

Amgen's New Cholesterol Drug Repatha: Godsend or Boat Anchor – the Market Knows



By Chuck Dinerstein, MD, MBA — March 20, 2017



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Amgen's Repatha was heralded over the weekend at the annual TCTMD meeting as NBC, among others, breathlessly reports: [New Drug Prevents Heart Attacks in High-Risk Patients](#) [1]. But on hearing the news, the renown pundit on medical studies, Nasdaq, repriced [Amgen's stock](#) [2] "After closing at \$180.11 Thursday, the stock slid nearly 7 percent early Friday to close at \$168.41." Why the disconnect?

Luckily for those of us who like data, the answer can be found in the results of the Repatha study itself. I have taken chart this from the [New England Journal of Medicine's](#) [3] companion release on Repatha's study.

Supplemental Table 4 – Patient Incidence of Cardiovascular Clinical Events

Endpoint	Evolocumab plus standard of care (N=2976) n (%)	Standard of care alone (N=1489) n (%)	Hazard Ratio (95% CI)
All cardiovascular events	29 (0.95)	31 (2.18)	0.47 (0.28-0.78)
MACE	28 (0.95)	30 (2.11)	0.47 (0.28, 0.78)
Death	4 (0.14)	6 (0.41)	
Cardiovascular or unknown	4 (0.1)	3 (0.2)	
Non-cardiovascular	0 (0.0)	3 (0.2)	
Coronary events	22 (0.75)	18 (1.30)	
Myocardial infarction	9 (0.3)	5 (0.3)	
Hospitalization for unstable angina	3 (0.1)	3 (0.2)	
Coronary revascularization	15 (0.5)	17 (1.1)	
Cerebrovascular events	4 (0.14)	7 (0.47)	
Stroke	3 (0.1)	2 (0.1)	
Transient ischemic attack	1 (0.0)	5 (0.3)	
Heart failure requiring hospitalization	1 (0.03)	1 (0.07)	

MACE refers to “a post hoc composite that includes death, major coronary events, and major cerebrovascular events.” It is a standard endpoint because each of its components alone is too infrequent to allow meaningful statistical analysis on affordable clinical trials. We need only concentrate on the numbers in the red box. Here comes the math, but I promise it will not be, shall we say, too mathy.

Absolute Event Reduction (AER) is how many events were prevented using Repatha (evolocumab)

$$\text{AER} = 2.18\% - 0.95\% = 1.23\% \text{ for deaths and } \text{AER} = 2.11\% - 0.95\% = 1.16\% \text{ for MACE}$$

So yes, this drug reduces both deaths and MACE, although the absolute reduction is small. But the real number of interest is called the number needed to treat or NNT, which tells us how many people need to be treated to save one life or to prevent one MACE episode. For a reference value, the NNT for using statins to prevent death is 83 [4], that is you need to treat 83 people to prevent one death. How about Repatha? The NNT calculation is

$$\text{NNT} = 1/\text{AER} = 1/1.23\% = 81.3 \text{ for deaths and } 1/1.16\% = 86.2 \text{ for MACE.}$$

These are pretty comparable numbers and remember this is the use of Repatha **in addition to** statins. We can use our numbers needed to treat to come up with some cost estimates. There are about 100 million individuals in the US requiring statins, and of those, about 4% [5] or 4 million patients are candidates for using Repatha. The drug cost for a year is \$14,000. Let us say every one of those patients is put on Repatha so

Annual cost of Repatha = 4,000,000 * \$14,000 = \$56,000,000,000 At least we can see Amgen’s excitement. But if we use our NNT information we can also determine how many of our 4 million patients will experience a benefit, I will use death’s NNT because it is a little better.

$$4,000,000 \text{ patients} / 81.3 \text{ patients per life saved} = 49,200 \text{ people}$$

Let me hasten to add that you cannot put a price on a life, but we can use this figure to determine

what each life saved cost society.

$\$56,000,000,000/49,200 = \$1,138,211.38$

To put this number in perspective, the National Institute for Health and Clinical Excellence (NICE), Britain's gatekeeper for the introduction of new drugs has [its threshold](#) [6] of about \$37,000 although it will go as high as \$124,000 for an end of life drug.

What I find fascinating is that after all Adam Smith's free market can do all these calculations in a short time and give all of us a thumbs up or down without the hype. In this instance, believe the market not the media.

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Links

[1] <http://www.nbcnews.com/health/heart-health/new-drug-prevent-heart-attacks-high-risk-patients-n734841>

[2] http://cnbcmbr-vh.akamaihd.net/i/mp4/VCPS/Y2017/M03D16/3000602033/5ED4-FM-TIRRELL-AMGN-031617_MBR_,170,130,090,070,050,030,024,0.mp4.csmil/master.m3u8?__b__=700

[3] <http://www.nejm.org/doi/full/10.1056/NEJMoa1500858#t=article>

[4] <http://www.thennt.com/nnt/statins-for-heart-disease-prevention-with-known-heart-disease/>

[5] http://www.health.harvard.edu/heart-health/help_for_your_cholesterol_when_the_statins_wont_do

[6] <https://www.ncbi.nlm.nih.gov/pubmed/18767894>