

HLS Therapeutics Supports Trial to Investigate the Effects of Vascepa® (Icosapent Ethyl) against COVID-19

TORONTO, May 21, 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 in collaboration with Amarin Corporation (NASDAQ:AMRN) it is supporting a trial to investigate the effects of Vascepa® (icosapent ethyl, or "IPE") on inflammatory biomarkers in individuals with COVID-19. The trial sponsored by the Canadian Medical and Surgical Knowledge Translation Research Group, is being led by Dr. Subodh Verma MD, PhD, FRCSC, FAHA, a cardiac surgeon-scientist at St Michael's Hospital in Toronto, Professor at the University of Toronto and Canada Research Chair in Cardiovascular Surgery, and Dr. Deepak L. Bhatt MD MPH, Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and Professor, Harvard Medical School.

The trial design is based on the scientific hypothesis that IPE may possess anti-inflammatory, anti-thrombotic, and potentially anti-viral properties ^(1, 2, 3, 4, 5, 6, 7) which could be beneficial to patients suffering from COVID-19. The goal of the trial is to document the short-term effect of IPE versus usual care on inflammatory biomarkers, such as C-reactive protein, in adults with documented COVID-19.

The trial is a 14-day long prospective, multi-site, two-armed, randomized, open-label study that will enroll approximately 100 individuals with COVID-19 who have undergone testing in Canada. Participants will be randomized (1:1) to receive either IPE (a loading dose of 4 g BID for 3 days, then 2 g BID for the subsequent 11 days) or usual care. Blood samples will be collected to determine if IPE use lowers circulating proinflammatory biomarkers. The trial is expected to commence in May 2020.

"The COVID-19 pandemic has created a great sense of urgency to identify novel treatment options for those afflicted with the virus," said Dr. Subodh Verma. "IPE, or Vascepa, is known to exert endothelial protective and anti-inflammatory effects, and in a large trial of patients with cardiovascular disease or diabetes has been shown to reduce cardiovascular death. There are emerging data that COVID-19 leads to increased inflammation and widespread endothelial injury and hence it is reasonable to test the hypothesis that IPE can reduce markers of inflammation in this disease."

"We are pleased to support a study that could bring relief to those suffering from COVID-19 and to help those in the healthcare community seeking treatment options to the virus," said Greg Gubitzi, CEO of HLS. "In the current situation, it will be necessary to gather data from many such trials in order to understand what those best treatment options are for patients."

ABOUT VASCEPA (ICOSAPENT ETHYL) CAPSULES

Vascepa is approved for use in Canada 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, and has not been demonstrated to be safe or effective for use in the treatment of those with COVID-19.

Vascepa was added to Health Canada's Register of Innovative Drugs and benefits from data protection for a term of eight years, as well as being the subject of multiple issued and pending patents based on its unique clinical profile. 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

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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.

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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 ext 101, g.godin@hlstherapeutics.com

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