HLS Therapeutics Inc.

HLS Therapeutics welcomes both CADTH's recommendation to reimburse Vascepa® (icosapent ethyl) for patients with established cardiovascular disease and PMPRB's notification on its introductory price

- **CADTH recommends Vascepa be reimbursed for patients with established cardiovascular disease under certain conditions.**
- **PMPRB notifies HLS that following PMPRB's review, Vascepa's introductory price submission did not trigger the pricing investigation criteria.**
- **HLS reaffirms its peak-year sales forecast for Vascepa.**
- **HLS management to hold investor update conference call with accompanying slides today at 5:30 p.m. EDT.**

TORONTO, July 20, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets welcomes the recent recommendation by the Canadian Agency for Drugs and Technologies in Health ("CADTH") that Vascepa be reimbursed by participating public drug plans for statin-treated patients with established cardiovascular diseases and elevated triglycerides.

Having worked diligently to ensure an appropriate introductory price, HLS also received notification by the PMPRB that, further to its review, Vascepa's price did not trigger the investigation criteria for excessive pricing.

Many patients may benefit as this recommendation helps make available a new treatment option

"We are very pleased to see Vascepa's benefit be recognized as a relevant agent to reduce the risk of major adverse cardiovascular events for patients that have documented cardiovascular disease. HLS, with the support of leading physicians, medical societies and other patient care advocates, is working to expand CADTH's recommendations in the future to address other groups of high-risk patients who have been shown to benefit from treatment with Vascepa, in particular those patients with diabetes and at least one risk factor, as approved by Health Canada," said Greg Gubitz, CEO of HLS.

Vascepa studied and indicated to help multiple groups of at-risk patients beyond conventional therapies

The clinical effectiveness and related safety profile of Vascepa was demonstrated in REDUCE-IT®[1], a global cardiovascular study. The results of REDUCE-IT, a five-year outcomes study involving 8,179 patients at risk, have been broadly published and following a priority review, led to the approval of Vascepa in Canada, to reduce the risk of cardiovascular events. Such clinical results were outlined in CADTH's Clinical Review Report prepared for their own committee. That briefing report accurately reported that treatment with Vascepa compared to placebo resulted in a 25% reduction in the risk of major ischemic cardiovascular events, including a 20% reduction in death due to cardiovascular causes, a 31% reduction in myocardial infarction, a 28% reduction in stroke and a 34% reduction in coronary revascularization procedures in patients with established cardiovascular disease, or high-risk diabetics already receiving treatment with statins. The report stated "*Patients with established CVD (defined as the 'secondary prevention' group) and patients with diabetes and one or more CV risk factor(s) (the 'primary prevention' or 'at high risk' group) can remain at high risk for a major adverse cardiovascular event (MACE)"* and later, *"Patients with established CVD and high-risk diabetics with elevated levels of triglycerides, i.e., those meeting the inclusion criteria from the included studies and the indication for this review, will be the target population for treatment with icosapent ethyl in clinical settings."*

"The CADTH recommendation to separate the diabetic population in two and exclude high-risk patients is perplexing to us as it is not rooted in good clinical practices and evidence-based medicine," said Mr. Gubitz.

REDUCE-IT showed that the use of Vascepa prevented more than 159 major cardiovascular events for every 1000 patients treated, or effectively one fewer major adverse cardiovascular event (MACE), like a heart attack or stroke, per six patients treated over a period of five years. Such events are painful, and potentially deadly to patients and expensive to society. These compelling clinical results prompted Health Canada to grant Vascepa a rare priority review, an approval pathway for treatment for a serious, life-threatening or debilitating disease for which no other drug exists in Canada.

"Cardiovascular trials with this magnitude of benefit are not often seen. Highly statistically significant, and clinically important, relative and absolute risk reductions were observed in REDUCE-IT, including cardiovascular death," said Dr. Lawrence Leiter, Endocrinologist, Director of the Lipid Clinic, St-Michael's Hospital, Toronto. "Given the dramatic benefits observed in the study, I will be extremely disappointed if those patients in my practice typical of those included in the REDUCE-IT trial do not have access to Vascepa."

Over the past 18 months, the highly qualified Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the U.S. FDA unanimously recommended to approve Vascepa, and the FDA and Health Canada did so by means of their approval of the indication in all studied patients. Additionally, in 2019, The American Diabetes Association (ADA) updated their Standards of Medical Care in Diabetes to add Vascepa to their guidelines and were soon followed by nine other medical societies including the American Heart Association.[2,3,4,5,6,7,8,9,10]

"As much as we are very pleased with the reimbursement recommendation for patients with established cardiovascular disease, diabetic or not, high-risk diabetic patients who rely on public health plans should not have to wait to have a cardiac event before they can get access to a drug intended to prevent those very events. This mentality negates the principles and the benefits of prevention," said Mr. Gubitz. "All diabetics at high risk should have a right to access the latest innovations and see that their longevity and their quality of life may be positively impacted by adding Vascepa to their statin, and we will continue to work towards that goal."

Vascepa's benefits and long-term potential remain strong

Fortunately, in the past, divided recommendations from CADTH have not always prevented the full in-label reimbursement of new therapies, especially when they have demonstrated such compelling clinical results. "We remain confident that public payors in Canada, who are the true custodians of Canadians' health and well-being, will recognize the importance and the value that Vascepa can bring to all at-risk patients included in the label's indication when making their reimbursement decisions," said Mr. Gubitz. "Based on that superb clinical value, we believe that Vascepa's long term sales potential and peak-year sales forecast of C$200M to $300M remain as we have reaffirmed today with upside potential."

In order to increase the economic value of Vascepa, and in order for all patients for which the drug has been approved by Health Canada to have timely access to this life-saving drug, HLS will work with all stakeholders to secure listing agreements with public payers and with provincial plans, either directly or via the pan-Canadian Pharmaceutical Alliance (pCPA).

CONFERENCE CALL & WEBCAST DETAILS
HLS will hold a conference call today at 5:30 p.m. Eastern Daylight Time with accompanying slides to discuss these developments. The call will be hosted by Mr. Greg Gubitz, Chief Executive Officer, Mr. Gilbert Godin, President and Chief Operating Officer and Mr. Tim Hendrickson, Chief Financial Officer. **To view the slides that accompany management's discussion, please use the webcast link.**

CONFERENCE ID:	6012139
DATE:	July 20, 2020
TIME:	5:30 p.m. EDT
DIAL-IN NUMBER:	1-888-231-8191 or 647-427-7450
WEBCAST LINK:	https://produceredition.webcasts.com/starthere.jsp?ei=1346090&tp_key=039f0dacdc
TAPED REPLAY:	1-855-859-2056 or 416-849-0833
REPLAY PASSCODE:	6012139

A link to the live audio webcast of the conference call will also be available on the events page of the investors section of HLS Therapeutics' website at www.hlstherapeutics.com. Please connect at least 15 minutes prior to the conference call to ensure adequate time for any software download that may be required to hear the webcast. The taped replay will be available for 14 days and the archived webcast will be available for 90 days.

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. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels. 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. Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for

Hypertriglyceridemia. N Engl J Med. 2019;380(1):11–22. doi:10.1056/NEJMoa1812792
2. American Diabetes Association http://main.diabetes.org/dorg/bod/2019-2020/ADA-Strategic-Architecture.pdf
3. American Heart Association https://www.heart.org
4. European Society of Cardiology https://www.escardio.org/The-ESC/Who-we-are
5. European Atherosclerosis Society https://www.eas-society.org/page/about_eas
6. National Lipid Association https://www.lipid.org/about
7. American Association of Clinical Endocrinologists https://www.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive
8. Brazilian Society of Cardiology Cardiovascular Prevention Guideline Update http://publicacoes.cardiol.br/portal/abc/ingles/aop/2019/aop-diretriz-prevencao-cardiovascular-ingles.pdf
9. The Thrombosis CanadaTM Clinical Guides. Stroke: Secondary Prevention. Accessed on April 13, 2020. URL: https://thrombosiscanada.ca/clinicalguides/#
10. Arnold SV, Bhatt DL, Barsness GW, et al; on behalf of the American Heart Association Council on Lifestyle and Cardiometabolic Health and Council on Clinical Cardiology. Clinical management of stable coronary artery disease in patients with type 2 diabetes mellitus: a scientific statement from the American Heart Association. Circulation. 2020;141:e000–e000. doi: 10.1161/CIR.0000000000000766

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 18, 2020, which has 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.

SOURCE HLS Therapeutics Inc.

For further information: HLS CONTACT INFORMATION: Dave Mason, Investor Relations, HLS Therapeutics Inc., (416) 247-9652, dave.mason@loderockadvisors.com; Gilbert Godin, President and Chief Operating Officer, HLS Therapeutics Inc., (484) 232-3400 ext101, g.godin@hlstherapeutics.com

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