News Releases

Cablivi® (caplacizumab) approved by Health Canada for adults living with acquired thrombotic thrombocytopenic purpura (aTTP)

- Cablivi® is the first treatment approved in Canada for aTTP, a life-threatening blood clotting disorder
- It's estimated that up to 20% of patients die from TTP episodes, despite currently available treatments[1,2]

TORONTO, March 2, 2020 /CNW/ - Following a priority review, Health Canada has approved Cablivi® (caplacizumab) for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy. aTTP is a rare blood disorder that causes clots to form in blood vessels throughout the body, which may lead to damage to critical organs and can cause fatal complications.[3] Cablivi® is the first therapeutic specifically indicated for the treatment of aTTP in Canada.

> *"aTTP is a devastating disease that can lead to death if not treated effectively. While current treatment options have improved patient outcomes, mortality still occurs due to complications," says Dr. Katerina Pavenski, a haematologist and apheresis doctor at St. Michael's Hospital in Toronto. "In clinical studies, caplacizumab led to quicker platelet recovery and disease remission, and had a significant impact on disease complications. With the approval of caplacizumab, we now have an additional therapeutic option to help improve outcomes in aTTP patients."*

Cablivi® prevents microthrombi (blood clots) from forming in the body, allowing the patient to recover quicker, reducing some of the complications associated with aTTP, and lowering disease recurrences.[4]

> *"Sanofi Genzyme is committed to developing innovative products in areas of healthcare where we can make a significant difference to patients' lives," says Marissa Poole, General Manager, Sanofi Genzyme Canada. "The approval of Cablivi® offers a much needed, new approach to treating this serious and potentially life-threatening disorder."*

A Critical Gap in Rare Blood Disorder Treatment

aTTP is a rare blood clotting disorder in which clots form in small blood vessels.[5] Vessels can be blocked by these clots and have the potential to damage the brain, heart, kidneys or other organs.[6] Patients may experience an array of symptoms from living with aTTP such as fatigue, fever, bleeding (i.e., from the nose or gums), diarrhea, chest pain, abdominal pain, neurologic symptoms (i.e., confusion, headaches, visual changes) or thrombocytopenia (bruising, purpura, petechiae).[7]

> *"Those living with aTTP face significant and potentially fatal hurdles including challenges with treatment," says Sydney Kodatsky, Chair, Answering TTP Foundation. "Early detection is critical to prevent irreversible damage to the organs and minimize the risk of death. Canadian patients with aTTP can now have access to this targeted drug and the hope it brings for a faster recovery from an aTTP crisis. Answering TTP Foundation is looking forward to working with provincial and territorial partners to ensure that this therapy is quickly made available at TTP treatment centers across the country and receives timely reimbursement by public and private plans."*

About Cablivi®

The approval of Cablivi® by Health Canada is based on the results of the multi-centre, randomized, double-blind placebo-controlled Phase 3 clinical study known as HERCULES.

In the HERCULES study, treatment with caplacizumab in combination with plasma exchange and immunosuppression resulted in a statistically significant reduction in time to platelet count response versus plasma exchange and immunosuppression alone (p=0.01).[8] Patients treated with Cablivi® demonstrated a 1.55 times higher likelihood to achieve platelet count response compared to patients treated with placebo.[9]

The most frequently reported adverse reactions (>15%) were epistaxis, headache and gingival bleeding. Seven patients (7%) in the CABLIVI group experienced an adverse reaction leading to study drug discontinuation. None of the adverse reactions leading to discontinuation were observed in more than 1% of patients.[10]

Cablivi® was developed by Ablynx, which was acquired by Sanofi in 2018. Cablivi® was approved in the European Union in August 2018 and in the United States in February 2019.[11] Cablivi® is part of the company's rare blood disorders franchise within Sanofi Genzyme, the specialty care global business unit of Sanofi.[12]

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi entities in Canada employ approximately 2,000 people. In 2018, we invested more than $127 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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Sanofi, Empowering Life

References

1 Scully, M et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. *Br J Haematol.* 2012; 158(3): 323-35
2 Joly B, et al. Thrombotic thrombocytopenic purpura. *Blood.* 2017; 129(21):2836-46
3 Answering T.T.P. Thrombotic Thrombocytopenic Purpura Foundation. TTP Overview. Available at: https://www.answeringttp.org/ttp-overview. Accessed January 20, 2020
4 Cablivi® (caplacizumab) Product Monograph. February, 2020
5 Cablivi® (caplacizumab) Product Monograph. February, 2020
6 Cablivi® (caplacizumab) Product Monograph. February, 2020
7 Answering T.T.P. Thrombotic Thrombocytopenic Purpura Foundation. TTP Overview. Available at: https://www.answeringttp.org/ttp-overview. Accessed January 13, 2020
8 Cablivi® (caplacizumab) Product Monograph. February, 2020

9 Cablivi® (caplacizumab) Product Monograph. February, 2020
10 Cablivi® (caplacizumab) Product Monograph. February, 2020
11 Cablivi® (caplacizumab) Product Monograph. February, 2020
12 Cablivi® (caplacizumab) Product Monograph. February, 2020

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