

Sanofi provides update on avalglucosidase alfa EU submission for patients with Pompe Disease

July 27, 2021

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for avalglucosidase alfa, a long-term enzyme replacement therapy for the treatment of people with Pompe disease. The CHMP positive opinion and recommended indication reflect the robust data from avalglucosidase alfa's clinical development program.

While Sanofi is pleased with the CHMP's recognition of the clinically meaningful improvements demonstrated in the avalglucosidase alfa development program, the CHMP considered that avalglucosidase alfa does not qualify as a New Active Substance (NAS). As a result, Sanofi will be requesting a re-examination of the CHMP opinion in relation to the NAS conclusion.

The positive opinion is based on data from the Phase 3 COMET study, which found that avalglucosidase alfa showed clinically meaningful improvements in respiratory function and movement endurance measures in people with late-onset Pompe disease.

About avalglucosidase alfa

Avalglucosidase alfa is an enzyme replacement therapy designed to target the mannose-6-phosphate (M6P) receptor, the underlying disease mechanism in Pompe disease. With approximately 15-fold increase in M6P content compared to the current standard of care, avalglucosidase alfa aims to help improve cellular enzyme uptake and enhance glycogen clearance in target tissues.

The CHMP positive opinion for avalglucosidase alfa follows the EMA's acceptance of Sanofi's MAA at the end of 2020.

Avalglucosidase alfa is also currently undergoing review in other countries including the U.S., U.K. and Japan. The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy, Fast Track and Priority Review designations to avalglucosidase alfa and the target FDA action date under the Prescription Drug User Fee Act is anticipated to be August 18, 2021. Avalglucosidase alfa has been granted Promising Innovative Medicine designation in the U.K.

The safety and efficacy of avalglucosidase alfa have not been fully evaluated by any regulatory authority worldwide.

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.

Media Relations Contact

Sally Bain
+1 (781) 264-1091
Sally.Bain@sanofi.com

Investor Relations Contacts Paris

Eva Schaefer-Jansen
Arnaud Delepine
Nathalie Pham

Investor Relations Contacts North America

Felix Lauscher
Fara Berkowitz
Suzanne Greco

Tel.: +33 (0)1 53 77 45 45
investor.relations@sanofi.com

<https://www.sanofi.com/en/investors/contact>

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