HLS Therapeutics Inc.

News Release

HLS Therapeutics Announces Health Canada Approval of NILEMDO® for the Reduction of LDL-Cholesterol in Canadians at Risk of Cardiovascular Disease

2025-11-18

- First-in-class oral treatment approved for patients requiring additional LDL-cholesterol reduction
- Supported by data from CLEAR Outcomes trial in nearly 14,000 patients demonstrating reduction in cardiovascular risk
- Commercial launch expected in Q2 2026
- Strengthens HLS's positioning as a leading Canadian Cardiovascular company
- Received Notice of Non-Compliance requesting additional information for NEXLIZET® (combo product) submission

TORONTO, Nov. 18, 2025 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a pharmaceutical company focused on addressing unmet needs in the treatment of psychiatric disorders and cardiovascular disease, announces that Health Canada has approved NILEMDO® (bempedoic acid) for use in Canada and has issued a Notice of Non-Compliance ("NON") for NEXLIZET® (bempedoic acid and ezetimibe). HLS in-licensed the exclusive rights to NILEMDO and NEXLIZET for the Canadian market from Esperion Therapeutics Inc. ("Esperion") (NASDAQ: ESPR) in May 2025.

NILEMDO

NILEMDO (also known as NEXLETOL® in the U.S.) is a once-daily oral therapy indicated to reduce LDL-C and the risk of major cardiovascular events in adults who require additional LDL-C lowering due to an inability to reach target levels with currently available therapies or due to statin intolerance. Cardiovascular disease is the second leading

cause of death in Canada[1], yet many high-risk patients still cannot achieve guideline-recommended LDL-C targets. As a result, more than half a million Canadians may benefit from bempedoic acid[2].

Dr. George Thanassoulis, MD, MSc, FRCPC, Professor of Medicine (Cardiology) at McGill University and a co-lead author of the Canadian Cardiovascular Society Lipid Guidelines, said, "Too many Canadians are unable to reach their LDL-C targets, even when following recommended treatments. NILEMDO (bempedoic acid) represents an important new option for these patients, including those patients who cannot tolerate statins. This therapy gives us a greater opportunity to reduce cardiovascular risk and help more patients live longer, healthier lives."

The approval is supported by data from the CLEAR Outcomes trial[3], a nearly 14,000-patient, randomized, double-blind cardiovascular outcomes study that demonstrated meaningful reduction in major adverse cardiovascular events ("MACE") in patients unable to take recommended statin therapy. NILEMDO provides a novel, oral pathway for LDL-C lowering while being less likely to cause muscle-related side effects that limit statin adherence. NILEMDO can be used alone or in combination with other LDL-lowering therapies, including statins, ezetimibe, and PCSK9 inhibitors.

"This approval represents a major milestone for HLS and for the many Canadians striving to better manage their cardiovascular health," said Craig Millian, CEO of HLS Therapeutics. "NILEMDO strengthens our cardiovascular portfolio and, along with Vascepa®, positions HLS as a leader in bringing novel oral CV medicines to the Canadian market. With the launch planned for Q2 2026, we believe that NILEMDO will play a significant role in our future growth and, importantly, this medicine will help more Canadians achieve their LDL-C goals and reduce their cardiovascular risk."

NILEMDO will be added to Health Canada's Register of Innovative Drugs and will benefit from eight years of data protection starting from its November 17, 2025, approval. This period, combined with existing and pending patents, provides market exclusivity for the drug extending until 2040. The eligible patents will be added to Health Canada's Patent Register following receipt of the Notice of Compliance ("NOC") and in accordance with Health Canada's process.

NEXLIZET

For NEXLIZET, HLS received a NON from Health Canada, indicating that the new drug submission had certain deficiencies following initial review. Health Canada did not raise any concerns regarding the clinical data, efficacy, or safety profile of NEXLIZET but indicated that further clarification and additional data addressing CMC (chemistry, manufacture and controls) and biopharmaceutics matters are required to support approval.

Mr. Millian added: "We are excited to launch NILEMDO in Canada in the second quarter of 2026. With support from our partner Esperion, we are working on addressing the outstanding regulatory requirements for NEXLIZET and will

respond to Health Canada as expeditiously as possible. NEXLIZET is currently approved and marketed successfully in the U.S., Europe and other global markets, and we look forward to making this important therapy available to Canadians in the future."

ABOUT HLS THERAPEUTICS INC.

Formed in 2015, HLS is a pharmaceutical company focused on the acquisition and commercialization of late-stage development, commercial stage promoted and established branded pharmaceutical products in the North American markets. HLS's focus is on products targeting the central nervous system and cardiovascular therapeutic areas. HLS's management team is composed of seasoned pharmaceutical executives with a strong track record of success in these therapeutic areas and at managing products in each of these lifecycle stages. For more information visit: **www.hlstherapeutics.com**

FORWARD LOOKING INFORMATION

This release includes forward-looking statements regarding HLS and its business. Such statements are based on the current expectations and views of future events of HLS's management. In some cases the forward-looking statements can be identified by words or phrases such as "may", "will", "expect", "plan", "anticipate", "intend", "potential", "estimate", "believe" or the negative of these terms, or other similar expressions intended to identify forward-looking statements, including, among others, statements with respect to HLS's pursuit of additional product and pipeline opportunities in certain therapeutic markets, statements regarding growth opportunities and expectations regarding financial performance. The forward-looking events and circumstances discussed in this release may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting HLS, including risks relating to the specialty pharmaceutical industry, risks related to the regulatory approval process, economic factors and many other factors beyond the control of HLS. Forward-looking statements and information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause HLS's actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statement or information. Accordingly, readers should not place undue reliance on any forward-looking statements or information. A discussion of the material risks and assumptions associated with this release can be found in the Company's Annual Information Form dated March 12, 2025, and Management's Discussion and Analysis dated November 12, 2025, both of which have been filed on SEDAR+ and can be accessed at **www.sedarplus.ca**. Accordingly, readers should not place undue reliance on any forward-looking statements or information. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and HLS undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

REFERENCES

https://www150.statcan.gc.ca/n1/daily-quotidien/250305/t001a-eng.htm?utm_source=chatgpt.com

Internal Company estimates

https://www.nejm.org/doi/full/10.1056/NEJMoa2215024?utm_source=chatgpt.com

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