

## **Amarin Announces CEO Succession Plan**

April 12, 2021

John Thero to Retire as President and CEO on August 1, 2021

Board Appoints Karim Mikhail, Current SVP and Head of Commercial for Europe, as Successor

DUBLIN, Ireland and BRIDGEWATER, N.J., April 12, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced that John F. Thero, 60, has informed the board of directors of his plan to retire as president and chief executive officer, effective August 1, 2021. He will also step down from the board at that time. The board has appointed Karim Mikhail, 50, Amarin's senior vice president and head of commercial for Europe, to succeed Mr. Thero as the company's next president and chief executive officer. Mr. Mikhail will join the board upon his effective date. Mr. Thero will continue to provide his guidance and expertise to the company in an advisory capacity through the end of 2021.

Mr. Mikhail joined Amarin in 2020 from THEODON, a global commercial strategy consultancy he founded in 2018. Prior to this, Mr. Mikhail spent more than 20 years at Merck, where from 2014 to 2018 he served as global commercial leader for Merck's \$4 billion lipid franchise, overseeing P&L and leading the worldwide launch of ezetimibe with the IMPROVE-IT study indication. In this role, he was responsible for reversing the business' decline in the U.S. market and globally, accelerating revenue by an additional \$380 million through the launch of ATOZET and driving EBITDA growth through international expansion. Prior to that, Mr. Mikhail led the successful commercial launch of dozens of products, including ezetimibe and various molecules in diabetes, hypertension, immunology, and oncology, and served as Merck's chief marketing officer for Europe, Middle East and Africa and chief operating officer for emerging markets. At Amarin, Mr. Mikhail has been responsible for preparing commercialization of the company's lead product in Europe, for which regulatory approval was received on March 30, 2021.

Dr. Lars Ekman, Chairman of Amarin's Board of Directors, commented, "After 12 years at Amarin, and the last seven as CEO, John has decided now is the right time to announce his retirement. We owe enormous gratitude to John as under his leadership roles, with the support of the entire Amarin team, the company has completed multiple successful clinical trials, launched its lead product VASCEPA® (icosapent ethyl) in the United States, and has initiated its international expansion plans, including commercialization in Europe following the recent marketing authorization of VAZKEPA from the European Commission. John and the entire board have taken a thoughtful approach to succession planning designed to ensure that Amarin is best positioned to both continue its progress in the United States and accelerate its growth trajectory globally. The board has been increasingly impressed with Karim's strategic and operational capabilities, and his clear passion for VASCEPA and vision for continuing Amarin's progress worldwide make him the clear choice to succeed John. We look forward to an exciting new chapter for the highly capable Amarin team under Karim's leadership."

"While announcing my retirement is a bittersweet moment for me, I have every confidence in Amarin and its outstanding employees who are dedicated to the patients and shareholders we serve," said Mr. Thero. "2021 is a pivotal year for Amarin as we continue to develop markets for our important drug, VASCEPA. As the first-and-only drug approved by each of the U.S. FDA, European Commission, and Health Canada for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy, we are proud of our role in ushering in a new era in cardiovascular care. With our unique therapeutic solution and deep bench of internal talent, I believe that now is an ideal time to transition leadership to Karim as we work to realize Amarin's full potential. Since Karim joined Amarin last year, he has proven himself to be an invaluable member of the leadership team and a true partner to me as we prepare for the commercialization of VAZKEPA in Europe. I am excited to continue working closely with him and the board to facilitate a successful transition over the coming months."

Mr. Mikhail stated, "I joined Amarin last year because I was inspired by the company's entrepreneurial spirit in addressing such a large unmet medical need and the potential to set a new standard of cardiovascular care. I am honored to take on this new role. We have an unparalleled product with outstanding evidence, positive efficacy and safety profile, and tremendous momentum with our near-term European launch plans and expected commercial approval in China near the end of 2021. Amarin's team is first rate and I am excited to build upon the strong commercial progress in the United States. I look forward to working with John, the board and the entire Amarin team as we capture the significant growth opportunities ahead."

# **About Karim Mikhail**

Mr. Mikhail, 50, joined Amarin in July 2020, and currently serves as senior vice president and head of commercial for Europe where he has responsibility for the company's commercialization of VAZKEPA in Europe. He was previously with Merck for 22 years, in seven different countries, spanning three continents, where he held positions of increasing responsibility, including as global commercial leader for Merck's \$4 billion lipid franchise and chief marketing officer for Europe, Middle East and Africa and chief operating officer for emerging markets. Mr. Mikhail led THEODON, a global commercial strategy consultancy he founded in 2018.

Mr. Mikhail is a pharmacist by training and holds a master's degree in biopharmaceutical marketing and management from the graduate school of business in Paris, École Supérieure de Commerce de Paris (ESCP).

### **About Amarin**

Amarin is an 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 rapidly. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, and Zug in Switzerland as well as 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.

#### **About Cardiovascular Risk**

Cardiovascular disease is the number one cause of death in the world. In the United States alone, cardiovascular disease results in 859,000 deaths per year. And the number of deaths in the United States attributed to cardiovascular disease continues to rise. In addition, in the United States there are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds). Stroke rates are 795,000 per year (approximately

1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. In aggregate, in the United States alone, there are more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, 1 every 13 seconds.

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk for cardiovascular events, such as heart attack, stroke or death. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent risk of cardiovascular events, especially those patients with elevated triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35%.<sup>2</sup> Significant cardiovascular risk remains after statin therapy. People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.<sup>3,4,5</sup>

## About REDUCE-IT®

REDUCE-IT was a global cardiovascular outcomes study designed to evaluate the effect of VASCEPA in adult patients with LDL-C controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides between 135-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other cardiovascular risk factor (primary prevention cohort).

REDUCE-IT, conducted over seven years and completed in 2018, followed 8,179 patients at over 400 clinical sites in 11 countries with the largest number of sites located within the United States. REDUCE-IT was conducted based on a special protocol assessment agreement with FDA. The design of the REDUCE-IT study was published in March 2017 in *Clinical Cardiology*. The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018. The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019. These and other publications can be found in the R&D section on the company's website at <a href="https://www.amarincorp.com">www.amarincorp.com</a>.

# About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first and only drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over ten million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA is approved and sold in Canada, Lebanon and the United Arab Emirates. In Europe, in March 2021 marketing authorization was 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.

# Indications and Limitation of Use (in the United States) VASCEPA is indicated:

 As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and

- o established cardiovascular disease or
- o diabetes mellitus and two or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

# Important Safety Information

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a
  double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of
  atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The
  incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel
  or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).
- Common adverse reactions in the hypertriglyceridemia trials (incidence >1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA as set forth below:

Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT

	VASCEPA		Placeho		VASCEPA vs Placebo
	N = 4089 n (%)	l/nor 100 nationt	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)
Primary composite endpoint					
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
Key secondary composite endpoint					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	13.7	0.74 (0.65, 0.83)
Other secondary endpoints					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	12.1	0.69 (0.58, 0.81)
Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	11 U	0.65 (0.55, 0.78)
Cardiovascular death [1]	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	1() ()	0.68 (0.53, 0.87)
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	IN 8	0.72 (0.55, 0.93)
[1] Includes adjudicated cardiovascular deaths and deaths of undetermined causality. [2] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.					

### FULL U.S. FDA-APPROVED VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements about expectations for continued company progress in the United States and accelerated growth trajectory globally, anticipated regulatory approvals and related timing and a smooth management transition. 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, such as delays due to COVID-19 restrictions, later arising data, regulatory reviews and pricing assessments, and the successful implementation of commercialization plans or other information, 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 annual report on Form 10-K. 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. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, di

## **Availability of Other Information About Amarin**

Investors and others should note that Amarin communicates with its investors and the public using the company website (www.amarincorp.com), the investor relations website (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 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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AMARIN, REDUCE-IT, VASCEPA and VAZKEPA are trademarks of Amarin Pharmaceuticals Ireland Limited. VAZKEPA is a registered trademark in Europe and other countries and regions and is pending registration in the United States.

<sup>1</sup> American Heart Association. Heart Disease and Stroke Statistics—2020 Update: A Report From the American Heart Association. Circulation. 2020;141:e139–e596.

- <sup>2</sup> Ganda OP, Bhatt DL, Mason RP, et al. Unmet need for adjunctive dyslipidemia therapy in hypertriglyceridemia management. *J Am Coll Cardiol.* 2018;72(3):330-343.
- <sup>3</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. *Am J Cardiol.* 2016;118:138-145.
- <sup>4</sup> Toth PP, Granowitz C, Hull M, et al. High triglycerides are associated with increased cardiovascular events, medical costs, and resource use: A real-world administrative claims analysis of statin-treated patients with high residual cardiovascular risk. *J Am Heart Assoc.* 2018;7(15):e008740.
- <sup>5</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease New insights from epidemiology, genetics, and biology. *Circ Res.* 2016;118:547-563.
- <sup>6</sup> Bhatt DL, Steg PG, Brinton E, et al., on behalf of the REDUCE-IT Investigators. Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial. *Clin Cardiol*. 2017;40:138-148.
- <sup>7</sup> Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N *Engl J Med.* 2019;380(1):11-22.
- <sup>8</sup> Bhatt DL, Steg PG, Miller M, et al., on behalf of the REDUCE-IT Investigators. Reduction in first and total ischemic events with icosapent ethyl across baseline triglyceride tertiles. *J Am Coll Cardiol*. 2019;74:1159-1161.