News Releases

Media Update: Once-weekly ALTUVIIIO® approved in Canada for the treatment of adults, adolescents and children living with hemophilia A

- *ALTUVIIIO® is a high-sustained factor VIII replacement therapy which provides effective bleed protection in adults, adolescents and children with hemophilia A*
- *Approval marks a paradigm shift in the hemophilia treatment landscape and recognizes a commitment to delivering innovation*

Toronto, March 27, 2025. Health Canada has issued Notice of Compliance (NOC) for ALTUVIIIO® (Antihemophilic Factor VIII [Recombinant, B-Domain deleted], Fc-VWF-XTEN fusion protein) for the treatment of adults, adolescents and children with hemophilia A (congenital Factor VIII [FVIII] deficiency).

Clinical trial data demonstrated a 77% reduction in annualized bleeding rates among participants who received ALTUVIIIO compared to their previous factor VIII prophylaxis regimens.

Hemophilia A is a rare, lifelong condition in which the ability of a person's blood to clot properly is impaired, leading to excessive bleeds and spontaneous bleeds into joints that can result in joint damage and chronic pain, and potentially impact quality of life. The severity of hemophilia A is determined by the level of clotting factor activity in a person's blood, and there is a negative correlation between risk of bleeding and factor activity levels.

Emil Wijnker
President, Canadian Hemophilia Society (CHS)
"The Canadian Hemophilia Society (CHS) welcomes Health Canada's approval of ALTUVIIIO®. The convenience of once-a-week IV infusions represents an important advancement, and having another treatment option available strengthens care possibilities for people living with hemophilia A."

Stephanie Veyrun-Manetti
General Manager Specialty Care and Country Lead Canada
"For over a decade, Sanofi has demonstrated its commitment to improving the lives of hemophilia patients, pursuing groundbreaking science and developing new approaches to treatment. This approval represents important progress in the treatment of patients with hemophilia A in Canada. As we continue to push the boundaries of what's possible, we are working towards a future where the impact of hemophilia A on daily life is minimal and patients can live without limitations."

Dr. Davide Matino
Hematologist
"The ultimate treatment goal in hemophilia care is to bridge the gap between living with hemophilia and living without limitations. With the approval of innovative therapies like ALTUVIIIO®, patients have the possibility of sustained factor levels which is setting a new standard of care that allow patients to experience extended periods of protection."

Dr. Anthony Chan
Pediatric Hematologist
"This approval underscores why the pursuit of advanced treatments is crucial for patients. Hemophilia A has been seen as a condition that dictates the terms of one's life. By maintaining factor levels in the normal to near-normal range for most of the time, this is a stepping stone towards a future where hemophilia A is no longer a life-limiting condition."

The ALTUVIIIO® Product Monograph includes data from previously treated patients with severe hemophilia A, including the pivotal XTEND-1 study in adults and adolescents and data from the XTEND-Kids study in children under 12 years of age. Please refer to the product monograph for more information. In the XTEND-1 study, once-weekly ALTUVIIIO® prophylaxis (50 IU/kg) met the primary endpoint, providing significant bleed protection for people with severe hemophilia A with a mean annualized bleeding rate (ABR) of 0.7 (95% CI: 0.5 – 1.0) and a median ABR of 0 (Q1, Q3: 0, 1.0) of treated bleeds. ALTUVIIIO® met the key secondary endpoint with a significant reduction of 77% in ABR based on treated bleeds versus prior factor VIII prophylaxis based on an intra-patient comparison (95% CI: 58%, 87%).

Data from the XTEND-Kids study showed that children younger than 12 years of age receiving once-weekly ALTUVIIIO® (50 IU/kg) for 52 weeks (n=73) experienced a mean ABR of 0.6 (95% CI: 0.4 - 0.9) and a median ABR of 0 (Q1, Q3: 0 - 1.0) of treated bleeds. Safety results were consistent with data from the XTEND-1 trial.

In XTEND-1, ALTUVIIIO at steady state maintained normal to near normal (>40 IU/dL) FVIII activity for a mean (SD) of 4.1 (0.7) days with once-weekly prophylaxis in adults. The FVIII activity over 10 IU/dL was maintained in 83.5% of adults and adolescents throughout the study. In children <12 years, ALTUVIIIO maintained normal to near normal (>40 IU/dL) FVIII activity for 2 to 3 days and >10 IU/dL FVIII activity for approximately 7 days.

Across these studies, ALTUVIIIO® has an established safety profile and there were no reports of factor VIII inhibitor development, although inhibitor formation is possible following administration of ALTUVIIIO®. The most common side effects (>10%) of ALTUVIIIO® are headache, joint pain and back pain.

About ALTUVIIIO ®

ALTUVIIIO® (Antihemophilic Factor FVIII [Recombinant, B-Domain deleted], Fc-VWF-XTEN fusion protein) is a first-in-class high-sustained factor VIII therapy that is designed to protect from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A. In adults and adolescents, ALTUVIIIO® has a 3 to 4-fold longer half-life relative to other standard and extended half-life factor VIII products, providing high-sustained factor activity levels within normal to near-normal range, allowing for once-weekly administration. ALTUVIIIO® is the first factor VIII therapy that has been shown to overcome the von Willebrand factor ceiling, which imposes a half-life limitation on earlier generation factor VIII therapies. ALTUVIIIO® builds on the innovative Fc fusion technology by adding a region of von Willebrand factor and XTEN polypeptides to extend its time in circulation.

ALTUVIIIO® is currently approved and marketed in the US, Taiwan, Japan and the European Commission for the treatment and prevention of bleeds and perioperative prophylaxis in hemophilia A under the name ALTUVOCT.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

In Canada, we employ over 2,000 people and invest 20% of our revenue annually in biopharma research, representing $1.2 billion CAD in R&D over the last decade, creating jobs, business, and opportunity throughout the country. We're also on track to deliver over $2 billion in new infrastructure investments by 2028, including two new vaccine manufacturing facilities at our Toronto Campus.

We have over 110 years of heritage dedicated to developing innovative health solutions for Canadians. What started as a small laboratory in May of 1914, recognized for having advanced some of the greatest contributions to public health, both nationally and globally, has evolved to become the largest biomanufacturing facility in Canada.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

For more information and media inquiries, please contact:
Bethany Rubin | +1 437-518-4769 | bethany.rubin@sanofi.com
Julien Guyomard |+1 416-434-3134 | julien.guyomard@sanofi.com