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PHARMA HIGHLIGHTS

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FDA Approves LARTRUVO™ (olaratumab) in Combination with Doxorubicin for Soft Tissue Sarcoma (STS)

Recently the U.S. Food and Drug Administration (FDA) has granted approval of Eli Lilly's LARTRUVO™ (olaratumab injection, 10 mg/mL), in combination with doxorubicin, for the treatment of adults with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery. LARTRUVO, in combination with doxorubicin, is the first FDA-approved front-line therapy for STS in four decades. 'The entire sarcoma patient community is excited to have an innovative medicine approved for the treatment of advanced soft tissue sarcoma,' said Bert E. Thomas, CEO of the Sarcoma Foundation of America. 'We are confident that the approval of LARTRUVO may help these patients live longer.' STS is a complex disease with multiple subtypes, making it hard to diagnose and difficult to treat. For decades, there have been no first-line therapeutic advancements for STS. According to the American Cancer Society, in 2015, there were an estimated 12,000 new STS cases diagnosed and nearly 5,000 deaths in the U.S. alone, representing an unmet medical need. LARTRUVO is the first monoclonal antibody approved to treat STS. It also received Fast Track, Orphan Drug and Breakthrough Therapy designations from the FDA for this indication, and was reviewed and approved under the FDA's Accelerated Approval program. This program allows for earlier approval of drugs that treat serious conditions and that fill an unmet medical need.

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements

Serious cutaneous adverse reactions and the role of genotyping

The HSA has issued advice to health-care professionals about cautions required with the use of allopurinol to minimize risk of allopurinol-induced serious cutaneous adverse reactions (SCAR). Allopurinol is recommended as first-line therapy for gout. An HSA-initiated local multicentre, case-control study found evidence of a strong association between HLAB*5801 allele and allopurinol induced SCAR, i.e. patients carrying the HLA-B*5801 allele have higher risk of developing allopurinol-induced SCAR (100 times) compared to one who does not have the allele. This is consistent with international data. The frequency of HLA-B*5801 prevalence is estimated at 18.5% in Singapore (approximately one in five Singaporeans or one in five Chinese, one in 15 Malaysians and one in 25 Indians). A cost-effectiveness analysis by Duke-NUS Graduate Medical School, in collaboration with the HSA and National University Health System, concluded that genotyping all patients with gout prior to initiation of allopurinol is currently not cost-effective. The HSA has received nine allopurinol-induced SCAR reports between March and August 2016. In the majority of these cases, allopurinol was used for gout in Chinese patients. The HSA has advised that while genotyping is not required as standard of care for new patients starting allopurinol, doctors may consider genotyping patients who have other pre-existing risk factors for allopurinol induced SCAR such as renal impairment and to identify the patients who are at a greater risk of allopurinol-induced SCAR. Genetic testing, when ordered for at-risk patients, should not substitute for appropriate clinical vigilance and patient management. **Source:** (http://www.hsa.gov.sg/

NICE Recommends Oral OTEZLA® (Apremilast) for Adults with Chronic Plaque Psoriasis

Celgene has announced that adult patients in England and Wales with chronic plaque psoriasis will now have access to oral OTEZLA ® (apremilast) after a positive final appraisal determination from the National Institute for Health and Care Excellence (NICE). The decision is the conclusion of a NICE Rapid Review. It ensures patients in England and Wales will join those in Scotland, who have been benefiting from access to OTEZLA since Scottish Medicines Consortium (SMC) recommended it in June 2015. It has been estimated that Psoriasis has affected around 960,000 adults in the UK, seriously impacting their daily lives. "NICE's decision to recommend Apremilast for the treatment of psoriasis is an important step forward in the management of a disease which for many patients can have a significant detrimental effect on their lives. Apremilast offers patients a much needed new oral treatment option that does not require routine laboratory monitoring. Clinical trials of apremilast demonstrated a reduction in severity of psoriasis and associated itching as well as improvement in hard to treat areas, such as the nails and scalp. The drug has the potential to fill an important gap in the psoriasis treatment pathway and its introduction is welcomed by patients and healthcare practitioners," commented Professor Chris Griffiths, Professor of Dermatology, University of Manchester. **Source:** https://igeahub.com/2016/10/27/nice-recommends-oral-otezla-apremilast-for-adults-with-chronic-plaque-psoriasis/

Placebo sweet spot for pain relief identified in brain

Scientists have identified for the first time the region in the brain responsible for the "placebo effect" in pain relief, when a fake treatment actually results in substantial reduction of pain, according to new research from Northwestern Medicine and the Rehabilitation Institute of Chicago (RIC). Pinpointing the sweet spot of the pain killing placebo effect could result in the design of more personalized medicine for the 100 million Americans with chronic pain. The finding also will lead to more precise and accurate clinical trials for pain medications by eliminating individuals with high placebo response before trials. The scientists discovered a unique brain region within the mid frontal gyrus that identifies placebo pill responders in one trial and can be validated (95 percent correct) in the placebo group of a second trial. The study was published Oct. 27, 2016, in PLOS Biology. "The new technology will allow physicians to see what part of the brain is activated during an individual's pain and choose the specific drug to target this spot," Apkarian said. "It also will provide more evidence-based measurements. Physicians will be able to measure how the patient's pain region is affected by the drug. “Currently, placebo response is primarily studied in healthy subjects within controlled experimental settings. While such experiments aid understanding of the biological and behavioral underpinning of placebo response in experimental (applied) pain, they translate poorly to the clinic, where pain is mainly chronic in nature, Baliki said. In this new study, scientists used functional magnetic resonance imaging (fMRI) combined with a standard clinical trial design for the first time to derive an unbiased brain-based neurological marker to predict analgesia associated with placebo treatment in patients with chronic knee osteoarthritis pain. Scientists showed placebo pill ingestion is associated with a strong analgesia effect, with more than half of the patients reporting significant pain relief. According to Baliki and Apkarian, if future similar studies can further expand and eventually provide a brain-based predictive best-therapy option for individual patients, it would dramatically decrease unnecessary exposure of patients to ineffective therapies and decrease the duration and magnitude of pain suffering and opioid use.

Source: https://www.sciencedaily.com

Shifting epidemiology in drug-resistant organisms, large integrated health outcomes study reveals

New research, funded by OpGen and conducted by Intermountain Healthcare and Enterprise Analysis Corporation (EAC), found that Methicillin Resistant Staphylococcus aureus (MRSA), Clostridium difficile (C. difficile) and ESBL harboring Gram-negative rods were the most common organisms treated by the Intermountain Healthcare system over an eight-year period between January 1, 2008 and December 31, 2015.The study examined data from Intermountain Healthcare over an eight-year period to characterize the trends occurring in C. difficile and MDROs. The study measured both the prevalence of infections, as well as impacts on patient care.

According to the study, out of the 900,000 hospital admissions during the study period, 12,905 (1.4%) were from patients positive for an MDRO and/or C. difficile. While MRSA continues to be the most common MDRO, rates have declined. MRSA, ESBL and CRE forms of E. coli were less frequently acquired in the hospital while VRE, multi-drug resistant Pseudomonas, and other CRE's were more frequently encountered in a healthcare setting. 70% of all MDROs and C. difficile cases originated from an ambulatory setting. While all-cause, in hospital mortality was relatively low (7%), significantly more patients with MDRO require continued medical care in some capacity. "For the last 10 to 15 years, the number of antibiotic-resistant bacteria continues to increase. We wanted to turn on the lights and look at all the different types of antibiotic-resistant bacteria that have been highlighted as serious and urgent threats by the Centers for Disease Control to see what the landscape looks like in our system," said Dr. Lopansri, Chief of the Infectious Diseases Division at Intermountain Medical Center. "Although MRSA still poses the greatest challenge, the rise in ESBLs is a major concern and mirrors findings reported at other centers in the U.S. One concern with ESBLs is that the most common antibiotic used to treat them are carbapenems, known as 'last-resort' antibiotics." "Our support for a study of this magnitude provides a benchmark to hospitals and health systems on what could be lurking in their facilities as we seek to validate the health and economic impact of our rapid MDRO products and services to improve infection control," said Evan Jones, Chairman and CEO of OpGen.

Source: https://www.sciencedaily.com