

Cablivi™ (cplacizumab) approved in Europe for adults with acquired thrombotic thrombocytopenic purpura (aTTP)

- * First therapeutic approved for the treatment of aTTP, a rare blood-clotting disorder
- * In addition, U.S. FDA to conduct priority review of cplacizumab with a target action date of February 6, 2019

Paris – September 3, 2018 – The European Commission has granted marketing authorization for Cablivi™ (cplacizumab) for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), a rare blood-clotting disorder. Cablivi is the first therapeutic specifically indicated for the treatment of aTTP.

aTTP is a life-threatening, autoimmune-based blood clotting disorder characterized by extensive clot formation in small blood vessels throughout the body, leading to severe thrombocytopenia (very low platelet count), microangiopathic hemolytic anemia (loss of red blood cells through destruction), ischemia (restricted blood supply to parts of the body) and widespread organ damage especially in the brain and heart.

Despite the current standard-of-care treatment, consisting of daily plasma exchange (PEX) and immunosuppression, episodes of aTTP are still associated with a mortality rate of up to 20%, with most deaths occurring within 30 days of diagnosis¹.

“aTTP is a devastating disease. Many patients undergoing current standard-of-care treatment continue to be at risk of developing acute thrombotic complications, including stroke and heart attack, recurrence of the disease, lack of treatment response and death,” said Marie Scully, M.D, professor of hematology at University College London Hospitals. *“The approval of Cablivi provides an important addition to the standard-of-care treatment for patients with aTTP in Europe because it can significantly reduce time to platelet count normalization and induce a clinically meaningful reduction in recurrences.”*

Cablivi was developed by Ablynx, a Sanofi company. Sanofi Genzyme, the specialty care global business unit of Sanofi, will work with relevant local authorities to make Cablivi available to patients in need in countries across Europe.

Cablivi is the company’s first Nanobody®-based medicine to receive approval and the first newly approved product that will be part of Sanofi Genzyme’s Rare Blood Disorders franchise. Earlier this year, Sanofi acquired Bioverativ which has treatments for hemophilia A and B.

“The approval of Cablivi provides new hope for people diagnosed with aTTP, who to date have faced a very difficult disease with limited treatment options,” said Bill Sibold, Executive Vice President and Head of Sanofi Genzyme. “This approval is the next step towards our goal of becoming the leading rare blood disorders company in the industry. We are excited about the opportunities to continue to expand our rare blood disorders business and to help many people with very serious diseases.”

aTTP Clinical Program and Results

The approval of Cablivi in the EU is based on the Phase II TITAN and Phase III HERCULES studies in 220 adult patients with aTTP. The efficacy and safety of caplacizumab in addition to standard-of-care treatment, daily PEX and immunosuppression, were demonstrated in these studies.

In the HERCULES study, treatment with caplacizumab in addition to standard-of-care resulted in a significantly shorter time to platelet count response ($p < 0.01$), the study's primary endpoint; a significant reduction in aTTP-related death, recurrence of aTTP, or at least one major thromboembolic event during study drug treatment ($p < 0.0001$); and a significantly lower number of aTTP recurrences in the overall study period ($p < 0.001$). Importantly, treatment with caplacizumab resulted in a clinically meaningful reduction in the use of PEX and length of stay in the intensive care unit (ICU) and the hospital, compared to the placebo group.

In clinical trials, caplacizumab demonstrated a safety profile, consistent with its mechanism of action. The most frequently reported adverse reactions were epistaxis, headache and gingival bleeding. No deaths were reported during study drug treatment in the caplacizumab group in the TITAN and HERCULES studies, while for the placebo group, two deaths were reported in the TITAN study and three deaths in the HERCULES study.

U.S. FDA Review of Caplacizumab

Additionally, the U.S. Food and Drug Administration (FDA) has accepted for priority review the Biologics License Application for caplacizumab for treatment of patients 18 years of age and older experiencing an episode of aTTP. The target action date for the FDA decision is February 6, 2019.

About Cablivi

Caplacizumab is a bivalent anti-vWF Nanobody that received Orphan Drug Designation in Europe and the United States in 2009, in Switzerland in 2017 and in Japan in 2018. Caplacizumab blocks the interaction of ultralarge von Willebrand Factor (vWF) multimers with platelets and, therefore, has an immediate effect on platelet adhesion and the ensuing formation and accumulation of the micro-clots that cause the severe thrombocytopenia, tissue ischemia and organ dysfunction in aTTP.

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.

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Sanofi Forward-Looking Statements

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ⁱ Benhamou, Y. et al., Haematologica 2012