Amarin Receives Positive CHMP Opinion for Icosapent Ethyl for Cardiovascular Risk Reduction

January 29, 2021

Positive opinion is based on extensive clinical study results, including results of the REDUCE-IT® cardiovascular outcomes study

European Commission decision on the Marketing Authorisation Application expected in April 2021

DUBLIN, Ireland and BRIDGEWATER, N.J., Jan. 29, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced that in response to Amarin's Marketing Authorisation Application submission, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending that a marketing authorisation be granted to icosapent ethyl in the European Union for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VAZKEPA®.

The CHMP recommendation is now expected to be reviewed by the European Commission, which has the authority to approve medicines for marketing in the European Union. A decision by the European Commission is expected to take place within 67 days of the CHMP opinion.

"We thank the EMA for its thoughtful review of our application and concluding it in a timely manner despite the challenges imposed by COVID-19," said Steven Ketchum, senior vice president, president of R&D and chief scientific officer of Amarin. "This positive CHMP opinion is a significant milestone for Amarin, taking us one step closer to making this important therapy available to millions of patients in the European Union at high risk of cardiovascular events such as heart attacks and strokes. We are dedicated to supporting a rethinking of cardiovascular disease risk reduction in Europe with further emphasis on preventative care."

The CHMP opinion is based on over a decade of development and testing of icosapent ethyl, including data from the REDUCE-IT® cardiovascular outcomes study. REDUCE-IT evaluated more than 8,000 high risk patients who despite having their cholesterol levels well controlled by statin therapy remained at significant risk of heart attack, stroke, or other major adverse cardiovascular events (MACE), including death. As published, patients in the REDUCE-IT study had a median follow-up period of nearly five years. Results from this study, in which all patients remained treated by statins (and by other contemporary therapies) and where half the patients received icosapent ethyl and the other half received placebo, demonstrated a 25% relative risk reduction ($p<0.001$) in the first occurrence of MACE in the intent-to-treat patient population with use of icosapent ethyl (4 grams daily) compared with placebo.

Based on communications with the EMA we expect the indication language to be generally consistent with the following:

That marketing authorisation be granted to icosapent ethyl to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (≥150 mg/dL), and

- established cardiovascular disease, or
- diabetes, and at least one other cardiovascular risk factor.

Ten years of market protection is expected to be granted in the European Union as part of a European Commission approval of the pending application. In addition, pending patent applications related to the REDUCE-IT study have the potential to extend exclusivity in Europe into 2039.

For more information about the CHMP announcement visit the EMA website (this link will take you to an external website) https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-25-29-january-2021

About Amarin
Amarin is a rapidly growing, innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our scientific research foundation to our focus on clinical trials, and now our commercial expansion, we are evolving and growing. In 2009, Amarin had fewer than twenty employees. Today, with offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, and Zug in Switzerland, Amarin has approximately 1,000 employees and commercial partners and suppliers around the world. We are committed to rethinking cardiovascular risk through the advancement of scientific understanding of the impact on society of significant residual risk that exists beyond traditional therapies, such as statins for cholesterol management.

Promotion Disclaimer
This press release is intended for investor relations purposes. Icosapent ethyl is not approved for marketing or sale in the European Union and nothing in this press release is intended to promote such use.

Forward-Looking Statements
This press release contains forward-looking statements, including statements about expectation for further regulatory review, the expected timing thereof, anticipated label language, anticipated grants of regulatory exclusivity and the potential for patent issuances and protection. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties that may individually or together impact the matters herein and cause actual results, events and performance to differ materially from such forward looking statements. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: events that could impact future regulatory assessment by the European Commission, such as delays due to COVID-19 restrictions, later arising data or other information, events that could interfere with the grant or issuance of a patent, continued validity or enforceability of a patent; uncertainties associated with litigation generally and patent litigation specifically; Amarin's ability generally to maintain adequate patent protection and successfully enforce patent claims against third parties; and uncertainties associated generally with research and development and regulatory submissions, reviews, action dates and approvals. 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.

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