

HLS Therapeutics Highlights Key Data on the Late Breaking RESPECT-EPA Study Presented at the American Heart Association

Independent RESPECT-EPA Study Now Third in a Series of Trials to Underscore Cardiovascular Risk Reduction Benefits of Eicosapentaenoic Acid ("EPA") for Patients

TORONTO, Nov. 7, 2022 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a pharmaceutical company focusing on central nervous system and cardiovascular markets, today highlighted key data presented at the American Heart Association ("AHA") 2022 Scientific Sessions relevant to VASCEPA[®] (icosapent ethyl) related to RESPECT-EPA, A Randomized Trial for Evaluation in Secondary Prevention Efficacy of Combination Therapy - Statin and Eicosapentaenoic Acid ("EPA").

RESPECT-EPA Third Study to Show Cardiovascular Benefit Consistent with REDUCE-IT[®] and JELIS

The RESPECT-EPA clinical trial is an independent study funded by the Japanese Heart Foundation. In 2005, the Japan EPA Lipid Intervention study ("JELIS") first demonstrated a beneficial effect of highly purified EPA on cardiovascular outcomes in patients with or without coronary artery disease ("CAD"). In 2019, Amarin Corporation (NASDAQ: AMRN) published the positive results of its double-blind placebo-controlled study REDUCE-IT in patients with cardiovascular risk and elevated TG levels. And now, RESPECT-EPA is the third study that demonstrated the value of highly purified EPA in reducing cardiovascular outcomes in patients with CAD.

The late breaking data presented at AHA using 1.8 grams per day of purified EPA is consistent with the substantial body of evidence from the REDUCE-IT and JELIS trials, which showed that highly purified prescription EPA plus statin significantly reduces the risk of cardiovascular events in high- and very high-risk statin-treated patients.

Importantly, the study achieved a borderline statistical significance with a 21.5% reduction in the primary composite endpoint measuring cardiovascular risk (p value 0.054) and achieved a statistically significant 26.6% reduction in the secondary composite endpoint of RESPECT-EPA (p value 0.03).^[i]

EPA level matters. In addition, a post-hoc analysis conducted by the investigators to control for attained EPA levels yielded a statistically significant 27.5% reduction in the primary endpoint (p value 0.02).^[ii]

"The results of the RESPECT-EPA trial are directionally consistent with prior outcomes studies of EPA such as REDUCE-IT in patients with cardiovascular disease," said Gilbert Godin, CEO of HLS. "This adds to the growing body of evidence supporting the use of EPA for cardiovascular risk reduction in patients with well treated LDL-C and persistent cardiovascular risk."

Other data presented at AHA 2022 support sustained low-density lipoprotein ("LDL") antioxidant effects for EPA in vitro compared with docosahexaenoic acid ("DHA") or mineral oil. The researchers concluded that the longer-term antioxidant actions of EPA may contribute to reduced events independent of placebo selection.^[iii] Additional in vitro data presented at the meeting found that neither mineral oil nor corn oil affected rates of LDL oxidation, a central mechanism of atherosclerosis, even at high concentrations.^[iv]

"We are very pleased with the data presented at AHA 2022, as it further underscores the clinical and therapeutic utility of VASCEPA," said Mr. Godin. "Clinicians should make the best choice possible for their patients and should have confidence in VASCEPA as a proven treatment option on top of statins to reduce cardiovascular risk and to help optimize treatment in appropriate high-risk patients."

Approved by Health Canada following a priority review, VASCEPA (icosapent ethyl) is the first and only drug in Canada indicated to reduce persistent residual cardiovascular risk in patients stabilized on a statin, with elevated triglycerides and other risk factors for cardiovascular disease. VASCEPA is made up of one active ingredient, icosapent ethyl, an innovative form of pure EPA. More than 25 clinical treatment guidelines, consensus statements and scientific statements from medical societies or journals around the globe (including the Canadian Cardiovascular Society, Thrombosis Canada and the Canadian Heart & Stroke Foundation) recommend the use of icosapent ethyl in at-risk patients.

HLS has in-licensed the exclusive rights to Vascepa for the Canadian market from Amarin.

ABOUT HLS THERAPEUTICS INC.

Formed in 2015, HLS is a 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, expectations regarding financial performance, and the NCIB and ASPP. 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 16, 2022, and Management's Discussion and Analysis dated August 10, 2022, 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.

REFERENCES

[i] Respect-EPA: Highly purified EPA appears to reduce risks of CV events in Japanese CAD patients on Statins. American College of Cardiology. <https://www.acc.org/latest-in-cardiology/articles/2022/11/01/22/00/sun-7pm-respect-epa-aha-2022>. Published November 6, 2022. Accessed November 6, 2022.

[ii] Respect-EPA: Highly purified EPA appears to reduce risks of CV events in Japanese CAD patients on Statins. American College of Cardiology. <https://www.acc.org/latest-in-cardiology/articles/2022/11/01/22/00/sun-7pm-respect-epa-aha-2022>. Published November 6, 2022. Accessed November 6, 2022.

[iii] Sherratt SC, Libby P, Bhatt DL, Mason P. Eicosapentaenoic Acid (EPA) inhibits low-density lipoprotein (LDL) oxidation compared to docosahexaenoic acid (DHA) and mineral oil in vitro. *Circulation*. 2022;146:A13685.

[iv] Sherratt SC, Libby P, Bhatt DL, Mason P. High concentration mineral oil, corn oil and their constitutive fatty acids do not influence low-density lipoprotein (LDL) oxidation rates in vitro. *Circulation*. 2022;146:A15024.

SOURCE HLS Therapeutics Inc.

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