
Lilly/BI launch Basaglar (biosimilar insulin glargine) in the US - December 16, 2016

Executive Highlights

- Lilly [announced](#) yesterday that BI-partnered Basaglar (biosimilar insulin glargine) is now available in the US. The product is already sold ex-US under brand name Abasaglar.
- We had the opportunity to speak with Lilly's VP of Diabetes in the US, Mr. Michael Mason, who described positive provider feedback on the product so far as well as upcoming patient support and savings programs.
- According to Dr. Mason, the list price of Basaglar in the US will be at a 15% discount to Sanofi's Lantus (insulin glargine). Lilly management shared that a five-pen box of Basaglar will be listed at \$316.85. For comparison, the wholesale acquisition cost of a five-pen box of Sanofi's Lantus (3 ml of U100 insulin glargine in each pen) is \$372.76. Based on these list prices, a patient taking 50 units of basal insulin per day would save ~\$56 per month (or ~\$1.86/day) by switching from Lantus to Basaglar, by our calculations.

Lilly/BI began shipping Basaglar (biosimilar insulin glargine) to US pharmacies [yesterday](#). We learned in a call with US Vice President of Lilly Diabetes Mr. Michael Mason that Basaglar will be priced at a 15% discount relative to Sanofi's Lantus. Lilly management further shared that the list price of a five-pen box of Basaglar will be listed at \$316.85 (each pen contains 3 ml of U100 insulin glargine). For comparison, the wholesale acquisition cost of a five-pen box of Sanofi's Lantus (3 ml of U100 insulin glargine in each pen) is \$372.76. Based on these list prices, a patient taking 50 units of basal insulin per day would save ~\$56 per month (or ~\$1.86/day) by switching from Lantus to Basaglar, by our calculations. That said, the cash price for both Basaglar and Lantus at three of our local pharmacies in San Francisco (two CVS' and one Walgreens) was somewhat higher than the list price. For a patient paying the full cash price at these pharmacies, a box of Basaglar totals \$380-\$385, while a box of Lantus costs \$410 - only a 6%-8% difference. Based on these cash prices, a patient in our area would save approximately \$1/day by switching to Basaglar, assuming they pay the full cash price. (Of course, Basaglar will be included in Lilly's [newly-announced discount insulin program](#), which will offer savings of up to 40% - a big win for patients who are uninsured or have high-deductible health plans.)

Many have hoped that the launch of biosimilar insulin in the US will curb rising insulin prices - some even [forecasted](#) discounts of up to 40%-50%. The 15% list price discount for Basaglar falls short of these sky-high expectations and is in line with the [10%-20% discounts](#) for the product in ex-US markets (under the trade name Abasaglar). That said, it's quite likely that rebates for Basaglar are quite significant, though this is only a matter of speculation given the opaque rebating process in the US. We'd expect that Lilly accepted very large rebates in exchange for exclusive formulary positioning on the [CVS Health](#) and [UnitedHealthcare](#) formularies. "This is a very good endorsement from two of the largest players in US health insurance," Dr. Mason emphasized. "They've looked at our clinical trials and our device, and they've decided to go with Basaglar." The biosimilar will also be covered by [Express Scripts](#) on equal footing with Lantus in 2017.

The US launch of Basaglar has been long-awaited and slated for December 15, 2016 since the companies [settled](#) a lawsuit with Sanofi over patent infringement of Lantus (insulin glargine) in September 2015. In addition to delaying US release, the agreement stipulated that Lilly/BI pay undisclosed royalties to Sanofi. The biosimilar insulin is already marketed as Abasaglar ex-US, where it has been performing quite well, with international sales up five-fold year-over-year (YOY) in [3Q16](#) (totaling ~\$19 million). That said, the US is the world's largest diabetes market, and Basaglar sales here will be quite telling for the franchise - Lilly

management acknowledged during the company's [3Q16 update](#) that building the product's US brand will take concerted effort. In our call, Dr. Mason shared that education of healthcare professionals on the prescription of Basaglar has been ongoing since September. We began seeing US promotion for Basaglar in the [ADA 2016 exhibit hall](#) in June - this was made possible by the [FDA approval](#) of Basaglar almost a year ahead of its launch date.

- **Basaglar's US launch comes in the same week as Lilly's [announcement](#) of a collaboration with Express Scripts to reduce out-of-pocket insulin costs for patients by up to 40%.** We were thrilled with the inclusion of Basaglar in this discount program at the time of announcement - we expect the program will be hugely popular as health plans continue to implement greater patient cost-sharing such as high deductibles or as health reforms potentially strip health coverage away from some portions of the population. We're especially pleased that, with the inclusion of Basaglar, the discount program will offer a full range of basal, rapid-acting, and human insulins for patients - we'd imagine that some patients may switch from Lantus to Basaglar out of sheer necessity in order to take advantage of this program. In addition to this discount program, Dr. Mason confirmed that a more traditional savings card will soon be available on [basaglar.com](#).
- **Lilly and BI have also launched the patient website [basaglar.com](#).** In our view, the website does a great job of explaining the identical amino acid sequences of Basaglar and Lantus, the comparable A1c-lowering efficacy, the details of the pre-filled KwikPen (distinguished from other KwikPens by its light gray color), and the indication of Basaglar for adult and pediatric patients with type 1 diabetes as well as adults with type 2 diabetes. At the same time, basal insulin labels have been notoriously bad at answering the most pertinent questions for patients: (i) how long will a dose lower blood glucose?; (ii) how should doses be adjusted if blood glucose is high?; (iii) how should doses be adjusted if blood glucose is low?. PK/PD studies of insulin glargine have not shown its action to last for a full 24-hours (it's indicated as a once-daily basal insulin but many patients take Lantus twice-daily in clinical practice), and so labeling Basaglar and other glargine products as once-daily basal insulins without adequately explaining how and when glucose-lowering action may start to taper off could create challenges for some patients. We hope that in commercializing Basaglar, educating providers, and rolling out patient support programs, Lilly/BI will clarify how to properly titrate and dose the product for maximum safety and efficacy.
- **Lilly/BI appear to be focusing on positioning Basaglar as an option for new basal insulin initiations, rather than focusing on switches from Lantus.** The Basaglar launch announcement highlights several patient support resources to ease the basal insulin initiation process for Basaglar patients. In particular, Lilly/BI will offer (i) a bilingual, interactive smartphone and tablet app that guides patients through Basaglar KwikPen injection; (ii) injection demo kits; (iii) and access to educational videos. On the [basaglar.com](#) website, the homepage invites patients to explore the product with the message, "Welcome to BASAGLAR, your *beginsulin*" - we have to admit, we love this pun! That said, Dr. Mason shared that there will also be support programs for patients transitioning onto Basaglar treatment from another basal insulin.
- **In speaking to the benefits of Basaglar, Dr. Mason emphasized Lilly's 90+ years of experience in diabetes.** He underscored that the company is committed to and well-versed in understanding the needs of patients on insulin therapy. We've certainly noticed this theme in the company's marketing of Basaglar thus far, including at AADE 2016 during a [product theater](#) and in Lilly's [exhibit hall presence](#). Dr. Mason further emphasized that feedback from providers has been positive so far, with little observed resistance among healthcare professionals. Indeed, we expect Lilly's long-standing reputation and expertise in the insulin field will help ease [concerns](#) about safety and quality control of biosimilar insulins.
- **Notably, Merck has also [submitted a New Drug Application to the FDA](#) for a biosimilar insulin glargine product (MK-1293) and is facing a similar [patent infringement lawsuit from Sanofi](#).** It'll be interesting indeed to see if the Merck story for MK-1293 plays out similarly to the Lilly/BI story for Basaglar. Dr. Mason assured us of Lilly's view that expanded patient choice is

always a good thing. "We welcome choice in the marketplace, and at the end of the day, we're focused on the needs of patients and healthcare professionals rather than our competitors."

-- by Payal Marathe, Helen Gao, and Kelly Close