

HLS Therapeutics Announces 8 Years of Data Protection for Vascepa®

- ***Peak-year sales estimate increases to CAD\$200-300 million, from CAD\$150-250 million***
- ***Commercial launch expected to take place in the mid-February 2020 timeframe***
- ***Vascepa is the subject of numerous Canadian issued and pending patents with expiration dates which could extend to 2039***

TORONTO, Jan. 6, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, announces that today Vascepa® was added to Health Canada's Register of Innovative Drugs and as a result it will benefit from data protection for a term of eight years from the date of the issuance of the notice of compliance. All amounts are in United States ("U.S.") dollars unless otherwise stated.

"We are pleased to announce this development and remain on track for a mid-February 2020 launch for Vascepa. Having taken into consideration all aspects of the granted indication for Vascepa, we now believe that peak year sales for the product in Canada could reach CAD\$200-300 million per year, up from our previous estimate of CAD\$150-250 million per year," said Greg Gubitz, CEO of HLS. "While the approval of a broad label raises our overall potential, it doesn't change what we need to do over the first 12 months of commercialization which is to lay-down the fundamental basis of the product's benefits with key opinion leaders, and seed the basis of public formulary coverage that should take place within the first 12 to 24 months. In turn, we would expect to reach our peak year sales run-rate approximately 4-5 years following product launch."

Previously, on December 31, 2019, Health Canada 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.

In addition to eight years of data protection, Vascepa is also the subject of numerous Canadian issued patents and pending patents with expiration dates which could extend to 2039.

HLS in-licensed the exclusive rights to Vascepa for the Canadian market from Amarin Corporation (NASDAQ:AMRN) in 2017. As a result of achieving data protection for Vascepa, HLS will make a \$3.75 million milestone payment to Amarin.

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.

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

<https://hlstherapeutics.investorroom.com/2020-01-06-HLS-Therapeutics-Announces-8-Years-of-Data-Protection-for-Vascepa-R>