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INSIDE THIS ISSUE:

A New Approach for the Treatment of Migraines

Migraine is the 3rd most prevalent and the 6th most disabling illness in the world. It is neurological symptom that most commonly affects one side of the head causing throbbing pain that can lead to nausea, vomiting and increased pain while moving, coughing, or sneezing.[1] After the attack which is called the postdrome, you might feel exhausted, weak and confused. The diagnosis of migraines is mainly done by exclusion, as the physician must make sure that there are no underlying neurological diseases or physical conditions causing these attacks.

There is no cure for migraine, but the treatment focuses on the management of the symptoms, relive and the prevention of further attacks. On September 28, 2021 the FDA have approved the first and only oral Calcitonin Gene-Related Peptide (CGRP)receptor antagonist Atogepant (Qulipta®) that is specifically developed for the preventive treatment of migraines.[2] The CGRP receptors are expressed in the regions of the nervous system that is associated with migraine pathophysiology. The study is done on Qulipta® and showed that it reduced the migraine attacks by 50% to 100%.

References:

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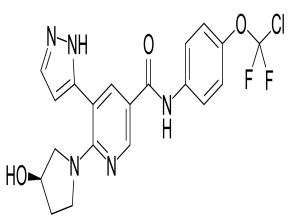
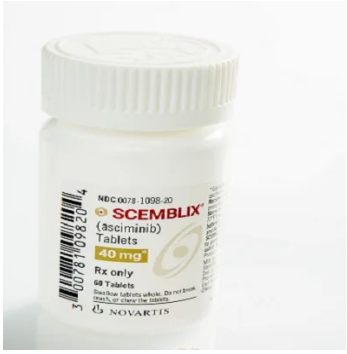
2. *"Atogepant Receives FDA Approval for the Preventive Treatment of Episodic Migraine in Adults." American Headache Society, 4 Oct. 2021, https://americanheadachesociety.org/news/atogepant-receives fda-approval-for- the-preventive-treatment-of-episodic-migraine-in-adults*

A New Chemo Therapy-Approach



Asciminib

Chronic Myeloid Leukemia is a type of blood cancer that happens due to the formation of an abnormal gene called BCR-ABL that takes place in immature version of the myeloid cells. This type of cancer happens often in adults and rarely occurs in children. It's often slow growing, but in some severe cases it is fast growing which makes it harder to treat. The first line of treatment for the Chronic Myeloid Leukemia is a type of blood cancer that happens due to the formation of an abnormal gene called BCR-ABL that takes place in immature version of the myeloid cells. This type of cancer happens often in adults and rarely occurs in children. It's often slow growing, but in some severe cases it is fast growing which makes it harder to treat. The first line of treatment for the CML are the tyrosine kinase inhibitors. They work by competing with the ATP for the ATP binding site on the tyrosine kinase protein, thereby inhibiting cancer cell proliferation.

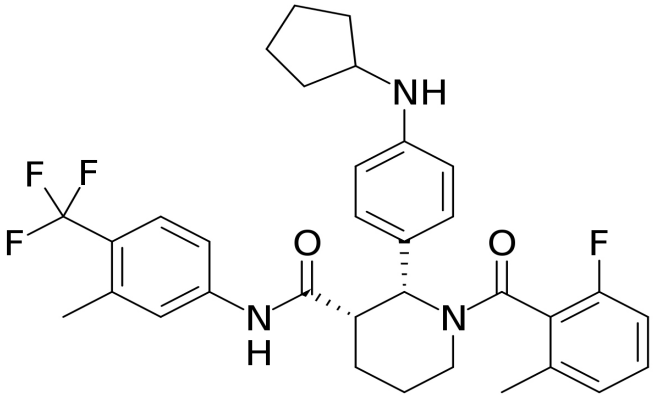


Imatinib was the first TKI to be discovered and used for the treatment of the CML which made a great success in treating the CML. However due to resistance developed, there's a need for new generations.[1] Consequently, second and third generations have been explored to overcome the resistance. Some patients have found to be resistant to all the available TKIs and when patients discontinue the TKI therapy, they relapsed due to presence of stem cells that are resistant to the TKI at first.[2] Asciminib (Scemblix®) has been developed to overcome this resistance and it finally took the FDA accelerated approval to be used for the treatment of CML in adults with Philadelphia chromosome positive in the chronic phase (PH+ CML-CP) that has already been treated with two or more TKI and found resistant. Also it was granted the full approval for the treatment of PH+CML-CP with T315I mutation on the 29th of October 2021. Asciminib was Accordingly, it gives new hope for the patients who are intolerant to or resistant TKIs .[3]

References:

1. ***Y;, Huang R;Kang Q;Liu H;Li. "New Insights into the Molecular Resistance Mechanisms of Chronic Myeloid Leukemia." Current Cancer Drug Targets, U.S. National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/26391311/.***
2. ***Thomson, Robert J. "Tyrosine Kinase Inhibitors." StatPearls [Internet]., U.S. National Library of Medicine, 14 Sept. 2021, https://www.ncbi.nlm.nih.gov/books/NBK563322/.***
3. ***Center for Drug Evaluation and Research. "FDA Approves Asciminib." U.S. Food and Drug Administration, FDA, https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-asciminib-philadelphia-chromosome-positive-chronic-myeloid-leukemia.***

A New Combination for the Treatment of ANCA-Associated Vasculitis



Avacopan

Tavenos®

Anti-Neutrophilic Cytoplasmic Autoantibody (ANCA) is an auto immune disease that affects the small blood vessels in the body. It happens due to the presence of autoantibodies called ANCA. These antibodies target the neutrophils in our bodies, which is a type of white blood cells. It specifically targets the cytoplasm of the neutrophils. As a result, the neutrophils attack the small blood vessels in the body, causing an inflammation which is called vasculitis. The inflammation happens in different organs in the body according to the place the genes affect, which make the symptoms of this disease vary and makes diagnoses hard.[1] When they target the cells in the skin, they cause a rash. But if they attack the kidneys, they will cause the leakage of protein and blood in the urine as well as kidney damage The only way to test for this disease is by doing a test for the presence of ANCA autoantibodies.

The patient issecluded for regular blood tests to make sure that their kidneys are not damaged. Sometimes when the disease is advanced they would take a biopsy to see the affected organ's damage.[2] Avacopen (tevneos®) is a new drug approved by the FDA on the 8th of October 2021. As of now you should be able to administer it as a combination therapy with the corticosteroids to help the patient maintain his remission phase and decrease the chances of relapse. The patient on Avacopen with another agent like rituximab, glucocorticoid, cyclophosphamide showed higher percentage of sustained remission after 52 weeks compared to the control group.[3]

References:

1. *FRANCISCO, E. M. (2021, November 12). First-in-class Medicine Recommended for Treatment of Rare Blood Vessel Inflammation. European Medicines Agency. Retrieved January 5, 2022, from https://www.ema.europa.eu/en/news/first-class-medicine-recommended-treatment-rare-blood-vessel-inflammation*
2. *"Anca Vasculitis." UNC Kidney Center, 26 Sept. 2018, https://unckidneycenter.org/kidneyhealthlibrary/glomerular-disease/anca-vasculitis/.*
3. *Jayne, David R.W., et al. "Randomized Trial of C5A Receptor Inhibitor Avacopan in ANCA-Associated Vasculitis." American Society of Nephrology, American Society of Nephrology, 1 Sept. 2017, https://jasn.asnjournals.org/content/28/9/2756.*

Black Box Warning

On the 31st of March 2021, the FDA has issued drug safety communication for lamotrigine. Studies showed a potential increased risk of heart arrhythmias in patients with heart disease, who are taking lamotrigine for seizure and mental health problems. There are still no studies to show if the whole class of this drug causes the same problem or it's specific to lamotrigine. This type of arrhythmia is a serious risk and life-threating side effect for patients with heart structural or functional disorders.

References

Center for Drug Evaluation and Research. "Increased Heart Risk with Lamotrigine in Patients with Heart Disease." U.S. Food and Drug Administration, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/studies-show-increased-risk-heart-rhythm-problems-seizure-and-mental-health-medicine-lamotrigine

Black Box Removal for Canagliflozin

On the 26th of August 2020, the FDA has reviewed the data provided from three clinical trials and came to the decision to remove the black box warning concerning canagliflozin about the risk of leg amputation. Canagliflozin is an antidiabetic drug belonging to the sodium-glucose cotransporter2 (SGLT2) inhibitors. The FDA has required a black box warning to be added to this drug information in 2017 to highlight the high risk of leg amputation for diabetic patients on this drug. This drug showed increased benefits for heart and kidney diseases for diabetic patients. Accordingly, the new data showed a lower risk of amputation than previously described especially while close monitoring. The risk of amputation is added in the warning and precaution section

References

Center for Drug Evaluation and Research. "FDA Removes Boxed Warning for Type 2 Diabetes Medicine Canagliflozin." U.S. Food and Drug Administration, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/fda-removes-boxed-warning

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