HLS Therapeutics Inc.

HLS Therapeutics Announces Health Canada Approval for Vascepa® to Reduce the Risk of Cardiovascular Events

- ***Health Canada approval follows priority review for Vascepa***
- ***Vascepa becomes the first and only HC-approved medication for reducing cardiovascular risk beyond cholesterol lowering therapy in the studied high-risk patients approved for treatment***
- ***Commercial launch expected to take place in the mid-February 2020 timeframe***
- ***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***
- ***Vascepa is the subject of numerous Canadian issued and pending patents with expiration dates which could extend to 2039***.

TORONTO, Dec. 31, 2019 /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 announce that Health Canada has approved the use of Vascepa® (icosapent ethyl) 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. HLS in-licensed the exclusive rights to Vascepa for the Canadian market from Amarin Corporation (NASDAQ:AMRN) in 2017.

"Cardiovascular disease is the leading cause of death worldwide and Vascepa provides a new treatment option for healthcare practitioners to enhance cardiovascular protection for the many Canadians at risk of a cardiac event," said Dr. Jean-Claude Tardif, Cardiologist and Director, Montreal Heart Institute Research Centre.

In the global REDUCE-IT® cardiovascular outcomes study, approximately 28 percent of patients in the control arm treated with statins and other contemporary therapy but not treated with Vascepa experienced a major adverse cardiovascular event (MACE), defined as the first occurrence of either myocardial infarction (heart attack), stroke, coronary revascularization, unstable angina requiring hospitalization or cardiovascular death.[2] As evidenced by this MACE occurrence, there is a group of patients who, despite controlling their cholesterol on statin therapy, continue to have a high need for additional preventative cardiovascular care. For those adult patients in this group who have elevated serum triglycerides (TG) levels (≥1.5mmol/L and < 5.6mmol/L) and established cardiovascular disease or diabetes and at least one additional risk factor for cardiovascular disease, Vascepa showed a 25% risk reduction in the first occurrence of major adverse cardiovascular events and is the first drug approved to help reduce this persistent cardiovascular risk in that specified population.

"As approved by Health Canada, Vascepa is intended to address a serious, life-threatening condition for which no drug is currently marketed in Canada, and for which there is substantial evidence of clinical effectiveness of the treatment. These factors led to Health Canada's priority review of the product and now serve as the foundation for Vascepa to be a transformative product for HLS," said Greg Gubitz, CEO of HLS. "Looking ahead, we are now in the final phase of preparation for the commercial launch of Vascepa in Canada, which we expect will take place in the mid-February 2020 timeframe."

Vascepa is the subject of numerous Canadian issued patents and pending patents with expiration dates which could extend to 2039. The eligible patents will be added to Health Canada's Patent Register following receipt of NOC and in accordance with Health Canada's process.

The approval of Vascepa is supported by data from REDUCE-IT®[2], an 8,179-patient cardiovascular outcomes study that was completed in 2018. REDUCE-IT was the first multinational cardiovascular outcomes study that evaluated the effect of pure and stable EPA therapy as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, had elevated serum triglyceride levels (≥1.5mmol/L and <5.6mmol/L). A large portion of the male and female patients enrolled in this outcomes study were diagnosed with type 2 diabetes. REDUCE-IT studied Vascepa at four grams/day as compared to placebo. The U.S. Food and Drug Administration (FDA) approved the use of Vascepa (icosapent ethyl) capsules to reduce cardiovascular risk in December 2019. More information on the REDUCE-IT study results can be found at https://www.nejm.org/doi/full/10.1056/NEJMoa1812792

HLS paid Amarin $5.0 million to in-license the exclusive Canadian rights to Vascepa in 2017 and a further $2.5 million on the successful REDUCE-IT trial results in 2018. As a result of this approval by Health Canada, HLS will pay a further $2.5 million milestone payment. All amounts are in U.S. dollars.

ABOUT CARDIOVASCULAR DISEASE
Worldwide, cardiovascular disease (CVD) remains the #1 cause of mortality of men and women.

Multiple primary and secondary prevention trials have shown a significant reduction of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual risk despite the achievement of target LDL-C levels.[3]

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease.[4, 5, 6, 7]

ABOUT VASCEPA (ICOSAPENT ETHYL) CAPSULES
Vascepa (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form (known as icosapent ethyl or IPE). Vascepa is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient icosapent ethyl from degradation. 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.

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

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.

REFERENCES
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