

HLS Therapeutics Announces that VASCEPA® (Icosapent Ethyl) is Found in Prespecified and Post Hoc Analyses to Significantly Reduce Stroke in At-Risk Patients in Analyses of Landmark REDUCE-IT® Study Presented at International Stroke Conference 2021

- ***28% and 32% significant reductions in first and total strokes, respectively, demonstrated with VASCEPA compared to placebo, as well as reductions in first and total ischemic strokes each by 36%, without increasing hemorrhagic stroke, in statin-treated patients with elevated cardiovascular risk***
- ***Consistent reductions in overall stroke and in ischemic stroke observed across multiple subgroups***
- ***Administration of pure icosapent ethyl, VASCEPA, represents a novel clinical approach to stroke reduction***

TORONTO, March 17, 2021 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX: HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, announces the presentation of REDUCE-IT® STROKE at the International Stroke Conference 2021, being held virtually from March 17 - March 19, 2021, adding to the growing body of knowledge on the clinical impact of VASCEPA® (icosapent ethyl). These new analyses supported by Amarin Corporation plc ("Amarin") were presented on behalf of all authors by Deepak L. Bhatt, M.D., M.P.H., Brigham and Women's Hospital, Harvard Medical School, Boston, MA.

"The REDUCE-IT STROKE analyses provide important data supporting a new approach to prevent strokes using icosapent ethyl in appropriate patients," commented Dr. Deepak L. Bhatt, M.D., M.P.H., Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital, Professor of Medicine at Harvard Medical School, and principal investigator of REDUCE-IT. "The findings of benefit in at-risk patients include significant reductions in overall strokes and in ischemic strokes. Importantly, with respect to safety, we did not observe any significant increase in hemorrhagic stroke. These results further strengthen the case for pure eicosapentaenoic acid (EPA) in the form of prescription icosapent ethyl as a key intervention beyond statins for stroke prevention in studied patients."

The REDUCE-IT STROKE analyses examined stroke rates across the enrolled patient population (n=8179). Enrolled patients were required to be treated with statins and other conventional therapies, and all patients had either established cardiovascular disease or diabetes and had other cardiovascular risk factors such as elevated triglyceride levels. Event rates for time to first fatal or nonfatal stroke were 2.4% for VASCEPA vs. 3.3% for placebo for a relative risk reduction (RRR) of 28% (p=0.01). Ischemic stroke time to first event rates were 2.0% for VASCEPA vs. 3.0% for placebo for a RRR of 36% (p=0.002). Hemorrhagic stroke occurred at low rates with no significant difference for VASCEPA vs. placebo (0.3% vs 0.2%; p=0.55).

Stroke is a major and often debilitating cardiovascular event significantly impacting not only patients and their loved ones, but also the healthcare system. Patients with elevated triglycerides despite statin therapy have increased risk for stroke-related events. An estimated 1.6 million Canadians have heart disease or are living with the effects of a stroke, according to the Public Health Agency of Canada. Among seniors, 14.8% of those ages 65 to 74 years report having heart disease, with the proportion climbing to 22.9% over age 75. In this same age group, 7.1% of Canadians report living with the effects of a stroke. There is also concern that cardiovascular disease could increase because of increased prevalence of obesity and diabetes, which are two of its risk factors¹.

"Strokes significantly impact the healthcare system, driving substantial immediate and long-term costs," said Jason Gross, VP Scientific Affairs, HLS. "The subgroup data presented at ISC 2021 provide new insight into the unique potential benefits of VASCEPA administration on alleviating the societal burden of strokes."

The REDUCE-IT STROKE abstract received the prestigious Paul Dudley White International Scholar Award, recognizing the authors with the highest ranked abstract across the United States at the International Stroke Conference 2021. The esteemed Paul Dudley White Award is named in honor of one of Boston's most revered cardiologists, Dr. Paul Dudley White, who was a founding father of the American Heart Association and an early leader in preventive cardiology.

REDUCE-IT was designed and powered for the primary composite endpoint, of which stroke was one of five prespecified components; it was not powered for subgroup analysis. Stroke was a prespecified secondary endpoint within the testing hierarchy; ischemic stroke was a prespecified tertiary endpoint; stroke subgroup analyses were post hoc. No information was collected on stroke related disability, such as Rankin scores.

Additional information on ISC 2021 can be found [here](#).

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, please visit: www.hlstherapeutics.com

REFERENCES

¹ <https://www.cpha.ca/decline-deaths-coronary-heart-disease-and-stroke#:~:text=An%20estimated%201.6%20million%20Canadians,to%2022.9%25%20over%20age%2075>

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.

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<https://hlstherapeutics.investorroom.com/2021-03-17-HLS-Therapeutics-Announces-that-VASCEPA-R-Icosapent-Ethyl-is-Found-in-Prespecified-and-Post-Hoc-Analyses-to-Significantly-Reduce-Stroke-in-At-Risk-Patients-in-Analyses-of-Landmark-REDUCE-IT-R-Study-Presented-at-International-Stroke-Conference-2>