HLS Therapeutics Inc.

HLS Therapeutics Files New Drug Submission for Vascepa® in Canada

- ***Cardiovascular disease is the leading cause of death globally***[1]
- ***NDS for Vascepa is supported by data from the REDUCE-IT™ trial, an international, multi-center cardiovascular outcomes study that showed a 25% placebo-controlled risk reduction in the first occurrence of major adverse cardiovascular events***
- ***Vascepa has been granted priority review status by Health Canada, which could reduce review time by up to four-and-a-half months***

TORONTO, April 29, 2019 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focused on central nervous system and cardiovascular markets, announces that it has filed a New Drug Submission ("NDS") with Health Canada for Vascepa®. Within the NDS, Vascepa (icosapent ethyl) is proposed to be indicated to reduce the risk of Major Adverse Cardiovascular Events ("MACE") in statin-treated patients with elevated triglycerides and other risk factors.

"We are pleased to reach this milestone with Vascepa and look forward to working with Health Canada to bring this innovative therapy to Canadians who may be at-risk of a major cardiac event," said Greg Gubitz, CEO of HLS. "With cardiovascular disease as the leading cause of death worldwide, we believe that Vascepa has the potential to be a platform from which we can enhance the quality of life for many Canadians and grow our cardiovascular business for years to come."

Vascepa has been granted priority review status by Health Canada which could accelerate the launch of Vascepa in the Canadian market by up to four-and-a-half months, if the product is ultimately approved by Health Canada.

In the fall of 2018, results of the REDUCE-IT™ study were presented and published showing that Vascepa achieved the primary endpoint of the study demonstrating a statistically significant 25% placebo-controlled risk reduction in the first occurrence of MACE. REDUCE-IT results also revealed statistically significant relative risk reductions in each component of the MACE composite, consisting of cardiovascular death, heart attack, stroke, coronary revascularization and hospitalization for unstable angina.

HLS's filing 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 prescription pure EPA therapy as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, had elevated triglyceride levels (at least 135 mg/dL). 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.

More information on the REDUCE-IT study results can be found at www.amarincorp.com.

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) 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 from degradation. Amarin, the developer from which HLS licensed Vascepa 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 has in-licensed the exclusive rights to Vascepa for the Canadian market. VASCEPA IS NOT APPROVED IN CANADA.

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.

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

[1] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

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SOURCE HLS Therapeutics Inc.

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