HLS Therapeutics Inc.

VASCEPA® (Icosapent Ethyl) Found to Significantly Reduce Ischemic Events in Patients with Prior Coronary Artery Bypass Grafting Procedures

- **Results from Post Hoc Subgroup Analyses of Landmark REDUCE-IT® Study Presented at American Heart Association's Virtual Scientific Sessions 2020**
- **VASCEPA®, compared with placebo, significantly reduced primary composite first and total MACE (major adverse cardiovascular events) in post hoc exploratory analyses of patients with a history of Coronary Artery Bypass Grafting (commonly referred to as Bypass Surgery) by 24% and 36%, respectively, and key secondary composite first hard MACE, comprised of heart attacks, stroke and cardiovascular death, by 31%**
- **The use of VASCEPA resulted in absolute risk reductions of MACE equal to, or greater than, 6.0% in these subgroup analyses, avoiding on average one cardiac event for every 17 patients treated**

TORONTO, Nov. 16, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, reported today on the presentation of REDUCE-IT® Coronary Artery Bypass Grafting ("CABG") analysis at the American Heart Association's ("AHA") Virtual Scientific Sessions 2020, being held virtually from November 13-17, 2020, adding to the growing body of knowledge on the clinical impact of VASCEPA® (icosapent ethyl). These new analyses were presented by Subodh Verma, M.D., Ph.D., a cardiac surgeon and Professor at the University of Toronto, Toronto, Ontario, Canada.

Dr. Subodh Verma, who was the lead author of this analysis, commented: "The analyses from REDUCE-IT indicate that VASCEPA (icosapent ethyl) reduces the need for CABG (commonly referred to as bypass surgery) by about 40%. Furthermore, in patients who have undergone CABG surgery this therapy profoundly reduces subsequent major cardiovascular events of cardiovascular death, heart attack or stroke by 31%. These data have important implications for our patients and the health care system."

"The REDUCE-IT CABG analysis results are another piece of the puzzle when looking at the potential use of icosapent ethyl in the procedural setting," commented Dr. Deepak L. Bhatt, M.D., M.P.H., Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School, principal investigator of REDUCE-IT. "The findings of benefit in at-risk patients with prior CABG are consistent with previously presented data on overall reductions in first and total coronary revascularization events, as well as in patients with prior percutaneous coronary interventions, and further strengthen the case for consideration of icosapent ethyl as an additional intervention for use by physicians to care for this patient population."

The REDUCE-IT CABG analysis looked at 1,837 (22.5%) of the patients enrolled in REDUCE-IT[1], representing all patients who had undergone a prior CABG procedure, a common form of surgical intervention to help treat coronary heart disease. Baseline characteristics were similar among patients randomized to VASCEPA versus placebo. Post hoc exploratory analyses of this subgroup showed that, for the composite endpoint of 5-point MACE, which was the prespecified primary endpoint for the full REDUCE-IT study cohort, time to first event for Vascepa was significantly better than placebo by 24% (p=0.004) and total (first and subsequent) events were also better by 36% (p=0.0002). For the REDUCE-IT study's key secondary composite endpoint of 3-point MACE, time to first event was better than placebo by 31% (p=0.001) in the subgroup of patients with a prior CABG.

Coronary revascularization procedures, such as CABG, are invasive, carry multiple risks, and can have significant direct and indirect costs. Patients with elevated triglycerides despite statin therapy have increased risk for ischemic events, including coronary revascularizations. These procedures, whether pre-scheduled or performed in an emergency, inevitably result in additional time spent in a healthcare setting.

REDUCE-IT was not specifically powered to examine individual cardiovascular endpoints or patient subgroups, therefore these revascularization analyses are nominal and exploratory with no adjustment for multiple comparisons. In addition, coronary revascularization as an endpoint can sometimes be considered subjective; however, these endpoints were adjudicated by an independent, blinded clinical endpoint committee. Results from the total coronary revascularization events analyses are consistent across the various recurrent event statistical models and are also consistent with the first coronary revascularization events results. Together, the REDUCE-IT first and total coronary revascularization events results support the robustness and consistency of the clinical benefit of VASCEPA therapy in reducing coronary revascularization.

These REDUCE-IT CABG results follow multiple scientific presentations of analysis results from other important patient subgroups in the REDUCE-IT study, including REDUCE-IT REVASC[2] and REDUCE-IT PCI.

Additional information on AHA Virtual Scientific Sessions 2020 can be found here.

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 the first-and-only prescription treatment comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. Vascepa was approved by Health Canada, 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

REFERENCES

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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 and Management's Discussion and Analysis dated November 4, 2020, both of which have 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.

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