HLS Therapeutics Inc.

HLS Therapeutics Announces that Amarin's REDUCE-IT™ Cardiovascular Outcomes Study of Vascepa® (icosapent ethyl) Capsules Met Primary Endpoint

- **REDUCE-IT is First Outcomes Study to Assess Treatment of Patients with LDL-C Controlled by Statin Therapy, Persistent Elevated Triglycerides and Other Cardiovascular Risk Factors**
- **Results Specific to Pure EPA Vascepa at 4 Grams Daily**
- **HLS has the Rights to Vascepa for the Canadian Market**
- **Amarin to Host Conference Call Scheduled for Today, Monday September 24, 2018 at 8:00 am ET**

TORONTO, Sept. 24, 2018 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX-V:HLS) announces that earlier today, Amarin Corporation plc (NASDAQ:AMRN), issued topline results from the Vascepa® cardiovascular ("CV") outcomes trial, REDUCE-IT™, a global study of 8,179 statin-treated adults with elevated CV risk. REDUCE-IT met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ($p<0.001$), in major adverse CV events ("MACE") in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. HLS has in-licensed the rights to Vascepa for the Canadian market.

Patients enrolled in REDUCE-IT had LDL-C between 41-100 mg/dL (median baseline LDL-C 75 mg/dL) controlled by statin therapy and various CV risk factors including persistent elevated triglycerides ("TGs") between 150-499 mg/dL (median baseline 216 mg/dL) and either established CV disease (secondary prevention cohort) or diabetes mellitus and at least one other CV risk factor (primary prevention cohort).

Key topline results include:

- **Efficacy:** Approximately 25% relative risk reduction, demonstrated to a high degree of statistical significance ($p<0.001$), in the primary endpoint composite of the first occurrence of MACE, including CV death, nonfatal myocardial infarction ("MI"), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints.
- **Safety:** Vascepa was well tolerated with a safety profile consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling. The proportions of patients experiencing adverse events and serious adverse events in REDUCE-IT were similar between the active and the placebo treatment groups. Median follow-up time in REDUCE-IT was 4.9 years.

Amarin will share the REDUCE-IT data in greater detail at the 2018 Scientific Sessions of the American Heart Association ("AHA") on November 10, 2018 in Chicago, Illinois. The presentation, classified as late-breaking clinical trial results, is scheduled to commence at 2:16 pm Central Time and listed as Main Event 1 for the time frame. This acceptance as a presentation of late-breaking clinical trial results was granted based on the ability of REDUCE-IT to address a critical question in CV prevention.

"We are very pleased with these topline study results and offer our congratulations to the entire Amarin team that brought the REDUCE-IT trial to completion," said Greg Gubitz, CEO of HLS. "Cardiovascular disease is the #1 killer of men and women worldwide[1] and the REDUCE-IT trial results could lead to a new paradigm in treatment for the millions of patients in Canada currently at risk for this disease."

"The release of these results is a major milestone in the development of HLS's cardiovascular franchise in Canada. We believe that there is strong market potential for Vascepa in Canada, where we have in-licensed the rights and where it would become the first and only prescription product in its class. We look forward to filing with Health Canada as soon as we have reviewed the final data, and ultimately to bringing this important new medicine to Canadians."

For more information on Vascepa and the REDUCE-IT trial, please see the press release issued today by Amarin, which can be found at: http://investor.amarincorp.com/press-releases

AMARIN CONFERENCE CALL AND WEBCAST INFORMATION
Amarin will host a conference call at 8:00 am ET, September 24, 2018 to discuss this information. The call will be accessible through the investor relations section of Amarin's website at www.amarincorp.com. The call can also be heard via telephone by dialing 877-407-8033. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through Amarin's website shortly after the call. For both dial-in numbers, please use conference ID 37638.

IMPORTANT CAUTIONARY INFORMATION ABOUT TOPLINE RESULTS
Existing and prospective investors are cautioned not to place undue reliance on topline results. As with any topline CV outcomes study result, further REDUCE-IT data assessment and data release will yield additional useful information to inform greater understanding of the study outcome. Aspects that could change and impact the final evaluation of the totality of the efficacy/safety data from REDUCE-IT may include: the magnitude of the treatment benefit on the primary composite endpoint, its components, secondary endpoints and the primary and secondary risk prevention cohorts; consideration of which components of the composite or secondary endpoints have the most clinical significance; the consistency of the primary and secondary endpoints; the consistency of the findings across cohorts and subgroups; tolerability and safety considerations and risk/benefit considerations; consideration of REDUCE-IT results in the context of other clinical studies; and study conduct and data quality, integrity and consistency.

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.

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 joint information circular of HLS and Automodular Corporation dated February 5, 2018 in respect of the merger of the two companies by way of a plan of arrangement, effective March 12, 2018, 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.

REFERENCES
[1] American Heart Association. Disease and Stroke Statistics-2016 Update

SOURCE HLS Therapeutics Inc.

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