



HLS Therapeutics Inc.

News Release

HLS Therapeutics Announces NILEMDO™ (bempedoic acid) is now available in Canada for the Reduction of LDL-Cholesterol in Patients at Risk of Cardiovascular Disease

2026-03-05

- First-in-class, once-daily oral non-statin therapy now available by prescription across Canada
- Addresses a significant unmet need for over half a million Canadians who can not get to their LDL-C goal on statin-based therapy or who are statin intolerant
- Supported by the landmark CLEAR Outcomes trial demonstrating reduction in major adverse cardiovascular events in nearly 14,000 patients

TORONTO, March 5, 2026 /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, today announced the commercial launch of NILEMDO™ (bempedoic acid) in Canada. NILEMDO is now available by prescription nationally. HLS in-licensed the exclusive rights to NILEMDO and NEXLIZET® (bempedoic acid and ezetimibe) for the Canadian market from Esperion Therapeutics Inc. ("Esperion") (NASDAQ: EPR) in May 2025.

Health Canada approved NILEMDO in November 2025. NILEMDO is indicated to reduce LDL-C and the risk of major cardiovascular events in adults who require additional low-density lipoprotein cholesterol ("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, yet many high-risk patients still cannot achieve guideline-recommended LDL-C targets.¹ HLS estimates that more than half a million Canadians may benefit from NILEMDO.²

"Despite considerable evidence and guideline recommendations, too many Canadians are still not reaching their

LDL-C targets" said Dr. Lawrence Leiter, Professor of Medicine and Nutritional Sciences at the University of Toronto. "Bempedoic acid (NILEMDO) offers a new option for Canadian patients who cannot achieve their LDL-C goal or are intolerant to statins. We now have a well-tolerated, once-daily oral therapy that is supported by strong clinical evidence including the large CLEAR Outcomes trial, that provides clinicians and their patients with a new means of reducing cardiovascular risk."

A NOVEL MECHANISM ADDRESSING A LARGE UNMET NEED

NILEMDO provides a novel, oral pathway for LDL-C lowering while being less likely to cause muscle-related side effects that limit statin adherence for many patients. In clinical practice, physicians typically initiate therapy with a statin, then add ezetimibe if additional LDL-C lowering is needed. NILEMDO fits directly into this established treatment paradigm, providing a meaningful step-up option for patients who remain above their LDL-C target on combination therapy or who cannot tolerate adequate statin doses. NILEMDO can be used alone or in combination with other LDL-lowering agents, including statins, ezetimibe, and PCSK9 inhibitors.

The approval of NILEMDO is supported by the CLEAR Outcomes trial, a landmark randomized, double-blind cardiovascular outcomes study in nearly 14,000 patients with high cardiovascular risk who were unable to take recommended statin therapy. The trial demonstrated that bempedoic acid significantly reduced the risk of major adverse cardiovascular events ("MACE"), including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, and coronary revascularization.³

"With the launch of NILEMDO, Canadians who have been unable to reach their LDL-C targets now have a new oral treatment option supported by robust cardiovascular outcomes data," 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 cardiovascular medicines to the Canadian market. Importantly, we believe this medicine will help more Canadians achieve their LDL-C goals and reduce their cardiovascular risk."

Nilemdo has been submitted for reimbursement under private and public plans and is currently under review. HLS is expecting meaningful private payer coverage in Q2 and potential for public reimbursement in late 2026.

LOOKING AHEAD: NEXLIZET

HLS is also advancing its regulatory submission for NEXLIZET (bempedoic acid and ezetimibe), a once-daily combination pill that combines two complementary LDL-lowering mechanisms. NEXLIZET demonstrated approximately 38% LDL-C reduction in clinical trials. HLS is working with its partner Esperion Therapeutics, Inc. to respond to Health Canada's outstanding requirements as expeditiously as possible and anticipates a 2027 commercial launch.

ABOUT NILEMDO (bempedoic acid)

NILEMDO (bempedoic acid) is a once-daily oral medicine indicated in Canada 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. NILEMDO is approved and marketed globally, including in the United States (as NEXLETOL®) and in Europe, where it has been available since 2020. In Canada, NILEMDO will benefit from eight years of data protection starting from its November 17, 2025, approval date. This period, combined with existing and pending patents, provides market exclusivity for the drug extending until 2040.

To view the full Nilemdo product monograph, please **click here**.

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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