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### **Current Pharma News**

#### Coffee might protect against Parkinson's

Published: December 29, 2018

Coffee is thought to protect the brain against Parkinson's disease. A recent study investigated which compounds might give coffee its neuroprotective powers. The findings may eventually lead to innovative new treatments.

### Bipolar: Physical activity may boost mood and energy

Published: December 29, 2018

New research, published in the journal JAMA Psychiatry, found that higher levels of physical activity boost mood and energy levels. The benefits were particularly noticeable in people with bipolar disorder. Being physically active might help people with bipolar disorder fight off depressive symptoms. In the United States, almost 3 percent of adults experienced bipolar disorder "in the past year." Around 4.4 percent of adults have bipolar at some point in their lives.

### Prostate cancer: New, quicker test to assess metastasis risk

Published: December 27, 2018

People with prostate cancer are at risk of metastatic tumors forming. A newly developed test can assess this risk more quickly than existing tests and is also cheaper to run. Researchers explain the benefits of a new test that measures the risk of metastasis in prostate cancer. According to the National Cancer Institute, about 11.2 percent of men will receive a prostate cancer diagnosis at some point in time.

### Study finds link between obesity and sense of smell

Published: December 27, 2018

A recent review concludes that people with obesity have a reduced ability to detect and discriminate smell compared with those who are not obese. A recent review highlights a possible link between obesity and olfaction. Obesity is a medical condition characterized by an excessive amount of body fat.

Source: medicalnewstoday.com

### Higher sugar-sweetened beverage consumption associated with greater kidney disease risk

Published: December 28, 2018

Higher collective consumption of sweetened fruit drinks, soda, and water was associated with a higher likelihood of developing chronic kidney disease (CKD) in a community-based study of African-American adults in Mississippi. The findings, which appear in an upcoming issue of the *Clinical Journal of the American Society of Nephrology* (CJASN), contribute to the growing body of evidence pointing to the negative health consequences of consuming sugar-sweetened beverages.

### MUSC researchers link higher levels of AGEs to ER-positive breast cancer risk

Published: December 28, 2018

Poor diet and lack of exercise are associated with cancer development, but the underlying biology is not well understood. Advanced glycation end products (AGEs) could offer a biological link to help us understand how certain lifestyle behaviors increase cancer risk or lessen the likelihood that an anti-cancer therapy will be effective.

### Study assesses link between vitamin D intake and obesity in occupational asthma patients

Published: December 28, 2018

Occupational asthma is common occurrence in a significant number of adults suffering from the disease. Even after the cessation of exposure, the asthma remains dominant. Previously, vitamin D intake was rarely evaluated in cases of occupational asthma regardless of it being an important part of nutrition. The main objective of this study is to assess the vitamin D intake in occupational asthma patients and its relation with body mass index, co-morbidities related to vitamin D deficit, lung function and quality of life.

# Researchers discover extent of opioid use and abuse in head and neck cancer patients

Published: December 27, 2018

Cancer patients are often prescribed pain medications, for example during recovery from 126 Current Pharma News

surgical procedures. However, for many cancer patients, the use of opioid pain medications during treatment can be a gateway to misuse or addiction once treatment ends. Now with cancer patients living longer than ever before, protecting quality of life in the months, years, or decades after treatment is becoming increasingly important, including guarding against the risk of opioid addiction.

### Neuronal cell death in Alzheimer's disease may actually not be a bad thing, shows study

Published: December 27, 2018

For the first time, scientists at the Champalimaud Centre for the Unknown (CCU), in Lisbon, Portugal, have shown that neuronal cell death in Alzheimer's disease (AD) may actually not be a bad thing - on the contrary, it may be the result of a cell quality control mechanism trying to protect the brain from the accumulation of malfunctioning neurons. Their results, which were obtained using fruit flies that had been genetically modified to mimic the symptoms of human AD, were published in the journal *Cell Reports*.

### New method of cancer stem cells activation to destroy tumors

Published: December 26, 2018

This risky method of anti-cancer therapy was suggested by scientists of Far Eastern Federal University (FEFU). Their review of mechanisms for molecular activation of stem cells of gliomas (most widely-spread brain tumors) was approved for publishing in the *Frontiers in Cellular Neuroscience* journal.

Source: news-medical.net

### FDA approves first treatment for rare blood disease

Published: December 21, 2018

USFDA approved Elzonris (tagraxofusp-erzs) infusion for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients, two years of age and older. Prior to today's approval the standard of care has been intensive chemotherapy followed by bone marrow transplantation which is not tolerable for many patients. BPDCN is an aggressive and rare disease of

the bone marrow and blood that can affect multiple organs, including the lymph nodes and the skin.

### Anticancer vaccines gain new lease of life with personalisation techniques

Published: December 21, 2018

Anticancer vaccines have gained a new lease of life with techniques to personalise them to individual patients. Personalisation has been made possible with high-throughput next generation sequencing. This technology identifies mutations that are unique to a patient's tumour and are not found elsewhere in the body, meaning that a vaccine mounts a cancerspecific immune response. Algorithms can predict which neoantigens should be targeted for vaccination

### Merck assigns Chimeric Antigen Receptor T-cell (CAR-T) rights to Intrexon

Published: December 20, 2018

Merck, a leading science and technology company, today announced it has evolved its agreement with Intrexon Corporation (NASDAQ: XON) for the development of Chimeric Antigen Receptor T-cell (CAR-T) therapies, genetically engineered T-cells with synthetic receptors that recognize a specific antigen expressed on tumor cells. The agreement with Intrexon and its wholly-owned subsidiary, Precigen, Inc. enables Merck to continue to implement its focused R&D strategy, while maintaining an investment in the future potential of next-generation CAR-T development.

# Pfizer receives positive CHMP opinion for oncology biosimilar, ZIRABEV $^{\text{TM}}$ (bevacizumab)

Date of published: 20 December 2018

Pfizer announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorization for ZIRABEV<sup>TM</sup> (bevacizumab), a potential biosimilar to Avastin (bevacizumab). ZIRABEV is a monoclonal antibody for the treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, unrespectable advanced, metastatic or recurrent nonsmall cell lung cancer (NSCLC), advanced and/or metastatic renal cell cancer and persistent, recurrent or metastatic carcinoma of the cervix. If approved, ZIRABEV has the potential to expand access to this

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life-changing biologic cancer therapy for appropriate patients and healthcare professionals across Europe. *Source: worldpharmanews.com* 

#### Half a million tests and many mosquitoes later, new buzz about a malaria prevention drug

Published: December 06, 2018

Researchers spent two years testing chemical compounds for their ability to inhibit the malaria parasite at an earlier stage in its lifecycle than most current drugs, revealing a new set of chemical starting points for the first drugs to prevent malaria instead of just treating the symptoms.

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### HIV vaccine protects non-human primates from infection

Published: December 14, 2018

New research shows that an experimental HIV vaccine strategy works in non-human primates. In the study, rhesus macaque monkeys produced neutralizing antibodies against one strain of HIV that resembles the resilient viral form that most commonly infects people, called a Tier 2 virus.

Source: sciencedaily.com

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# **New Drug Approvals**

Drug Name	<b>Active Ingredient</b>	Approval date	FDA-approved use(s)
Ultomiris	Ravulizumab	12/21/2018	To treat paroxysmal nocturnal hemoglobinuria (PNH)
Elzonris	Tagraxofusp-erzs	12/21/2018	To treat blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Asparlas	Calaspargase pegol- mknl	12/20/2018	To treat acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years
Motegrity	Prucalopride	12/14/2018	To treat chronic idiopathic constipation
Xospata	Gilteritinib	11/28/2018	To treat patients who have relapsed or refractory acute myeloid leukemia (AML)
Firdapse	Amifampridine	11/28/2018	To treat Lambert-Eaton myasthenic syndrome (LEMS) in adults
Vitrakvi	Larotrectinib	11/26/2018	To treat patients whose cancers have a specific genetic feature (biomarker)
Daurismo	Glasdegib	11/21/2018	To treat newly-diagnosed acute myeloid leukemia (AML) in adult patients
Gamifant	Emapalumab-lzsg	11/20/2018	To treat primary hemophagocytic lymphohistiocytosis (HLH)
Aemcolo	Rifamycin	11/16/2018	To treat travelers' diarrhea
Yupelri	Revefenacin	11/8/2018	To treat patients with chronic obstructive pulmonary disease (COPD)
Lorbrena	Lorlatinib	11/2/2018	To treat patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer
Xofluza	Baloxavir marboxil	10/24/2018	For the treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours.
Talzenna	Talazoparib	10/16/2018	For the treatment of locally advanced or metastatic breast cancer patients with a germline BRCA mutation.
Tegsedi	Inotersen	10/5/2018	To treat polyneuropathy of hereditary transthyretin- mediated amyloidosis in adults
Revcovi	Elapegademase-lvlr	10/5/2018	To treat Adenosine Deaminase-Severe Combined Immunodeficiency (ADA-SCID)
Nuzyra	Omadacycline	10/3/2018	To treat community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections
Seysara	Sarecycline	10/1/2018	To treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older
Libtayo	Cemiplimab-rwlc	9/28/2018	To treat cutaneous squamous cell carcinoma (CSCC)

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Vizimpro	Dacomitinib	9/27/2018	To treat metastatic non-small-cell lung cancer
Emgality	Galcanezumab-gnlm	9/27/2018	For the preventive treatment of migraine in adults
Copiktra	Duvelisib	9/24/2018	To treat relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma and follicular lymphoma
Ajovy	Fremanezumab-vfrm	9/14/2018	For the preventive treatment of migraine in adults
Lumoxiti	Moxetumomab pasudotox-tdfk	9/13/2018	To treat hairy cell leukemia
Pifeltro	Doravirine	8/30/2018	To treat HIV-1 infection in adult patients
Xerava	Eravacycline	8/27/2018	To treat complicated intra-abdominal infections in patients 18 years of age and older
Takhzyro	Lanadelumab	8/23/2018	To treat types I and II hereditary angioedema
Oxervate	Cenegermin-bkbj	8/22/2018	To treat neurotrophic keratitis
Diacomit	Stiripentol	8/20/2018	To treat seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam
Galafold	Migalastat	8/10/2018	To treat treat adults with Fabry disease.
Annovera	Segesterone acetate and ethinyl estradiol vaginal system	8/10/2018	New vaginal ring used to prevent pregnancy for an entire year
Onpattro	Patisiran	8/10/2018	To treat the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adult patients
Poteligeo	Mogamulizumab-kpkc	8/8/2018	To treat two rare types of non-Hodgkin lymphoma

References: drugs.com

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### **New Indications & Dosage Forms for Existing Drugs**

#### Glycerol phenylbutyrate (Oral Liquid)

Glycerol phenylbutyrate is a nitrogen-binding agent for the chronic management of patients with urea cycle disorders.

Date of Indication Approval: December 21, 2018

#### **Dasatinib** (Tablets)

Dasatinib is a kinase inhibitor indicated for the treatment of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia and Philadelphia chromosome-positive acute lymphoblastic leukemia. Date of Indication Approval: December 21, 2018

#### Olaparib (Tablets)

Olaparib is a first-in-class oral poly ADP ribose polymerase (PARP) inhibitor for the treatment of BRCA-mutated, advanced ovarian cancer; for the maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer; and for the treatment of germline BRCA-mutated metastatic breast cancer.

Date of Indication Approval: December 19, 2018

#### **Pembrolizumab for Injection**

Pembrolizumab is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, hepatocellular carcinoma, and Merkel cell carcinoma.

Date of Indication Approval: December 19, 2018

#### **Tacrolimus Extended-Release (Tablets)**

Tacrolimus is a once-daily extended-release immunosuppressant for the prophylaxis of organ rejection in kidney transplant patients.

Date of Indication Approval: December 19, 2018

#### **Romiplostim**

Romiplostim is a thrombopoietin mimetic peptibody for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP).

Date of Indication Approval: December 14, 2018

#### **Atezolizumab (Injection)**

Atezolizumab is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with advanced urothelial carcinoma and patients with metastatic non-small cell lung cancer (NSCLC).

Date of Indication Approval: December 14, 2018

#### Venetoclax (Tablets)

Venetoclax is an oral B-cell lymphoma-2 (BCL-2) inhibitor for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with or without 17p deletion who have received at least 1 prior treatment; and for the combination treatment of newly-diagnosed acute myeloid leukemia (AML) in patients who are 75 years of age of over, or have other medical conditions that prevent the use of standard chemotherapy.

Date of Indication Approval: November 21, 2018

#### **Tocilizumab** (Injection)

Tocilizumab is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody for the treatment rheumatoid arthritis; systemic juvenile idiopathic arthritis (SJIA); polyarticular juvenile idiopathic arthritis (PJIA); giant cell arteritis; and CAR T cell-induced severe or life-threatening cytokine release syndrome.

Date of Dosage Form Approval: November 19, 2018

#### **Brentuximab vedotin (Injection)**

Brentuximab vedotin is a CD30-directed antibody-drug conjugate (ADC) indicated for the treatment of Hodgkin lymphoma, anaplastic large cell lymphoma, and CD30-expressing mycosis fungoides.

Date of Indication Approval: November 16, 2018

#### **Eltrombopag (Tablets)**

Eltrombopag is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic)

New Indications and Dosage Forms for Existing

thrombocytopenic purpura, thrombocytopenia in patients with chronic hepatitis C, and patients with severe aplastic anemia.

Date of Indication Approval: November 20, 2018

#### **Elotuzumab (Injection)**

Empliciti (elotuzumab) is a Signaling Lymphocyte Activation Molecule (SLAMF7)-directed immunostimulatory antibody indicated for the combination treatment of patients with multiple myeloma.

Date of Dosage Form Approval: November 06, 2018

Source:.drugs.com

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### **Herbal & Alternative Medicine News**

### Peptide isolated from spirulina extract may counteract arterial hypertension

Published: December 31, 2018

Spirulina (scientific name *Arthrospira platensis*) is considered as a "superfood" because of its possible health benefits. Spirulina is a cyanobacterium capable of photosynthesis. Sometimes classified as a "blue algae", it was supposedly used as a food by the Aztecs. Althogh its mechanism of action is still subjected to investigation, a research from the Vascular Physiopathology Laboratory of the I.R.C.C.S shows that one of its extracts may counteract arterial hypertension by dilating blood vessels.

Source: news-medical.net

#### Green leafy vegetables may prevent liver steatosis Published: December 17, 2018

Liver steatosis, or fatty liver, is a common liver disease that affects approximately 25 per cent of the population. There is currently no approved treatment for the disease, which can deteriorate into life-threatening conditions such as cirrhosis and liver cancer. However, in a recent study published in *PNAS* researchers from Karolinska Institutet in Sweden shows how a larger intake of inorganic nitrate, which occurs naturally in many types of leafy vegetable, reduces accumulation of fat in the liver. Their results were confirmed by using two different cell culture studies in human liver cells.

Source: eurekalert.org

### Chromatography explores the health benefits of mushrooms

Published: December 12, 2018

Probiotics are foods that contain helpful bacteria. We can get probiotics from fermented foods and yogurts. Prebiotics are types of fibre that humans cannot digest but our helpful gut flora can. Bananas, legumes and mushrooms etc. contain prebiotics. Prebiotics provide the nutrients that our helpful gut flora need to thrive. A research team from Thailand investigated the prebiotic properties in seven varieties of edible mushrooms. After extracting carbohydrates from the mushrooms, they analysed them using the

team found that the mushrooms extracts displayed highly efficient prebiotic properties. This enhances the humble mushrooms reputation as an attractive functional food.

Source: chromatographytoday.com

### Adaptogenic ashwagandha improves muscle adaptations

Published: December 21, 2018

Adaptogens are unique plants or herbs that support adrenal system. They help balance the stress hormones on daily basis. Patented ashwagandha extracts (a well known adaptogens) have positive impact on strength adaptations in active men. They continue to prove promising in sports nutrition, as a recently published study on *Nutients* shows that taking an aqueous extract of Ashwagandha improves upper and lower-body strength, supports a favorable distribution of body mass, and was well tolerated clinically in recreationally active men over a 12-week resistance training and supplementation period.

Source: naturalproductsinsider.com

# Branded black cumin seed extract shows potent anti-inflammatory activity in asthma-related mediators in in vitro study

Published: December 17, 2018

Sabinsa Corp. (East Windsor, NJ) reports that its branded black cumin (*Nigella sativa*) seed extract, Nigellin BCS, was the best-performing black cumin seed extract used in an asthma-related study recently published in *Frontiers in Pharmacology*. This emerging antioxidant ingredient has traditionally been used in the management of numerous health conditions, with recent research beginning to validate historically reported benefits. In this case, they relied upon use of supercritical fluid extraction (SCFE) technology to provide an active solution. While this is not a human study, the results suggests a potential benefit for people with asthmatic conditions who supplement with black cumin seed extract.

Source: nutritionaloutlook.com

#### Oils from garlic and other common herbs and medicinal plants may be useful against Lyme disease symptoms that persist despite standard antibiotic treatment new lab-dish testing shows.

Published: December 04, 2018

Researchers tested essential oils-oils pressed from plants or their fruits that contain the plant's main fragrance, or "essence." Ten of the oils, including those from garlic cloves, myrrh trees, thyme leaves, cinnamon bark, allspice berries, and cumin seeds, showed strong killing activity against dormant and slow-growing "persistent" forms of the Lyme disease bacterium, researchers found. "We found that these essential oils were even better at killing the 'persistent' forms of Lyme bacteria than standard Lyme antibiotics," says Ying Zhang, professor of molecular microbiology and immunology at Johns Hopkins University's Bloomberg School of Public Health.

Source: futurity.org

### Punarnava for diabetes: benefits of the ayurvedic herb

Published: October 12, 2018

Punarnava is a creeper that grows in the wild in India and Brazil throughout the year. Punarnava, also known as *Boerhavia diffusa*, helps manage your blood sugar levels and keeps them in control. This herb has long been used in herbal medicines for various health conditions. We tell you why Punarnava could be a great herbal medicine for managing diabetes well.

Source: ndtv.com

### Molecular mechanisms of ancient herbal remedies

Published: October 10, 2018

The herbal medicine, a leaf extract from the shrub *Mallotus oppositifolius*, was previously found to be effective in controlling seizures but the mechanism was unknown. The discovery, published in *Nature Communications*, found that two components of the Mallotus leaf extract activate KCNQ2/3, a potassium ion channel essential for controlling electrical activity in the brain. The two components were somewhat effective alone, but in combination were highly effective both at activating KCNQ2/3 channels and at preventing life-threatening seizures.

Source: sciencedaily.com

Pleurotus eryngii: A native Mediterranean mushroom found to protect the liver from disease

Published: December 22, 2018

One of the potential alternatives that researchers considered is P. eryngii, a mushroom that originated from the Mediterranean region. Previous studies have shown that P. eryngii contains many bioactive compounds, including polysaccharides, sterols, and peptides. Among these, polysaccharides were shown to be the most potent since it has antioxidant, antiaging. antivirus. and anti-lipid peroxidation properties. Aside from these, polysaccharides are also highly stable, water-soluble, and non-toxic, which makes them suitable for medicinal applications. Although there have been studies regarding the antihyperlipidemic effects of polysaccharides from P. these focused eryngii, none of exopolysaccharides.

Source: food.news

#### Lemongrass tea can prevent memory decline

Published: December 22, 2018

Nigerian researchers tested the ability of lemongrass (*Cymbopogon citratus*) to protect memory from the effects of amnesia. In a scopolamine-induced amnesia model, mice treated with a water-based extract of lemongrass demonstrated better memories than their untreated kin. The researchers recommended the use of lemongrass as a plant-based therapy for patients who are suffering from Alzheimer's disease, dementia, and other diseases that involve declining memories.

Source: food.news

### Geranium demonstrates antidepressant and anxiolytic properties

Published: December 22, 2018

Geranium is commonly found in the form of an essential oil. It is widely used in traditional medicine as a calming agent and as a treatment for different skin conditions. In fact, several studies have looked at the science behind these claims. A study, published in *Phytotherapy Research*, researchers conducted an in vivo test to determine the potential of geranium essential oil as an anxiolytic and antidepressant. They used male Swiss albino mice as the animal models and injected them with various concentrations of the essential oil in the abdominal area. The results of the

test showed that geranium significantly improves anxiety and depression.

Source: news-medical.net

### Ginger and rosemary oil found to lower cholesterol levels

Published: December 22, 2018

The researchers determined the ability of rosemary and ginger oil to reduce cholesterol levels in rats given a high-fat diet. High-fat diet increased glucose, total cholesterol, triglyceride, and alkaline phosphatase levels while it reduced concentrations of good cholesterol. Treatment with ginger and rosemary oil, either separately or together, modulated the changes in these parameters.

The researchers concluded that Rosemary and Ginger oil significantly reduce cholesterol levels. Moreover, they attributed this effect to the components found in rosemary oil, which include alpha-pinene, camphor, cineole, and borneol, as well as the compounds

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linalool, terpineol, borneol, and eucalyptol in ginger

Source: science.news

### Researchers decipher the antitumor mechanism of an Amazonian plant

Published: September 28, 2018

A piece of research conducted by the Free Radicals and Oxidative Stress Group at the UPV/EHU's Faculty of Medicine and Nursing has deciphered the antitumor mechanism exerted by the plant *Vismia baccifera*, originally from the Amazonian region of Colombia, in human liver cancer cells. The journal *Heliyon* has published the results of the study in which this plant was found to induce oxidative stress in cells, which eventually leads to cell death.

Source: elbiruniblogspotcom.blogspot.com