



## MEMORANDUM

### Novartis 2Q14 - Galvus up 13% to \$328 million, to be withdrawn in Germany; Google smart lens partnership featured prominently - July 18, 2014

#### Executive Highlights

- Sales of the Galvus (vildagliptin) franchise rose 13% year-over-year as reported (14% in constant currencies) and 7% sequentially in 2Q14 to \$328 million.
- Due to a German government decision that could have subjected Galvus to generic-level pricing, Novartis has stopped distributing Galvus in Germany.
- Management highlighted the recently announced in-licensing of Google's smart contact lens program, which includes a glucose-sensing lens project.

*This morning, Novartis CEO Mr. Joseph Jimenez led the company's 2Q14 financial update. Both the DPP-4 inhibitor franchise Galvus (vildagliptin) and the ophthalmologic drug Lucentis (intravitreal ranibizumab, for diabetic macular edema and other indications) posted solid results, although Galvus will face growth headwinds moving forward due to a German reimbursement decision that forced the product's withdrawal from that market. Notably, the recent news of Novartis' [partnership](#) with Google[x]'s smart contact lens program received multiple enthusiastic mentions - this was not surprising given that both Mr. Jimenez as well as Google co-founder Sergey Brin both commented very positively on the deal on the day it was announced.*

*This report contains our top five highlights from the call - inside, see more details on all points:*

- 1) Global sales of the Galvus (vildagliptin) franchise grew 13% year-over-year (YOY) as reported (14% in constant currencies) in 2Q14 to \$328 million, continuing its consistently strong performance amidst the broader DPP-4 inhibitor class slowdown. Notably, Mr. Jimenez emphasized on Q&A that Galvus will remain a global growth driver for Novartis.*
- 2) Due to a poor comparative effectiveness ruling by the German government that could have subjected Galvus to generic-level pricing, Novartis has stopped distributing Galvus in Germany, a market that represented ~9% of Galvus sales in 1H14.*
- 3) The company's recently announced [smart contact lens partnership](#) with Google (with applications as a glucose sensor) was featured as one of the company's top four 2Q14 innovation leadership highlights. **During Q&A, management emphasized that the timeline for the project is more likely to be a matter of a few years "rather than a decade"** and the glucose monitoring piece of the partnership was characterized as nearer-term (relatively speaking).*
- 4) Novartis' revenue from the ophthalmologic drug Lucentis (intravitreal ranibizumab) grew 7% YOY in 2Q14 to \$619 million, driven by new indications including diabetic macular edema.*
- 5) In June, Novartis terminated a [trial](#) investigating its IL-17A mAb secukinumab in newly-diagnosed type 1 diabetes.*

#### TOP FIVE FINANCIAL AND PIPELINE HIGHLIGHTS

**1. Global sales of the Galvus (vildagliptin) franchise grew 13% YOY as reported (14% in constant currencies) in 2Q14 to \$328 million.** Sequentially, sales rose 7% in 2Q14 following a 6% sequential slide in 1Q14. As a reminder, Galvus and its metformin fixed-dose combination Eucreas are only

marketed outside of the US. The Galvus franchise continues to show strong performance in the face of a broader DPP-4 inhibitor class slowdown - we do not yet have 2Q14 financial results for other DPP-4 inhibitors, but in [1Q14](#) Merck's market-leading Januvia (sitagliptin) grew only 3%. The fact that the DPP-4 inhibitor class slowdown is most pronounced in the US reflects Galvus' relative strength.

- **We learned earlier this year that Novartis is suing India-based Biocon for infringing on its patent on Galvus.** Since then, we have not learned anything about the scope, scale, or timing of this suit. The generics situation in many countries, particularly India, continues to be a convoluted one. The size of the diabetes patient population in the country is enormous and growing, though most cannot afford to pay high premiums for diabetes medications. Certainly, in both the developing and the developed world, major pharmaceutical companies in diabetes will face increasing pressure from generics.

**2. Management disclosed that Galvus will no longer be marketed in Germany, following a failure to negotiate an acceptable price with German authorities.** Germany represented ~9% of total Galvus sales in 1H14. Novartis had first disclosed in [3Q13](#) that it was considering withdrawing Galvus from the German market as a worst-case scenario, following a ruling from the German Federal Joint Committee (G-BA) that the drug showed "no additional benefit" relative to sulfonylureas. This G-BA decision was part of a class-wide review of DPP-4 inhibitors cost effectiveness, which resulted in similarly negative rulings for Lilly/BI's Trajenta (linagliptin) and AZ's Onglyza (saxagliptin), but notably not for Merck's Januvia (sitagliptin). The "no additional benefit" ruling subjects the products to generic-level pricing. Adding to the frustration is the fact that the negative G-BA rulings were not due to the clinical trial results, but rather due to the G-BA's narrow requirements for trial design.

- **During Q&A, management pointed out that both German patients and the German government's budget suffer as a result of this decision, as patients will lose choice and will be forced to switch to more costly DPP-4 inhibitors.** Although Novartis stopped distributing Galvus in Germany on July 1, the roughly three months of existing Galvus stock in the country will continue to be distributed and reimbursed fully, giving providers and patients time to select an alternative treatment option. We were a bit surprised to hear other DPP-4 inhibitors were more costly.
- **Negative G-BA rulings have also struck the SGLT-2 inhibitor class in recent months.** J&J's Invokana (canagliflozin) is potentially on the verge of a negative G-BA decision (read our [report](#)). AZ had withdrawn Forxiga (dapagliflozin) following a negative G-BA ruling, but we learned during the company's [1Q14 update](#) that, following successful arbitration on pricing, the product will be re-launched. **This encouraging news suggests that the G-BA might be willing to reconsider its rulings in certain circumstances, although we have not yet learned how AZ was able to accomplish this.**

**3. Novartis' very recently announced in-licensing of Google[x]'s smart contact lens technology (read our [report](#)) was listed in the presentation as one of the company's biggest 2Q14 accomplishments.** One of the main focus areas for the smart lens project, and the one that Google's high-tech research lab Google[x] used to reveal the project (read our [initial article](#) in diaTribe), is the development of a glucose-sensing contact lens. During Q&A, when asked about timing, management did not provide many specifics but did suggest that a product is more likely to be a few years out than a decade out. Most of the time until then, the companies will be working on proof-of-concept studies and prototyping.

- **From Google[x]'s [initial announcement](#) to Novartis' commentary on the fresh partnership during the 2Q14 call, there has been a notable broadening of the project's scope.** The initial announcement by Google in January, 2014 was completely focused on diabetes and the development of a glucose-sensing contact lens. However, the new in-licensing partnership introduced a new focus area for Novartis, presbyopia (where the lens of the eye loses its ability to focus with age, making it difficult to see objects up close). During Q&A, Novartis management stated that the "holy grail for this space" is the development of autofocus lens technology for presbyopia, but that this is a longer-term project. The glucose-sensing lens, management said, remains the more

near-term project, and we imagine that the "few years" comment applies more to this side of the program.

**4. Novartis' ophthalmic drug Lucentis revenue grew 7% YOY as reported and in constant currencies in 2Q14 to \$619 million.** Sales were flat sequentially. Management highlighted that Lucentis 2Q14 growth was largely driven by new indications, which include visual impairment due to diabetic macular edema. Lucentis appears to be emerging from a challenging 2013 that was impacted by competition from drugs such as Genentech's Avastin (bevacizumab) and Bayer's Eylea (aflibercept) that are cheaper but are not formally indicated for wet age-related macular degeneration (Lucentis' original indication). During Q&A, management noted that the economic pressure to use off-label agents instead of Lucentis is particularly high in Italy and France.

- **As background, Novartis markets Lucentis ex-US only.** Roche/Genentech market the drug within the US.
- **The Lucentis pre-filled syringe has been launched in Japan and France.** In some countries, as management disclosed during Q&A, the syringe now represents more than 50% of Lucentis sales volume.

**5. Earlier this year we noticed a Novartis-sponsored [study](#) investigating the company's psoriasis drug secukinumab (an anti-IL-17A mAb) as a way to preserve beta cells in newly-diagnosed type 1 diabetes, but the trial has since been discontinued.** The study was registered as terminated on ClinicalTrials.gov (Identifier: [NCT02044848](#)) in late June.

- **The SGLT-1/SGLT-2 dual inhibitor LIK066 remains in phase 2, with a regulatory submission not expected before 2018 (consistent with previous guidance).** A 12-week dose-finding study of LIK066 was withdrawn in April prior to enrollment, according to ClinicalTrials.gov (Identifier: [NCT01824264](#)), while a study testing the candidate's effect on glucose absorption was completed in January (ClinicalTrials.gov Identifier: [NCT01915849](#)).
- **Novartis completed a phase 2 trial of LEZ763, an unspecified oral once-daily treatment for type 2 diabetes back in September (ClinicalTrials.gov Identifier: [NCT01619332](#)).** The status of this trial has not changed since 4Q13. This candidate has flown under the radar for quite a ways, as (to our knowledge) we have not heard any mention of this compound from management and it does not appear on the company pipeline.

## Questions and Answers

**Q: I noticed that you are removing Galvus from the German market. I was just wondering how much stock is in that market that could perpetuate into the second half? Do you think you can grow the brand in the second half with the negative impact from that?**

A: As of July 1, we stopped distributing Galvus in Germany. They offered us a price basically equivalent to generic therapies and were unwilling to budge. Interestingly enough, this means that these patients will ultimately be switched to even higher price DPP-4 inhibitors, which means that this is going to cost the German government money. Having said all that, and to help you with your forecast without being too specific, we think there are about three months of inventory in Germany that will be run out. To put things in overall perspective for the brand, we believe that this brand will continue to be a growth driver for the company across the globe.

**Q: Can you give us an idea about the timeline for the smart lens project?**

A: We're not giving much guidance on timelines. What I can say is that we're not talking a decade out. I think this will be a few years, though, as there is work that we need to do around the proof-of-concept and prototyping both in terms of the more near-term glucose-sensing smart lens that you alluded to for diabetics as well as the accommodative technology, which is a little bit further out but that really represents an opportunity to go after the holy grail in this space: autofocus technology, which we are really excited about. If anybody can do it, Joe and I are putting a good bet on Google's capabilities combined with ours.

**Q: How much more room in terms of penetration do you have for Lucentis in the diabetic macular edema market? Can you confirm that that is basically where all the growth for the product is coming from at the moment?**

A: Wet AMD [age-related macular degeneration, Lucentis' original indication] is still a growth market for the company and it will be for a number of years. You have offsetting price effects, but eventually we think we will see reasonable growth in that market. **But you are right that it is the new indications that are the primary drivers of the expansion.**

*-- by Manu Venkat and Kelly Close*