HLS Therapeutics Inc.

HLS Therapeutics Provides Investor Update on the Canadian Launch of Vascepa® (Icosapent Ethyl)

- ***Vascepa to be available on or about February 18, 2020, supported by a national Cardiovascular salesforce***
- ***Vascepa becomes the first and only Health Canada-approved medication for reducing cardiovascular risk beyond cholesterol-lowering therapy in the studied high-risk patients approved for treatment***
- ***Vascepa is supported by data from the REDUCE-IT® trial, an international 8,179 patient outcomes study that showed a 25% placebo-controlled risk reduction in the first occurrence of major adverse cardiovascular events***
- ***Cardiovascular disease is the number one killer globally[1] and HLS is taking steps to make Vascepa accessible and affordable to the Canadian population***

TORONTO, Jan. 28, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, is pleased to update investors that Vascepa® (icosapent ethyl, or "IPE") will become available to Canadians on or about February 18, 2020. At launch, Vascepa will be supported by the Company's national Cardiovascular salesforce, initially sized at 22 representatives, in addition to eight other field-based roles.

On December 31, 2019, Vascepa was approved by Health Canada and is indicated to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides who are at high risk of cardiovascular events due to established cardiovascular disease or diabetes and at least one other cardiovascular risk factor.

Vascepa was granted a Priority Review as it met Health Canada's criteria of intending to address a serious, life-threatening or debilitating disease or condition for which no drug was marketed in Canada, and for which there is substantial evidence of clinical effectiveness of the treatment.

As a result of its approval, Vascepa is now the first and only drug in Canada indicated to reduce persistent residual cardiovascular risk in patients stabilized on a statin, with elevated triglycerides and other risk factors for cardiovascular disease.

Cardiovascular Disease is an Urgent Public Health Issue
"There is no doubt that cardiovascular disease is an urgent and growing public health issue, with more than half of Canadian adults[2] impacted by the disease in ways that can be tragic and costly," said Greg Gubitz, Chief Executive Officer of HLS. "Cardiovascular disease costs Canadians more than $21.2 billion each year[2], and stroke alone costs the Canadian economy $3.6 billion a year in physician services, hospital costs, lost wages and decreased productivity[2]. Vascepa was developed and tested over the course of a decade and at a cost of more than $500.0 million in order to bring a new preventative care solution that may help the many family members, friends and neighbors who may be at risk for a cardiac event. We look forward to bringing this product to Canadians in the coming weeks."

Health Canada's regulatory approval was based on data from the 8,179 patient REDUCE-IT® outcomes trial, a landmark cardiovascular outcome study that has been referred to as the most significant of the last 25 years in the field of preventative cardiology[3].

The REDUCE-IT trial results showed[4]:

- First occurrence of Major Adverse Cardiovascular Events (MACE) reduced by 25%
- Cardiovascular Death Reduced by 20%
- Fatal or Nonfatal Heart Attacks Reduced by 31%
- Fatal or Nonfatal Stroke Reduced by 28%
- Urgent or Emergent Coronary Revascularization Reduced by 35%
- Hospitalization for Unstable Angina Reduced by 32%
- Number Needed to Treat (NNT[5]) for Primary Composite Endpoint: 21. This means that on average, for every 21 patients treated with Vascepa one coronary event will be prevented. For perspective, NNTs for cholesterol-managing drugs atorvastatin (Lipitor®)[6] and evolocumab (Repatha®)[7] were reported to be 45 and 67, respectively. These cholesterol-managing drugs are not competitors with Vascepa as Vascepa is not a therapy for cholesterol (LDL-C) management nor has Vascepa been evaluated in a head-to-head

study with these drugs.

Recently, an analysis of the REDUCE-IT study data, aimed at determining the extent to which icosapent ethyl reduces the risk of subsequent cardiovascular events, was also carried out[5]. The results from this analysis suggest that as patients continued treatment after the first event, icosapent ethyl not only reduces the residual risk of a first cardiovascular event by 25%, but also prevents the occurrence of subsequent events by 32%, 31% and 48% for the second, third and fourth or more events, respectively, or 159 events for every 1,000 patients[5].

Scientific and Medical Recognition Outside Canada
Vascepa and the REDUCE-IT study data have received widespread support within the North American and European medical communities. In November 2019, the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the U.S. Food and Drug Administration (FDA) reviewed and voted unanimously (16-0) to recommend approval of Amarin's submission for an indication and label expansion for Vascepa (icosapent ethyl) capsules in the US to reduce the risk of cardiovascular events in high-risk patients based on results from the REDUCE-IT trial.

In the US and in Europe, a growing number of medical societies including the American Heart Association (AHA), the American Diabetes Association (ADA), the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS) have already updated their Clinical Practice Guidelines for the Management of Dyslipidaemias and are recognizing the importance of the REDUCE-IT study by recommending the usage of Vascepa (icosapent ethyl) in appropriate patients.

Also significant was the recognition coming from the publication of the REDUCE-IT results in the New England Journal of Medicine[4], the Journal of American Cardiology[5] and the American Heart Association.

Affordably Priced Vascepa Positions HLS to Potentially Help Canadian Patients
Upon approval, and in preparation for the launch, HLS began engaging with private payers to help establish the coverage of Vascepa for those Canadians who are covered by private insurance plans. Provincial drug plans are also being actively engaged in compliance with the relevant public processes of the various provinces.

The price of a 1-gram capsule of Vascepa will be $2.45. The monthly treatment cost, based on a 2-gram twice daily administration, will be $294. Once coverage has been approved by payers, the cost to covered patients is expected to be lower based on individual plan benefits.

To support this pricing from a pharmacoeconomic perspective, HLS commissioned and submitted to various Health Technology Assessment ("HTA") organizations, an unpublished cost-utility analysis. The objective of the analysis was to estimate the difference in benefit and cost of Vascepa compared to placebo, as adjunct therapy to statins, for both the primary and secondary prevention of cardiovascular events in a population of patients described in the REDUCE-IT trial. This health-economic modeling was based on a 20-year time horizon and carried out from a societal perspective in which the cost of drug acquisition, is evaluated against health care costs associated with cardiovascular events (fatal and non-fatal MI, fatal and non-fatal stroke, coronary revascularization, unstable angina), as well as medical visits, laboratory tests, management of adverse events and loss of productivity if the drug was not used.

In the health-economics study presented by HLS to HTA organizations, at less than $10 per day, Vascepa has been shown to be cost-effective with an estimated cost-per quality-adjusted life-year (QALY) of $42,797. QALY is a measure of disease burden, including both the quality and the quantity of life lived. Based on this industry standard measure for comparing costs of therapies, Vascepa is significantly less than that of several newer therapies, including other cardiovascular drugs[8,9].

Mr. Gubitz added: "Our goal is to make Vascepa accessible to all Canadian patients who may stand to benefit from it, and we believe we have priced it at an accordingly cost-effective and affordable level. Canadians deserve access to the latest innovations to reduce the risk of cardiovascular death and the consequences of other major cardiovascular events. With its strong trial results and accessible pricing, we believe Vascepa can deliver significant long-term benefit for both Canadians and our health care system."

HLS plans to use the results of the REDUCE-IT study, pharmacoeconomic analysis and other medical information and data, as the Company continues in its discussions with HTA organizations and payers to support Vascepa coverage.

SAFETY
In REDUCE-IT, adverse events occurring with Vascepa (icosapent ethyl) use at greater than 5% and greater than placebo were: peripheral edema (6.5% Vascepa versus 5.0%), although there was no increase in the rate of heart failure in Vascepa patients; constipation (5.4% Vascepa versus 3.6%); and atrial fibrillation (5.3% Vascepa versus 3.9%).

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 visit: www.hlstherapeutics.com

REFERENCES

1. The top 10 causes of death [Internet]. World Health Organization. 2018 [cited 2020Jan 27]. Available from: https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death
2. 2019 Report on Heart, Stroke and Vascular Cognitive Impairment (Pg 14) [Internet]. Heart and Stroke Foundation of Canada. 2020 [cited 27 January 2020]. Available from: https://www.heartandstroke.ca/-/media/pdf-files/canada/2019-report/heartandstrokereport2019.ashx
3. Fornell D, editor. FDA Expands Vascepa to Reduce Cardiovascular Events in Elevated Triglyceride Patients [Internet]. Diagnostic and Interventional Cardiology (DAIC). 2019 [cited 2020Jan27]. Available from: https://www.dicardiology.com/article/fda-expands-vascepa-reduce-cardiovascular-events-elevated-triglyceride-patients
4. Bhatt DL, Steg PG, Miller M, Brinton EA, Jacobson TA, Ketchum SB, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. New England Journal of Medicine. 2019Mar;380(1):11–22. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1812792
5. Bhatt DL, Steg PG, Miller M, Brinton EA, Jacobson TA, Ketchum SB, et al. Effects of Icosapent Ethyl on Total Ischemic Events. Journal of the American College of Cardiology. 2019;73(22):2791–802. Available from: https://www.sciencedirect.com/science/article/pii/S0735109719337969
6. Larosa JC, Grundy SM, Waters DD, Shear C, Barter P, Fruchart J-C, et al. Intensive Lipid Lowering with Atorvastatin in Patients with Stable Coronary Disease. New England Journal of Medicine. 2005Jul;352(14):1425–35. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa050461
7. Sabatine MS, Giugliano RP, Keech AC, Honarpour N, Wiviott SD, Murphy SA, et al. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. New England Journal of Medicine. 2017Apr;376(18):1713–22. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1615664
8. CADTH Canadian Drug Expert Committee Final Recommendation- Evolocumab [Internet]. Canadian Agency for Drugs and Technologies in Health (CADTH). 2016 [cited 27 January 2020]. Available from: https://www.cadth.ca/sites/default/files/cdr/complete/SR0441_complete_Rapatha-Feb-23_16_e.pdf
9. CADTH Canadian Drug Expert Committee Final Recommendation- Alirocumab [Internet]. Canadian Agency for Drugs and Technologies in Health (CADTH). 2016 [cited 27 January 2020]. Available from: https://www.cadth.ca/sites/default/files/cdr/complete/SR0469_complete_Praluent_Jul-20-16.pdf

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 April 1, 2019, 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.

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