

Amarin and CSL Seqirus Announce Exclusive License and Distribution Agreement to Commercialize VAZKEPA® (Icosapent Ethyl) in Australia and New Zealand

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DUBLIN, Ireland and BRIDGEWATER, N.J. and MELBOURNE, Australia, Feb. 28, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) and CSL Seqirus today announced that the two companies have entered into an exclusive license and distribution agreement under which Amarin will license exclusive rights to VAZKEPA to CSL Seqirus to secure pricing and reimbursement and commercialize the product across Australia and New Zealand.

"We are excited to announce this agreement with CSL Seqirus in Australia and New Zealand, a world-class licensing partner for pharmaceuticals," said Karim Mikhail, President & CEO, Amarin. "CSL Seqirus' highly experienced market access and commercialization teams in Australia and New Zealand are well-positioned to support the pricing and reimbursement efforts, particularly with their strong record in successfully supporting pharmaceutical benefits listings, and eventual marketing and promotion for VAZKEPA and help us to deliver this important medicine to patients in these countries."

According to the Australian Institute of Health and Welfare (AIHW), approximately 1.3 million patients in Australia have established cardiovascular disease (CVD)ⁱ and approximately 75% are currently treated with a statin.ⁱⁱ CVD and diabetes are health priorities in NZ. Māori and Pacific peoples have a high incidence of CVD and diabetes and experience significant inequity in both access to medicines and clinical outcomes.

Under the terms of the agreement, CSL Seqirus will in-license VAZKEPA from Amarin and will be responsible for market access and reimbursement efforts, distribution, and commercial promotion for VAZKEPA across Australia and New Zealand. Amarin will receive an upfront payment and be eligible for event-related milestone payments of up to approximately \$8 million and additional product-related milestone payments of up to approximately \$4 million. Amarin will be responsible for supplying finished product to CSL Seqirus at a profitable transfer price paid to Amarin.

About Amarin

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our foundation in scientific research to our focus on clinical trials, and now our commercial expansion, we are evolving and growing rapidly. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, Zug in Switzerland, and other countries in Europe as well as commercial partners and suppliers around the world. We are committed to increasing the scientific understanding of the cardiovascular risk that persists beyond traditional therapies and advancing the treatment of that risk.

About CSL Seqirus

CSL Seqirus is part of [CSL Limited](#) (ASX: CSL). As one of the largest influenza vaccine providers in the world, CSL Seqirus is a major contributor to the prevention of influenza globally and a transcontinental partner in pandemic preparedness. With state-of-the-art production facilities in the U.S., the U.K. and Australia, and leading R&D capabilities, CSL Seqirus utilizes egg, cell and adjuvant technologies to offer a broad portfolio of differentiated influenza vaccines in more than 20 countries around the world.

In Australia, CSL Seqirus operates the only local manufacturing facility for seasonal and pandemic influenza vaccine and produces a range of unique medicines in the national interest including antivenoms and the world's only human vaccine for Q fever. The company also in-licenses a broad range of paediatric and adult vaccines and specialty pharmaceutical products.

About CSL

[CSL](#) (ASX: CSL; USOTC: CSLLY) is a leading global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL – including our three businesses, CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 30,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For inspiring stories about the promise of biotechnology, visit [CSLBehring.com/Vifa](#) and follow us on [Twitter.com/CSL](#).

For more information about CSL, visit [www.csl.com](#).

About VAZKEPA® (icosapent ethyl) Capsules

VAZKEPA capsules are the first prescription treatment comprised solely of the active ingredient, icosapent ethyl, a highly purified form of eicosapentaenoic acid. Since launch, icosapent ethyl has been prescribed over 18 million times. In addition to the United States, icosapent ethyl is approved and sold in Canada, Lebanon, the United Arab Emirates under the brand name VASCEPA. In March 2021, marketing authorization was granted to icosapent ethyl in the European Union under the brand name VAZKEPA to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (≥ 150 mg/dL [≥ 1.7 mmol/L]) and established cardiovascular disease or diabetes and at least one other cardiovascular risk factor¹. In April 2021 marketing authorization for VAZKEPA (icosapent ethyl) was granted in Great Britain (applying to England, Scotland and Wales). VAZKEPA (icosapent ethyl) is currently approved and sold in Europe in Sweden, Denmark, Finland, Austria and the UK.

Forward-Looking Statements

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation

Reform Act of 1995, including beliefs about Amarin's regulatory approval in Switzerland and the potential impact in that country; Amarin's overall efforts to expand access and reimbursement to VAZKEPA across global markets; and the overall potential and future success of VASCEPA/VAZKEPA generally. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 Amarin's annual report on Form 10-K for the full year ended 2021. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Amarin undertakes no obligation to update or revise the information contained in its forward-looking statements, whether as a result of new information, future events or circumstances or otherwise. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

Availability of Other Information About Amarin

Amarin communicates with its investors and the public using the company website (www.amarincorp.com) and the investor relations website (investor.amarincorp.com), including but not limited to investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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¹ Vazkepa[®] (icosapent ethyl): Summary of Product Characteristics. Available from: https://www.ema.europa.eu/en/documents/product-information/vazkepa-epar-product-information_en.pdf [accessed Nov 2022]

ⁱ Australian Institute of Health and Welfare (AIHW)

CHD,

PAD, STIA population

ⁱⁱ "Attainment of low density lipoprotein cholesterol goals in statin treated patients: Real world evidence from Australia" Study 61K Records