardiology

Summary: Drinking tea at least three times a week is linked with a longer and healthier life, according to a new study.

2. Caffeine may offset some health risks of diets high in fat, sugar

Date: December 20, 2019

Source: University of Illinois at Urbana-Champaign, News Bureau

Summary: In a study of rats, scientists found that caffeine limited weight gain and cholesterol production, despite a diet that was high in fat and sugar.

3. Experts review evidence yoga is good for the brain

Date: December 12, 2019

Source: University of Illinois at Urbana-Champaign, News Bureau

Summary: Scientists have known for decades that aerobic exercise strengthens the brain and contributes to the growth of new neurons, but few studies have examined how yoga affects the brain. A review of the science finds evidence that yoga enhances many of the same brain structures and functions that benefit from aerobic exercise.

References: www.sciencedaily.com

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