

HLS Therapeutics Inc.

HLS Therapeutics Comments on U.S. Court of Appeals Decision in Amarin Patent Litigation

- **U.S. decision does not relate to Vascepa in Canada**
- **Vascepa was granted 8 years of data exclusivity by Health Canada upon approval**
- **Vascepa patent estate could potentially extend protection in Canada to 2039**

TORONTO, Sept. 3, 2020 /CNW/ - HLS Therapeutics Inc. ("HLS" or the "Company") (TSX:HLS), a specialty pharmaceutical company focusing on central nervous system and cardiovascular markets, comments on the U.S. Court of Appeals for the Federal Circuit ruling in Amarin Corporation plc's ("Amarin") ongoing patent litigation. The Court upheld the March ruling by the U.S. District Court for the District of Nevada in favor of two generic companies in connection with their abbreviated new drug applications, or ANDAs, related to Amarin's VASCEPA® (icosapent ethyl) capsule franchise. HLS has in-licensed the exclusive rights to VASCEPA for the Canadian market from Amarin.

HLS affirms that that this litigation and judgment do not impact VASCEPA in Canada as:

- Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this litigation and judgment;
- VASCEPA was added to Health Canada's Register of Innovative Drugs in January 2020 and benefits from eight years of data protection until December 2027;
- VASCEPA is also the subject of numerous Canadian issued patents and pending patents that were not part of the U.S. litigation and that could extend patent protection in Canada to 2039; and
- No litigation is pending in Canada regarding VASCEPA.

"As with the U.S. district court ruling earlier this year in March, the appeals court ruling in the U.S. does not affect the Canadian business for VASCEPA or our growth outlook for the product, which we believe could achieve a peak-year revenue run-rate of \$275-325 million," said Gilbert Godin, President and COO of HLS. "Since our launch earlier this year, we continue to move forward on our plan to bring this new and unique treatment option to the many Canadians who suffer from cardiovascular disease, which remains the world's number one killer."

To view Amarin's response to the court's ruling, please see their press release dated September 3, 2020 titled, ["Amarin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation"](#).

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 most recent Management Discussion and Analysis 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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