

Nexviazyme™ (avalglucosidase alfa for injection) is now approved in Canada for patients with late-onset Pompe disease (acid α -glucosidase deficiency)

MISSISSAUGA, ON, Nov. 15, 2021 /CNW/ - Nexviazyme™ (avalglucosidase alfa for injection) is now approved in Canada for the long-term treatment of patients older than 6 months of age with late-onset Pompe disease (acid α -glucosidase deficiency).¹ Pompe disease is a rare autosomal recessive metabolic disorder defined by a deficiency of acid α -glucosidase (GAA), causing an accumulation of lysosomal glycogen that leads to damaged muscles, including the diaphragm that supports respiratory function and skeletal muscles that affect mobility, impacting functional endurance and breathing.² Nexviazyme is an enzyme replacement therapy (ERT) designed to provide an exogenous source of GAA to the body to drive cellular enzyme uptake and enhance glycogen clearance in target tissues.³

"Due to the severity of Pompe disease, it significantly affects patients' mobility and breathing, things that we often take for granted," says Dr. Mark Tarnopolsky, Director of Neuromuscular and Neurometabolic Clinic, McMaster University Medical Center. "The Health Canada approval of Nexviazyme is an important milestone for Canadian Pompe patients and may represent a new standard of care."

It's estimated that between 5,000 and 10,000 people worldwide have Pompe disease.⁴ Many patients with late-onset Pompe disease experience long delays until diagnosis.⁵

"This approval is incredible news for patients and their families who are living with this debilitating disease and have limited options," says Brad Crittenden, Executive Director, Canadian Association of Pompe. "While a Pompe diagnosis is overwhelming and scary, it's a positive step to know that new options are becoming available to those who need it."

"Our main goal is to support those who suffer from chronic conditions and rare diseases like Pompe disease," says Carrie McElroy, Interim General Manager for Sanofi Genzyme and Interim Canada Country Lead. "While no cure currently exists, it's important to be able to provide new treatment options and continued research for Canadian patients living with Pompe disease."

About Sanofi Canada

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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¹ Nexviazyme product monograph, November 12, 2021.

² Dr. Ans T van der Ploeg, MD & Arnold JJ Resuser, PhD. The Lancet: Pompe's disease. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(08\)61555-X/ppt](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61555-X/ppt)

³ Nexviazyme product monograph, November 12, 2021.

⁴ Emory University School of Medicine. Pompe Disease: What you need to know.

https://med.emory.edu/departments/human-genetics/_documents/_documents-clinical-trials/Pompe%20dx.pdf. Accessed: November 8, 2021.

⁵ Craig Campbell, MD, Department of Neurology, Paediatrics, University of Western Ontario. Infantile and later -onset paediatric Pompe disease (glycogen storage disease type II). <https://cpsp.cps.ca/uploads/studies/Pompe-disease-Protocol-.pdf>. Accessed: November 4, 2021.

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