



## **ANCHOR Study Results Overview**

**April 18, 2010**

**Nasdaq: AMRN**

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# Forward-Looking Statement

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*This presentation contains forward-looking statements, including those relating to the Company's market opportunity and other statements that are predictive in nature, that depend upon or refer to future events or conditions. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. See discussion of Risk Factors in the Company's Annual Report on Form 10-K as filed with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. Amarin's product candidates are in various stages of development and are not available for sale or use outside of approved clinical trials.*

# Overview of Lead Product - AMR101

- **Strong clinical results support best-in-class indications for very high triglycerides ( $\geq 500$  mg/dL) and mixed dyslipidemia ( $\geq 200$  mg/dL -  $< 500$  mg/dL, on statin therapy)**
  - All endpoints met for pivotal MARINE trial as reported November 29, 2010
  - All endpoints met for pivotal ANCHOR trial as reported April 18, 2011
  - Data suggests dosing flexibility and no increase in LDL-C providing significant market differentiation
  - Strong safety profile that is comparable to placebo
  - Encouraging important lipid biomarker results
- **Blockbuster sales potential in a relatively untapped markets**
  - Very high triglycerides market is a growing market with revenues in excess of \$1 billion
  - No omega-3 based product is approved for the larger mixed-dyslipidemia market
- **AMR101 is an unpartnered drug candidate**
- **Well-defined clinical and regulatory path**
  - SPA agreements with FDA for each of MARINE and ANCHOR Phase 3 trials
  - NDA expected to be filed in Q3, 2011

**Unique Opportunity: Significant Differentiation & Risk Mitigation**

# Phase 3 Program: Concurrently Run Pivotal Trials

	MARINE TRIAL	ANCHOR TRIAL
Size:	229 patients	702 patients
Population:	Patients with <u>very high</u> triglycerides ( $\geq 500$ mg/dL)	Patients with mixed dyslipidemia ( <u>high</u> triglycerides $\geq 200$ mg/dL and $< 500$ mg/dL on statin therapy)
Duration:	12 week treatment period (after 6-8 week run-in period)	Same
Dose:	2 g and 4 g of AMR101 per day	Same
Control:	Placebo-controlled, double-blind	Same
Primary endpoint:	Reduction in triglyceride levels	Same plus secondary endpoint: LDL-C non-inferiority to PBO
Follow-on:	Patients are offered a 40 week open-label extension period (Results not required for NDA)	Phase 3b follow-on outcome study is to be commenced prior to NDA (Results not required for NDA)
Principal Investigator	H. Bays, M.D. (Louisville, KY)	Professor C. Ballantyne, M.D. (Houston, TX)

# ANCHOR Study Population

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- Baseline Triglycerides (TGs);
  - 4 gram dosing cohort – 265 mg/dL
  - 2 gram dosing cohort – 254 mg/dL
  - Placebo cohort - 259 mg/dL
- Baseline LDL-C = 83 mg/dL
- All patients were high-risk and on optimized background statin therapy
  - simvastatin (Zocor), atorvastatin (Lipitor) , rosuvastatin (Crestor)
- 61% Male
- Majority of patients were diabetic (73%)


# ANCHOR Study Results - Lipid Results; Median Changes

- 4 grams of AMR101 as compared to placebo;
  - Reduced TGs by 21.5% ( $p < 0.0001$ )
  - Reduced non-HDL-C by 13.6% ( $p < 0.0001$ )
  - Reduced LDL-C by 6.2% (demonstrated superiority over statin alone) ( $p = 0.0067$ )
  - LDL-C upper confidence boundary -1.7%\*
- 2 grams of AMR101 as compared to placebo;
  - Reduced TGs by 10.1% ( $p = 0.0005$ )
  - Reduced non-HDL-C by 5.5% ( $p = 0.0054$ )
  - Reduced LDL-C by 3.6% ( $p = 0.0867$ )
  - LDL-C upper confidence boundary 0.05%\*

\*Upper boundary needed to be  $< +6\%$

April, 2011

# ANCHOR Study Results - Additional Data

- Reduction in achieved pre-specified secondary endpoints
  - Non-HDL-C
  - Apo B
  - Lp-PLA<sub>2</sub>
  - VLDL-C

All statistically significant, both doses
- TG reductions even greater with higher statin efficacy regimens
- AMR101 Safety
  - Well tolerated with safety comparable to placebo
  - Safety/tolerability more favorable than other triglyceride lowering therapies
  - No treatment related SAEs

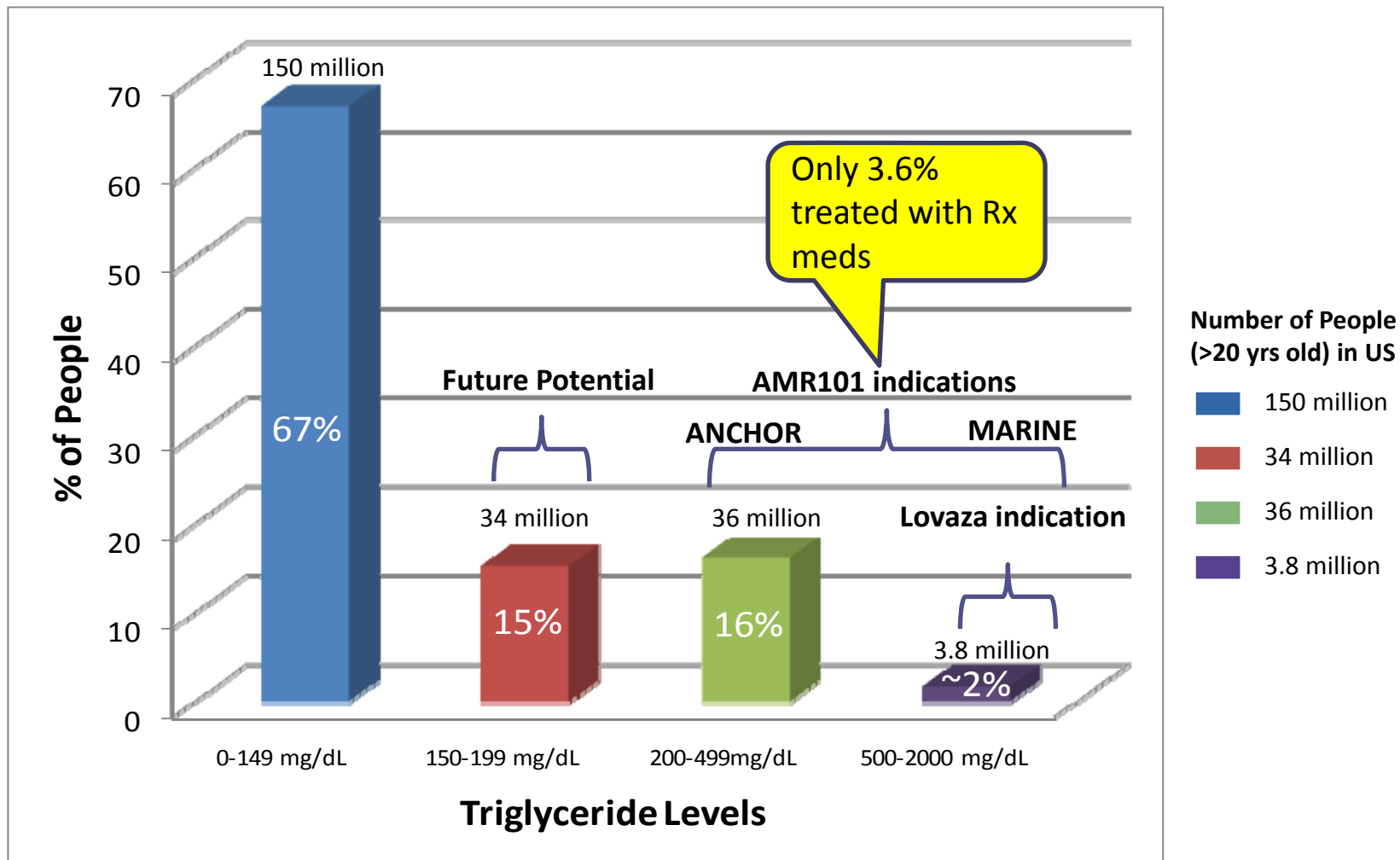
# Summary of Largest Omega-3 Mixed Dyslipidemia Studies

	COMBOS Study Lovaza (Ethyl EPA/DHA)	ANCHOR Study AMR101 (Ethyl-EPA)
Population	TG 200-500 mg/dL	TG 200-499 mg/dL
N	254	702
Baseline TG	269 mg/dL	259 mg/dL
Statin Use	Single statin; fixed dose simvastatin 40 mg/day	3 statins; treated to goal simva-, rosuva-, or atorvastatin
Risk Profile	Any risk (Hx of CV events ≤ 6 months excluded) LDL-C <10% above NCEP ATP III goal	High risk ATP III LDL-C <100 mg/dL
OM-3 & Dosage	Lovaza 4 g/day	AMR101 - 2 or 4 g/day
Design	Powered for TG ↓ only	Powered for TG ↓ & to exclude LDL-C elevation
Duration	8 weeks	12 weeks
Endpoint	Non-HDL-C	TG reduction
Result	TG ↓ 23%; LDL-C ↑ 3.5%	4 g/day: TG ↓ 21.5%*; LDL-C ↓ 6.2%
Status	Indication not approved	SPA endpoints achieved

\*ANCHOR enrolled a limited number of patients with TG baselines <200 mg/dL. In patients with TG baseline >200 mg/dL, TG levels decreased 23%.



# Large Underpenetrated Market Opportunities



Source: Archives of Internal Medicine, 2009;169(6):572-578

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# MARINE Study Results Overview

## MARINE Study Results – Lipid Results; Median Changes

- 4 grams of AMR101 as compared to placebo;
  - Reduced TGs by 33% ( $p < 0.0001$ ); 45% in patients with TG > 750 mg/dl ( $p = 0.0001$ )
  - Reduced non-HDL-C by 18% ( $p < 0.001$ )
  - Reduced LDL-C by a non-significant 2.3%\*
- 2 grams of AMR101 as compared to placebo;
  - Reduced TGs by 20% ( $p = 0.0051$ ); 33% in patients with TG > 750 mg/dl ( $p = 0.0016$ )
  - Reduced non-HDL-C by 8% ( $p < 0.05$ )
  - Increased LDL-C by a non-significant 5.2%\*
- Greater median reductions in TGs seen in patients on statins

\*This is the first and only study to show no elevation of LDL in this treated population (compared to fibrates and prescription omega-3 acid ethyl esters). Typical LDL-C elevations are ~50% with other approved therapies.

# MARINE Study Results - Additional Data

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- Reduction in achieved pre-specified biomarker endpoints ( $p < 0.05$  for all and  $p < 0.01$  for some)
  - Apo B
  - Lp-PLA<sub>2</sub>
  - VLDL-C
  - Total Cholesterol
- AMR101 Safety
  - Well tolerated
  - Safety comparable to placebo
  - Safety more favorable than other triglyceride lowering therapies
  - No treatment related SAEs
  - Data to be presented at NLA in May 2011