CLOSER LOOK

MEMORANDUM

# Amgen 1Q16 - First release of Repatha (evolocumab) revenues at $16 million; Repatha "one of our largest opportunities" with recent positive clinical data + launches outside of US - May 2, 2016

**Executive Highlights**

- Amgen provided its 1Q16 update late last week in a call led by CEO Mr. Bob Bradway, in which the company broke out Repatha (evolocumab) sales for the first time: revenues totaled $16 million in 1Q16. Management expressed strong enthusiasm for the product throughout the call, highlighting recent positive clinical data and advances in international markets.

*Amgen provided its 1Q16 update late last week in a call led by CEO Mr. Bob Bradway, in which the company broke out Repatha (evolocumab) sales for the first time: revenues totaled $16 million in 1Q16, with $14 million from US sales and $2 million from rest-of-world (ROW) sales. This gives Repatha a small edge ahead as the PCSK9 inhibitor market leader for 1Q16, compared to $13 million for Sanofi/Regeneron's Praluent (alirocumab). Overall, management expressed strong enthusiasm for Repatha throughout the call, labeling the product as "one of our largest opportunities" and pointing to the recent positive phase 3 GAUSS-3 data announced in February. Regarding Repatha's international presence, management highlighted that it is launching in Japan, Brazil, and multiple European countries with "good early signs." The company noted that reimbursement negotiations are "on track" in Europe and that the product received pricing approval in Japan, with launch activities with partner sellers progressing well. In addition, management expressed excitement about the launch of the monthly dosing option later this year - a promising option that can help with patient adherence. Similar to Amgen's last update, the company highlighted upcoming cardiovascular outcomes data in 2H16. Throughout the call and Q&A, management pointed to the potential of these data as being very promising in helping move reimbursement and access issues forward, particularly in overcoming the challenges around the strict payer utilization management criteria. We also remain hopeful that these CVOT findings can make this a drug that could be used in people with diabetes and could bring this breakthrough drug class closer to patients who need it. Please see below for the call's Q&A.*

**Questions and Answers**

**Q: Could you just expand around your comments for Repatha? I think it's our understanding that 70% to 80% of scripts are abandoned at the pharmacy. What's your view on what needs to change to lower that rate? And how should we think about the change that outcomes data, if positive, could have there? And is there a rate, a hazard ratio, for example, in the outcomes data that you think would cause a significant shift in some of those utilization management criteria?**

A: When I look at Repatha, it is about a 77% rejection rate, not abandonment, that's happening at the pharmacy. So a lot of the prescriptions being denied are because they don't quite fit the prior authorization process, which has been required. Talking to cardiologists, it's clear that they are extremely frustrated at the moment because the patients they're sending in are appropriate patients who are not being properly managed on their maximum tolerated statin at the moment. We are spending quite a bit of time with payers at the moment, and helping them see the unintended consequences of a rather onerous paper-based prior authorization system, which is resulting in so many patients not getting access to drug when they should.

So, I think with a bit more discussion, people will understand the importance of getting appropriate patients on drug. I think some of the question in terms of narrowing the population is around what the outcomes will show. And there's no doubt in my mind that once we have limited proof that this drug actually results not only

in lowering LDL, but in actually reducing the risk of heart attack and stroke, that more patients will gain access to the drug.

**Q: With regard to REPATHA access, assuming you get positive CVOT data later this year, what's your understanding of the process you'll need to follow in order to ease current utilization management? I'm wondering how fast things could open up, or if you're going to need to get the data and the label and renegotiate with payers first before you're able to tag a noticeable difference on that front?**

A: We're expecting the data in the latter end of this year. Once the data becomes clear, it'll become public. And I think people will have to make up their minds on what that actually means. It will be presented then in a peer-reviewed publication and presented at one of the large congresses where the data will become clear to all the prescribing cardiologists. We, of course, from a commercial perspective are not in a position to negotiate or talk to payers about the data until the FDA has approved it in our label. In the interim, however, our medical affairs organization can respond to questions that we receive from the payers in a balanced and medical way. But I'm assuming once this becomes clear, the details will just clarify the unique value of this particular product.

I think the other comment I would make is that you may have seen that some of the US-based guidelines for treatment of hyperlipidemia and cardiovascular risks were recently updated and included the concept of using the PCSK9 inhibitors after stepping through some other therapeutic options that have the cardiovascular outcomes data.

It's my understanding from talking with many of the key opinion leaders who are either involved in the guidelines or just thought leaders in the field, there's a clear desire to update these guidelines as fast as possible when the cardiovascular outcomes data are available. So that's an independent process from anything to do with getting good data into the label and can be a very important thing that payers look at when they make access decision.

**Q: Just thinking a little bit big picture on the Repatha launch, I think you called it like a slow launch. And you were talking about working with payers. How much are you willing to participate and deal with price vs. say, mortality outcomes? So what's the balance of lowering price and mortality outcomes as far as opening up access?**

A: Clearly as we've said, we bring our products to market with a clear debate and discussion around the pharmaco-economic value of the products. There was an extrapolated value that these drugs would actually result in reduction of stroke, heart attack, and early untimely death, and I think we will continue to bring the value to market. There are rebates in the marketplace at the moment and that dynamic will continue over time as we jostle for formulary positions. But I think what we bring to market at the moment is a pretty decent and acceptable value proposition to treat patients at high risk.

**Q: Could you just discuss a little bit more about Repatha in EU and Japan in terms of your experience of access and reimbursement? And if you think that the CVOT outcomes data will change the negotiation, or would that be a new round of negotiations?**

A: So I think if you've heard people talk about the performance in Europe where once the price has been set and reimbursement is agreed, there's no longer an economic decision around every prescription, so uptake happens quite fast. So I believe that as we get into growing into this marketplace, pricing is just about set. When you come in with larger expanded patient population groups, there's a chance in Europe, you have to go back in it in a country-by-country negotiation. In Japan, historically, that hasn't happened as much, and the pricing we receive in Japan seems to be a longer play-through from pricing.

*-- by Melissa An, Emily Regier, and Kelly Close*