



Leading a New Paradigm in Preventative Cardiovascular Care

Goldman Sachs 42nd Annual Global Healthcare Conference June 8, 2021



## MARIN

#### Forward-looking statements

This presentation contains forward-looking statements, such as those relating to the commercial potential of VASCEPA® (VAZKEPA in Europe), clinical and regulatory efforts and timelines, potential regulatory and pricing approvals, patent litigation, generic product launch, intellectual property, cash flow, research and development, and other statements that are forward-looking in nature and depend upon or refer to future events or conditions, including financial guidance and milestones. These statements involve known and unknown risks, uncertainties and other factors that can cause actual results to differ materially. Investors should not place undue reliance on forward-looking statements, which speak only as of the presentation date of this presentation. Please refer to the "Risk Factors" section in Amarin's most recent Forms 10-K and 10-Q filed with the SEC and cautionary statements outlined in recent press releases for more complete descriptions of risks in an investment in Amarin.

This presentation is intended for communication with investors and not for drug promotion.

AMARIN, VASCEPA, VAZKEPA and REDUCE-IT 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.

#### **Milestones Achieved**

- European Commission (EC) authorized marketing of Amarin's VAZKEPA in European Union (Mar'21)
- Medicines and Healthcare Product Regulatory Agency (MHRA) authorized marketing of Amarin's VAZKEPA in England, Scotland and Wales (Apr'21)
- Regulatory authorities in Mainland China and Hong Kong, in response to submission by Amarin's commercial partner, accepted icosapent ethyl for review with decisions expected before end of 2021
- I7 medical societies now recommend use of icosapent ethyl (IPE)

#### **Financial**

- Operating spending in United States (US) intentionally slowed to help offset market headwinds of COVID-19 and other factors
- Atypical generic competition in the US accounted for ~9% of icosapent ethyl prescriptions as estimated by Symphony Health in Q1'21
- Net total revenue for Q1'21 was \$142.2 million, including \$140.8 from net product sales in the US and none from net product sales in Europe where VAZKEPA is expected to launch before the end of Q3'21
  - Net product sales in US in Q1'21 were down 3% from prior year due to 1) COVID-19; 2) severe winter weather; 3) generic competition and 4) calendar anomaly reported in Q1'20 which, as expected, was not repeated in Q1'21
- Expense management improved bottom line in Q1'21; profitable excluding non-cash costs

#### **Management Changes**

Transition plans/retirements announced for CEO and general counsel

#### **United States**

 As impact of COVID-19 on patients avoiding doctors' visits recedes, resume launch and growth of VASCEPA for persistent cardiovascular risk based on the landmark REDUCE-IT<sup>®</sup> outcomes study (P-CVR)

#### Europe

- Pursue market (reimbursement) access on a country-by-country basis using approved label and supporting clinical effectiveness data
- Commence commercial launch pursuant to market access, including expected launch in Germany before the end of Q3'21

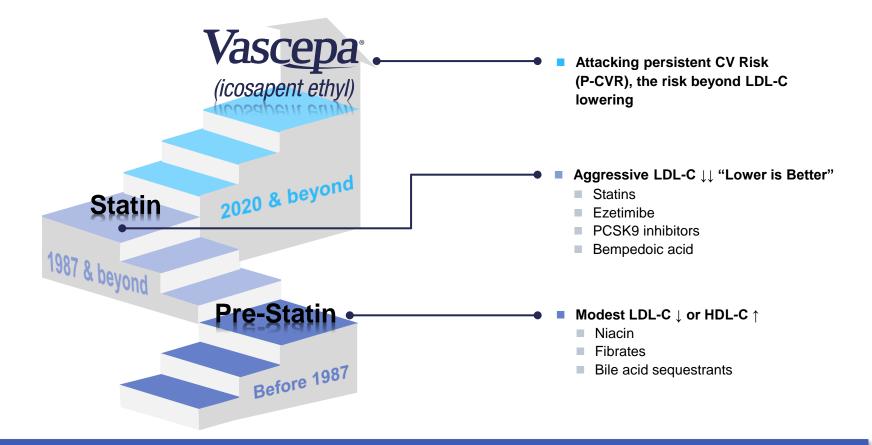
#### China and Rest of World (RoW)

Support existing commercial partners, including regulatory support in Middle East and China (approval in China targeted for near end of 2021), and prepare for further international expansion after approval and market access progress in Europe

#### Other

 Increasingly evaluate and pursue product pipeline opportunities (e.g., ongoing COVID-19 studies) and diversification opportunities

## VASCEPA Is a New Preventative Cardiovascular (CV) Care Treatment Option Beyond LDL-C Lowering



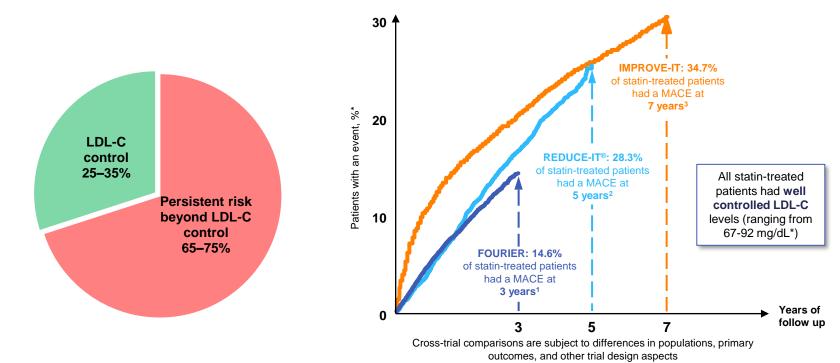
VASCEPA is the only drug proven to reduce persistent CV risk in the population studied (P-CVR)

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Controlled LDL-C doesn't eliminate CV risk; P-CVR often remains 25%-35% lowering major adverse CV events (MACE)

shown in CV outcome studies of statin therapies

Placebo groups from multiple recent trials show high P-CVR despite statin-based standard-of-care 14.6% to 34.7% of patients treated for LDL-C but not for P-CVR experienced a major adverse cardiovascular event (MACE) in 3-7 Years



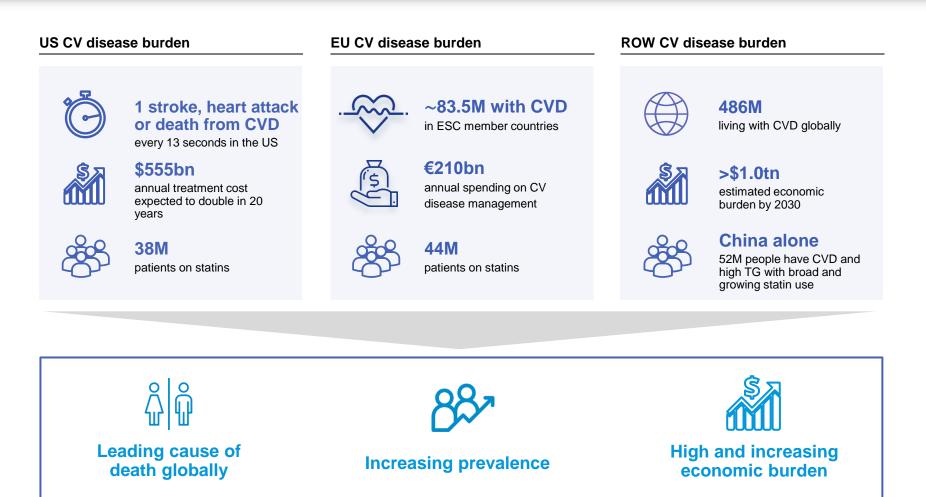
Note: FOURIER, REDUCE-IT® and IMPROVE-IT trials evaluated evolocumab, icosapent ethyl and ezetimibe / simvastatin, respectively

 $^{\ast}$  67 mg/dL is equivalent to 0.8 mmol/L and 92 mg/dL is equivalent to 1.0 mmol/L

1. Sabatine MS, et al. N Engl J Med. 2017;376(18):1713-1722; 2. Bhatt DL, et al; for REDUCE-IT<sup>®</sup> Investigators. N Engl J Med. 2019;380(1):11-22; 3. Cannon CP, et al. N Engl J Med. 2015;372(25):2387-2397

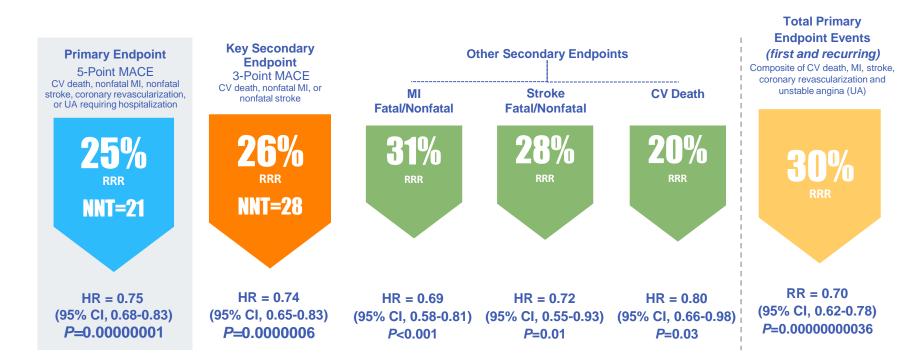
# Cardiovascular Disease (CVD) Is an Enormous and Worsening Public Health Burden





Sources: http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\_491543.pdf; Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/fastats/leadingcauses-of-death AHA: Cardiovascular Disease: A Costly Burden for America — Projections through 2035.htm, January, 20, 2017; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation. 2020; 141:e1–e458; European Society of Cardiology: Cardiovascular Disease Statistics 2017, European Heart Journal, Volume 39, Issue 7, 14 February 2018, Pages 508–579; European Heart Network Report, 2017; World Health Organization, https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds); 2020 AHA Fact Sheet, https://www.heart.org/-/media/files/about-us/statistics/2020-heart-disease--stroke-statistical-update-fact-sheetucm505489.pdf; WEF-Harvard Global Economic Burden, http://www3.weforum.org/docs/WEF\_Harvard\_HE\_GlobalEconomicBurdenNonCommunicableDiseases\_2011.pdf; Chinese Circulation Journal, July, 2019, Vol 34 Number 7 (Series Number 253); IMS China database 2014-2018Q3

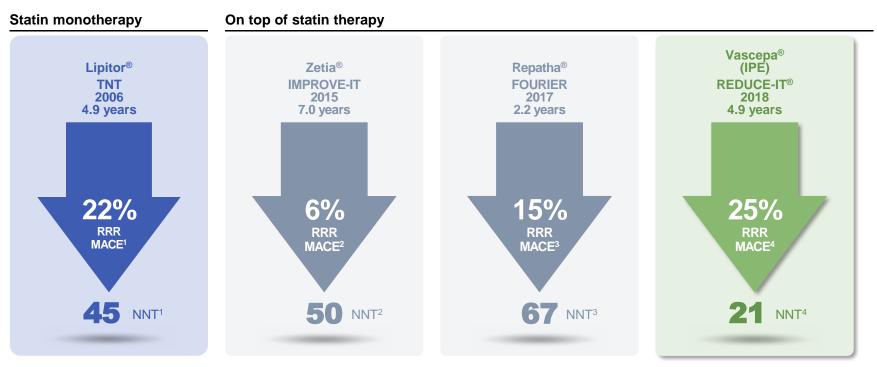
## VASCEPA Is Unique: Demonstrated CV Risk Reduction Beyond Standard-of-Care (including Statins) in Landmark CVOT



- Significant reductions across the prespecified testing hierarchy <sup>1</sup>
- ✓ Generally consistent reductions across subgroups
- Analyses suggest lipid, lipoprotein, and inflammatory markers (including TG) likely have limited contribution to the overall CV benefit demonstrated with icosapent ethyl (IPE)
- ✓ Analysis suggests CV benefit derived from multifactorial effects of icosapent ethyl administered at high levels
- Well-tolerated safety profile with overall adverse event rates similar for both VASCEPA and placebo patients as per US FDA, Health Canada, and European Commission approved labels for VASCEPA/VAZKEPA and peer-reviewed publication

HR = hazard ratio; NNT = number needed to treat

1. Bhatt DL et al; for REDUCE-IT® Investigators. N Engl J Med. 2019;380(1):11-22



#### NNT: Number of patients who need to be treated to prevent one additional bad outcome

Results above are based on first occurrence of MACE\*; VASCEPA in total events analysis (first and recurring MACE) resulted on average in 1 fewer MACE per 6 patients treated

\*Based on primary composite endpoints of each trial

Note: Cross-trial comparisons are subject to differences in populations, primary outcomes, study duration and other trial design aspects. Information provided for context only; none of the products have same indication as Vascepa<sup>®</sup> 1. LaRosa JC, et. al., N Engl J Med 2005;352:1425-35; 2. Cannon CP, et al. N Engl J Med. 2015;372(25):2387-2397; 3. Sabatine MS, et al. N Engl J Med. 2017;376(18):1713-1722; 4. Bhatt DL et al; for REDUCE-IT<sup>®</sup> Investigators. N Engl J Med. 2019;380(1):11-22

## Broad Third-Party Support for VASCEPA (Icosapent Ethyl)

#### 17 leading medical societies recognizing importance of Icosapent Ethyl:

- American Association of Clinical Endocrinologists
- American Diabetes Association
- American College of Endocrinology
- American Heart Association
- American Stroke Association
- Brazilian Society of Cardiology
- Canadian Cardiovascular Society
- Chinese Journal of Internal Medicine (a journal of the Chinese Medical Association)

#### Analyses show VASCEPA to be cost effective

- Institute for Clinical and Economic Review (ICER) report shows VASCEPA as cost effective for CV risk reduction (Oct'19)
- Comprehensive analysis determined Icosapent Ethyl to be highly cost-effective in patients from the REDUCE-IT study, and may even demonstrate cost-savings in the majority of simulations (Nov'19)

#### Cardiovascular outcomes study results published in leading medical journals

- The New England Journal of Medicine
- Journal of American College of Cardiology

## VASCEPA has been prescribed over 10 million times

US FDA Advisory Committee voted unanimously (16-0) in favor of VASCEPA approval for P-CVR; favorable benefit/risk profile characterized in efficacy and safety portions of FDA-approved label

- Chinese Society of Cardiology
- Colombian Society of Cardiology & Colombian Association of Endocrinology, Diabetes and Metabolism
- Egyptian Heart Journal
- Endocrine Society
- European Society of Cardiology
- European Atherosclerosis Society
- Japanese Circulation Society
- National Lipid Association
- Thrombosis Canada





- European Heart Journal
- Circulation (AHA)

## Large Global Need and Opportunity for VASCEPA



2021 and Beyond Expanding to Europe and RoW

# **Rest of World (RoW)**

#### Billion-dollar opportunity

Status of partnered geographies:

Canada: Launched via partner in 2020

**Middle East**: Launched via distributor in select countries for TG lowering; now pursuing P-CVR indications

**China**: Phase 3 clinical study of VASCEPA successfully completed in 2020; regulatory submission accepted with an anticipated decision near the end of 2021

Many other large potential market opportunities for VASCEPA remain unaddressed (e.g., Russia, Latin America, Australia, etc.); they will receive increased focus after securing market access in Europe

# **US Commercial Focus**

Before 2021; Mostly R&D and

Europe

# US

#### **Multi-billion-dollar opportunity**

Regulatory status:

Approved for P-CVR and original niche indication of treating TG >500 mg/dL

Market access status: Broadly covered Deemed cost effective by ICER

Commercial status:

#### Launched in 2020 for P-CVR

Marketed/sold by Amarin

Largest portion of 2020 estimated net revenue of ~\$600 million

Generic competition in atypical generic market with potential for branded VASCEPA to grow faster than generics

#### Multi-billion-dollar opportunity

#### Regulatory status:

Approved for P-CVR

Market access status:

Positioned for potential net pricing at least as good as in US (as was achieved in Canada) supported by CVOT results that were not available when priced in US

Formal market access negotiations commencing following March 2021 label approval

Commercial status:

#### Country-by-country launches expected to start in 2021

To be marketed/sold by Amarin in largest countries

No direct competitor; earlier products failed CVOTs

### **United States Commercial Priorities**

#### Increase US VASCEPA use and profits

- Increase education of healthcare professionals and patients
  - Continue to adapt during COVID-19 era
  - Leverage medical guidelines and data showing that <u>no other drug has the same effect</u> as VASCEPA
- Increase in-person meetings with healthcare professionals in a phased manner as patients resume routine physician visits as the impact of COVID-19 recedes
  - Leverage sales force expansion completed in Mar'20 to reach more doctors more frequently
- Sponsor numerous medical education programs and scientific presentations/publications;
  - >100 presented/published in recent years
- Leverage recent improvements in already broad managed care coverage
- Manage spending to reflect variability of COVID-19 and generic entry to support profit growth while allowing for quarterly variability, including potential impact of generic supply stockpiled prior to launch

#### Adjust to threat of generic competition in atypical market environment for generics

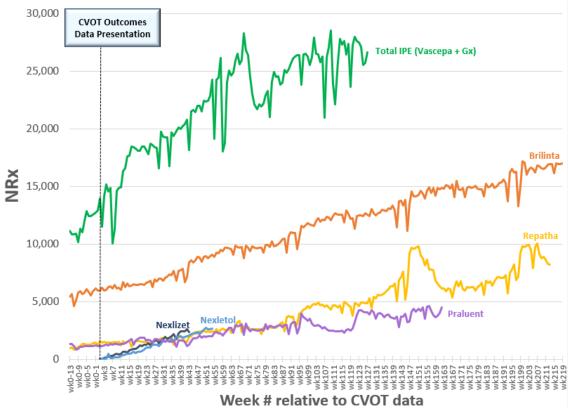
- VASCEPA is not a mature product still largely unknown
- Generic supply is expected to remain limited and potentially variable due to manufacturing complexities, costs and lead times combined with limited investment by generic companies in supply capacity
- Historical analogue from EPADEL in Japan ~60% branded share maintained despite generic competition for >10 years





## VASCEPA Growth Compares Well to Other Drugs with Positive CVOT Results in Recent Years (none compete with VASCEPA)

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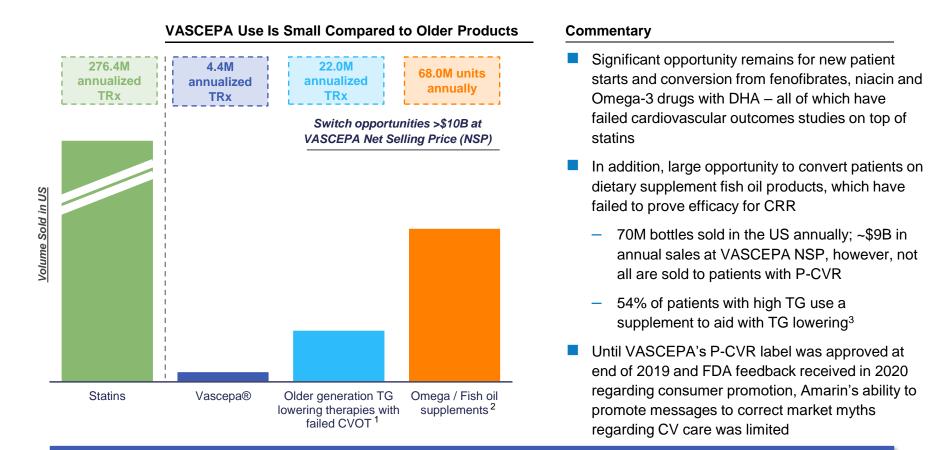


- VASCEPA growth has exceeded most other recent "CVOT" peers
- VASCEPA growth is increasing despite launching shortly before the onset of COVID-19
- Physician and patient awareness of VASCEPA remain low
- Opportunity to increase face to face interactions and resume other launch initiatives as the impact of COVID-19 recedes
- COVID-19 impact during 2020 and 2021 was significant in densely populated areas where Amarin has the most selling experience
- Standard blood (lipid) tests are typically required for VASCEPA prescriptions which can't be done via televisits

Source: Symphony Health Solutions, PHAST Weekly, WE 4/16/2021

Note: New Rx data for each product are shown relative to its CVOT data presentation, defined as Wk 0; Nexlizet and Nexletol are relative to launch week after receiving FDA approval; Nexlizet as of 6/12/2020; Vascepa® as of 11/10/18; Nexletol as of as of 3/27/2020; Brilinta as of 03/14/15; Repatha as of 03/17/17; Praulent as of 03/10/18 CRR = Cardiovascular risk reduction (the form of such labels vary between drugs – Vascepa® is for reduction of P-CVR)



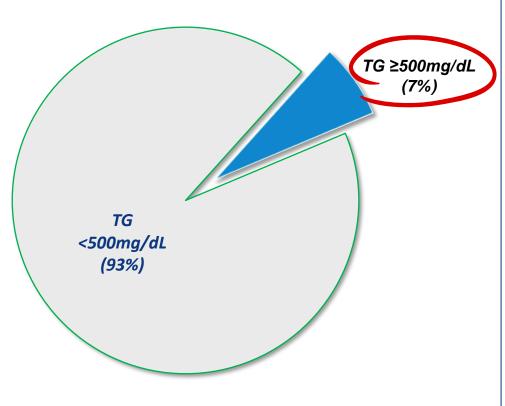


#### Like statins, VASCEPA has the potential to be ubiquitous for CV prevention treatment

Source: IQVIA NPA Market Dynamics accessed on 12/17/20; MAT on-therapy patients; <sup>1</sup>Older generation TG lowering therapies with failed CVOT includes generic & branded fenofibrates, gemfibrozil, niacin, generic omega-3, and Lovaza; <sup>2</sup> Nielson data 52-weeks ending 04/18/20; <sup>3</sup> Based on Amarin primary market research survey



Approximately 7% of VASCEPA's prescriptions are for patients that have TG ≥500 mg/dL, and some of these are prescribed for CRR rather than TG lowering



Hikma launched generic IPE in Nov'20

- Thus far, generic supply appears limited
- Indication is only for TG <u>></u>500 mg/dL
- Net pricing of generic is higher than branded VASCEPA for many payers and patients (WAC price is 12.3% below branded VASCEPA, rebate levels to many payers exceed this WAC price difference)

No other generic launched

- Dr. Reddy's Labs and Teva received FDA approval for generic IPE in May'20 and Aug'20, respectively
- Apotex ANDA currently not approved

Amarin pursuing various legal actions to enforce its rights, including infringement lawsuit filed against Hikma in Nov'20 and expanded in Jan'21 to include payer, HealthNet

TG  $\geq$ 500 mg/dL indication is not being pursued in Europe and various other markets to avoid potential generic entry for skinny label





#### ~49M people in the European Union (EU) with CV disease<sup>1</sup>

- Includes 38 million diagnosed with ischemic heart disease (IHD), stroke or peripheral heart disease
- IHD and stroke are, respectively, the first and second most common single causes of death in the EU

#### Recent VAZKEPA approvals open door to commercialization in EU and Great Britain (GB)<sup>2</sup>

- European Commission and MHRA authorization of IPE to be marketed and sold in EU and GB for 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
- Approved label acknowledges IPE's multifactorial mechanisms of action
- Brand name VAZKEPA for Europe supports effective translation into multiple languages
  - Pronounced using a short "e" Vaz-kĕ-pah
- First and only drug approved for P-CVR indication

#### **Commercialization Plans**

- Market access (reimbursement) initiatives to accelerate post approval
- Leverage robust clinical efficacy of VAZKEPA and supportive pharmacoeconomic data (e.g., high costs associated with treating strokes, heart attacks and other major adverse cardiovascular events (MACE))
- Amarin team in Europe of ~50 professionals in January 2021 and expected to grow to ~300 by the end of 2021, with 150 sales professionals to be deployed in May 2021, for pre-launch market awareness initiatives in Germany
- Market awareness initiatives underway in advance of VAZKEPA launch in Europe
  - Leading medical societies in Europe, ESC and EAS, already include icosapent ethyl in their medical guidelines
- Launch in Germany expected before the end of Q3'21 after initial awareness campaign to be followed by launches elsewhere in Europe subject to successfully securing market access

#### **Exclusivity expected for many years**

- Regulatory exclusivity expected for 10 years from March 26, 2021 approval, possibly 11 years
- Patents issued expire in 2033
- Filed patent applications could extend protection into 2039





## China First-in-Class Opportunity

- Study achieved primary endpoint with VASCEPA lowering TG levels by 19.9% (p<0.001) compared to placebo at the end of 12-week treatment period
- VASCEPA was well-tolerated with a safety profile similar to placebo and there were no treatment-related serious adverse events
- Mirrored MARINE study results, demonstrating consistency in treatment outcomes across Western and Asian patient populations

#### Seeking to position VASCEPA as first-in-class therapy

First approval in China creates potentially high hurdle for future competitive product(s), if any

#### Commercial partner, Edding, preparing for product launch

- Successfully promotes multiple products in China
- Understands the importance of VASCEPA's high quality manufacturing through Amarin for both product effectiveness and market growth reasons

# Chinese Society of Cardiology now already includes icosapent ethyl in their medical guidelines for primary prevention of CV diseases

#### Regulatory, reimbursement and commercialization plans underway

- NMPA accepted for review the New Drug Application for VASCEPA, approval decision for Mainland China anticipated near end of 2021; similar review underway in Hong Kong
- Similar to Europe, market access and launch initiatives to accelerate approaching and after regulatory approval



## VASCEPA/VAZKEPA Infectious Disease Potential Opportunities

# Based on data related to the mechanism of action and effects of VASCEPA/VAZKEPA, it is hypothesized that VASCEPA/VAZKEPA may play a potential beneficial role in:

- Preventing SARS-CoV-2 infection
- Potentially reducing clinical severity in patients infected by the virus

#### Supporting four investigator-initiated studies

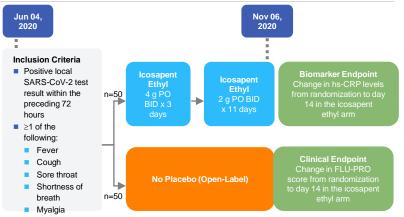
- Canada: COVID-19 CardioLink-9 clinical trial Completed
  - Results were positive and presented in Dec'20
  - Small study; data from other studies needed to support hypothesis
- Argentina: PREPARE-IT clinical trials First of two studies started in '20 and is ongoing
  - Investigating the effects of VASCEPA/VAZKEPA on reducing SARS-CoV-2 infections
  - 2,000 participants; potential results mid-'21
- United States: MITIGATE clinical trial Ongoing
  - Investigating the effects of VASCEPA/VAZKEPA on laboratory-confirmed viral upper respiratory infection rates
  - 1,500 participants; patient enrollment ongoing, potential results in '22

Amarin supports but does not manage investigator-initiated studies (timing per above represents rough estimates)

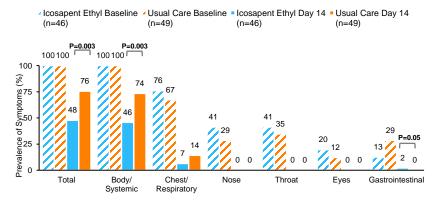
After more clinical data are available, assessments will be advanced regarding potential regulatory and commercial opportunities of VASCEPA/VAZKEPA and COVID-19 and/or potentially other infectious diseases

## CardioLink-9: Investigational Study of Effects of VASCEPA on Inflammatory Biomarkers in COVID-19 Infected Patients

Study design



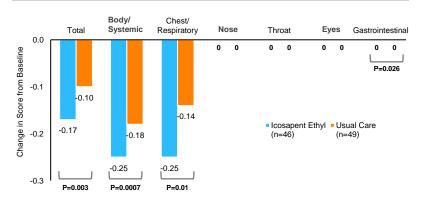
Clinical endpoint: prevalence of FLU-PRO symptoms<sup>2</sup>



Inflammatory biomarker endpoint: unadjusted hs-CRP changes from baseline to day 14<sup>1</sup>

	Baseline (mg/L)	Day 14 (mg/L)	Median Percent Change from Baseline	Median Change from Baseline (mg/L)	P-value (within group)
lcosapent Ethyl (n=44)	3.2 (0.9, 11.6)	1.6 (0.6, 4.4)	-25.0 (-80.1, 26.7)	-0.5 (-6.9, 0.4)	0.011
Usual Care (n=47)	2.3 (0.7, 6.5)	2.1 (0.5, 5.8)	-5.6 (57.1, 84.2)	-0.1 (-3.2, 1.7)	0.51
P-value (between groups) 0.082					

## FLU-PRO scores: changes in total and individual domain scores from baseline to day 14



FLU-PRO, InFLUenza Patient-Reported Outcome; hs-CRP, high-sensitivity C-reactive protein. https://clinicaltrials.gov/ct2/show/NCT04412018; https://www.vascepacovid19.com/#about. Bhatt DL et al. NLA 2020 Late Breaking Presentation

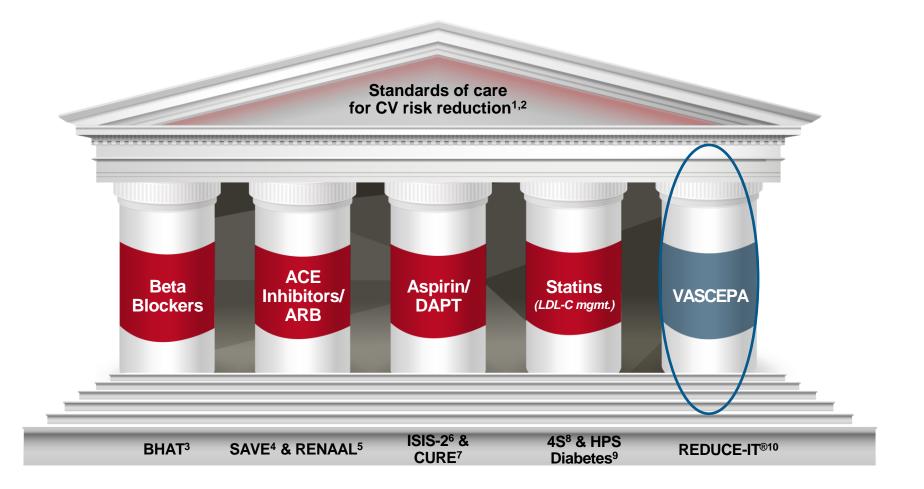
<sup>1</sup> Data is presented as median (interquartile range); <sup>2</sup> Values shown are based on number of patients with non-missing assessments at respective visits

## (Millions) (Unaudited) As of March 31, 2021



Cash and Investments	\$538.7			
Debt				
NOTES	None			
ROYALTY-BEARING INSTRUMENTS	None	Repayment completed in 2020		
Common Stock and Equivalent Shares <sup>1</sup>				
COMMON SHARES	395			
OPTIONS AND RESTRICTED STOCK	30	Aggregate of all outstanding regardless of price or vesting		
TOTAL IF ALL EXERCISED	425			
Tax Jurisdiction (primary)	Ireland	Loss carryforwards of ~\$900		

### VASCEPA Is Becoming the Next Pillar of CV Care



1. American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2019;139(10):e56-e66; 2. Jernberg T et al. JAMA. 2011;305(16):1677-1684; 3. Goldstein S. *Circulation*. 1983;67(6 pt 2):153-157; 4. SAVE Investigators. *N Engl J Med*. 1992;327(10):669-677; 5. RENAAL Study Investigators. *N Engl J Med*. 2001;345:861-869; 6. ISIS-2 (Second International Study of Infarct Survival) Collaborative Group. *Lancet*. 1988;2(8607):349-360; 7. Clopidogrel in Unstable Angina to Prevent Recurrent Events Trial Investigators. *N Engl J Med*. 2001;345(7):49-502; 8. Scandinavian Simvastatin Survival Study Group. *Lancet*. 1994;344(8934):1383-1389; 9. Heart Protection Study Collaborative Group. *Lancet*. 1994;345(7):459-450; 8. Cloaperative Group. *Lancet*. 1994;344(8934):1383-1389; 9. Heart Protection Study Collaborative Group. *Lancet*. 1994;345(7):459-





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