

HLS Therapeutics Announces that Icosapent Ethyl (Vascepa®) is Included in the 2021 Canadian Cardiovascular Society (CCS) Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in Adults

- ***CCS dyslipidemia management guidelines published in the Canadian Journal of Cardiology (CJC) on March 26, 2021***
- ***Strong recommendation for the use of icosapent ethyl for Primary Prevention (diabetes and ≥ 1 cardiovascular disease (CVD) risk factors) and Secondary Prevention (atherosclerotic cardiovascular disease (ASCVD))***
- ***Guidelines do not recommend the use of over-the-counter omega-3 polyunsaturated fatty acids supplements to reduce CVD risk***

TORONTO, March 29, 2021 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, announces that the Canadian Cardiovascular Society ("CCS") has included icosapent ethyl (Vascepa) in its 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult, published in the Canadian Journal of Cardiology. The guideline authors recommend the use of icosapent ethyl to lower the risk of cardiovascular ("CV") events in patients with ASCVD, or with diabetes and ≥ 1 CVD risk factors, who have an elevated fasting triglyceride level between 1.5-5.6 mmol/L despite treatment with maximally tolerated statin therapy. The Guidelines specifically do not recommend the use of over-the-counter omega-3 polyunsaturated fatty acids supplements (marketed as natural health products in Canada) and specified the lack of CV benefit of omega-3 fatty acids from dietary sources or other formulations/supplements.

"By including Vascepa in the guidelines, the CCS is indicating its focus on improving patient care by reducing the risk of atherosclerotic cardiovascular disease," said Gilbert Godin, CEO of HLS. "To have this highly credible medical society recognize the benefit of Vascepa as a new treatment option for Canadians on statins with elevated triglycerides who are at risk of cardiovascular events such as Heart Attack, Stroke, Revascularization or Death is a tremendous development for those eligible patients."

In Canada, up to two million people have triglycerides ≥ 1.5 mmol/L and established cardiovascular disease, or diabetes with risk factors despite statin treatment.^{1,2,3}

"These updated guidelines from the Canadian Cardiovascular Society reaffirm the importance of the REDUCE-IT trial findings to Canadian patients, not only in enhancing care, but also in broadening awareness of the need for an icosapent ethyl treatment among patients who may have their cholesterol controlled with a statin, but still face a residual risk of major cardiac events," said Dr Jean-Claude Tardif, Director of the Research Center at the Montreal Heart Institute and professor of medicine at University of Montreal. "Based on what we have learned on icosapent ethyl, I foresee the beginning of a change in clinical practice in how best to treat patients with multifactorial risks of cardiovascular events beyond cholesterol management."

Added Mr. Godin: "With this new recommendation, Vascepa is now included in the treatment guidelines or otherwise recommended for use by 14 major medical associations internationally, solidifying its role as an important treatment option beyond cholesterol management for millions of patients worldwide at risk for a cardiovascular event."

The icosapent ethyl recommendation was classified as '**Strong Recommendation; High-Quality Evidence**' and supported by the results of the REDUCE-IT cardiovascular outcomes study. The Guidelines state: "As icosapent ethyl is a purified form of ethyl EPA, the results of REDUCE-IT cannot be extrapolated to other non-prescription omega-3 fatty acids, which typically contain a mixture of EPA and docosahexaenoic acid ("DHA")."

The CCS does not provide endorsements or any form of certification for brand name commercial products. Accordingly, the inclusion of icosapent ethyl in the CCS Guidelines should not be understood as an endorsement by CCS of Vascepa.

The complete **2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult** addressing Primary and Secondary Prevention of Cardiovascular Diseases with icosapent ethyl published in the Canadian Journal of Cardiology can be accessed online here [https://www.onlinecjc.ca/article/S0828-282X\(21\)00165-3/fulltext](https://www.onlinecjc.ca/article/S0828-282X(21)00165-3/fulltext) (payment/subscription may be needed).

ABOUT VASCEPA (ICOSAPENT ETHYL) CAPSULES

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was approved by Health Canada, was added to Health Canada's Register of Innovative Drugs and benefits from data protection for a term of eight years, as well as being the subject of multiple issued and pending patents based on its unique clinical profile. HLS in-licensed the exclusive rights to VASCEPA for the Canadian market from Amarin Corporation (NASDAQ:AMRN).

ABOUT HLS THERAPEUTICS INC.

Formed in 2015, HLS is a specialty 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, please visit: www.hlstherapeutics.com

REFERENCES

¹<https://www150.statcan.gc.ca/n1/pub/82-003-x/2016001/article/14305/tbl/tbl02-eng.htm>

²<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2989357/>

³<https://www150.statcan.gc.ca/n1/pub/82-625-x/2018001/article/54982-eng.htm>

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 17, 2021 and Management's Discussion and Analysis dated March 17, 2021, both of which have been filed on SEDAR and can be accessed at www.sedar.com. 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.

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