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Amarin and HLS Therapeutics Announce Agreement to Commercialize Vascepa® in Canada

BEDMINSTER, N.J., DUBLIN, Ireland, and TORONTO, Sept. 25, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) and HLS Therapeutics Inc. ("HLS"), announced today an exclusive agreement between the parties to register, commercialize and distribute Vascepa® (icosapent ethyl) capsules in Canada. Amarin and HLS anticipate submitting an application to Canadian regulatory authorities to seek approval to commercialize Vascepa in Canada.

"We are excited to enter into a collaboration with HLS to seek regulatory approval and commercialize Vascepa in Canada," stated John F. Thero, president and chief executive officer of Amarin. "The proven track record of HLS's leadership in commercializing pharmaceutical products in Canada, along with our shared vision and commitment, bestow confidence that we will provide Vascepa as a treatment option for millions of Canadians."

"HLS is delighted to work with Amarin, as we expect Vascepa to be the first **highly pure, omega-3 fatty acid product available by prescription in Canada**," stated Greg Gubitza, chief executive officer of HLS Therapeutics. "Amarin's \$200+ million cardiovascular outcomes study, REDUCE-IT, has a significant number of Canadian key opinion leaders and clinical sites involved. As cardiovascular disease is the number one killer in the world¹, HLS is proud to be associated with Amarin's mission to improve cardiovascular health."

Heart disease is a leading cause of death in Canada¹. Twenty-five percent of Canadians have high triglycerides², a key comorbidity associated with cardiovascular disease, and about 2.4 million Canadians live with heart disease³. HLS and Amarin believe Vascepa has the potential to become an important part of the physician's armamentarium in the treatment of the millions of Canadians dealing with these conditions.

Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. Amarin is responsible for providing assistance towards local filings, supplying finished product, maintaining intellectual property and continuing the development and funding of REDUCE-IT. Terms of the agreement include up-front and milestone payments to Amarin of up to US\$65.0 million. These payments include a non-refundable upfront payment of US\$5.0 million, as well as development, regulatory and sale-based milestones totaling up to an additional US\$60.0 million. The agreement also provides for HLS to pay Amarin tiered double digit royalties on net sales of Vascepa in Canada. Amarin is obligated to supply finished product to HLS under negotiated supply terms. The agreement for supply and commercialization is for Canada only and includes all Canadian provinces.

About Vascepa® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa is known in scientific literature as AMR101. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

FDA-Approved Indication and Usage

- 1 Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
- 1 The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa

- 1 Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- 1 Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- 1 The most common reported adverse reaction (incidence > 2% and greater than placebo) was arthralgia (2.3% for

- Vascepa, 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo.
- 1 Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
 - 1 In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
 - 1 Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
 - 1 Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Vascepa is not approved for use in Canada. Nothing in this press release should be construed as promoting the use of Vascepa where not approved.

About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly pure omega-3 fatty acid product available by prescription. For more information about Vascepa, visit www.vascepa.com. For more information about Amarin, visit www.amarincorp.com.

About HLS Therapeutics

HLS Therapeutics Inc. is a specialty pharmaceutical company acquiring and distributing commercial stage and legacy, branded pharmaceutical drugs for the North American markets. HLS's management team is comprised of seasoned pharmaceutical executives with a strong track record of success. Building on the expertise of the founders, HLS is focused on treatment products for the central nervous system, and cardiovascular specialties. For more information about HLS, visit www.hlstherapeutics.com.

Forward-looking statements

This press release contains forward-looking statements, including expectations regarding regulatory submissions and approvals and commercialization of Vascepa in Canada, as well as timing related thereto; future expectation regarding timing and continuation of Amarin's REDUCE-IT cardiovascular outcomes study; statements regarding the potential and therapeutic benefits of Vascepa; and potential milestone and other payments to be paid to Amarin, an obligation of Amarin, under this agreement. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that clinical data and regulatory reviews may alter current expectations related to anticipated prospects for approval; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be obtained or upheld in patent litigation. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Availability of other information about Amarin

Investors and others should note that we communicate with our investors and the public using our company website (www.amarincorp.com), our investor relations website (<http://investor.amarincorp.com>), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a

result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

References

- ¹ https://www.medpagetoday.com/PublicHealthPolicy/PublicHealth/67946?xid=nl_mpt_DHE_2017-09-16&eun=g811140d0r&pos=0
- ² <http://www.statcan.gc.ca/pub/82-625-x/2010001/article/11136-eng.htm>
- ³ <https://www.canada.ca/en/public-health/services/diseases/heart-disease-heart-health.html>

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