



European Association for the Study of Diabetes - 49th Annual Meeting

September 22-27, 2013; Barcelona, Spain - Exhibit Hall - Draft

Executive Highlights

The EASD 2013 exhibit hall had a device highlights from J&J, Medtronic, Sanofi, and YOFi Meter. J&J was showing off the new OneTouch Verio meter, which gives patients color coded indicators and automatic "progress" messages. The focus on enhanced on-meter features was also present in the Sanofi booth, where we saw the MyStarExtra meter (made by AgaMatrix) on display for the first time ever - it provides patients with a three-day fasting glucose average, a trend arrow, and even an A1c estimate! The product is launching in Spain and Italy this year, with more countries to follow in 2014. As we understand it, Sanofi also has meter updates coming for the newest iPhones along with an Android system. Our exhibit hall trip also brought us to the YOFi Meter exhibit - the "all-in-one" device is a single handheld that contains a 20-strip cassette (Infopia strips), a lancing cassette, a color touchscreen, a cellular chip that automatically sends data to the cloud (in partnership with Qualcomm), and a built-in pedometer. Launch is slated for "next September;" although the representative would not say where. This mHealth focus was also present in Medtronic's booth, where we saw the new Connected Care pump/CGM remote monitoring device up close for the first time - great to see multiple companies on board with seamlessly sending device data to the cloud. Medtronic's booth also brought an update on the Enhanced Enlite sensor (called "Enlite 2" on Medtronic's F4Q13 earnings call), which received a CE Mark in September. It has two main innovations: an 80% reduction in implanted volume size over the Enlite and improved sensor-transmitter communication. The rep could not say if these improvements translate to better accuracy.

On the drug side, companies marketed new products and highlighted CVOT data. On the first day of the hall, Novo Nordisk's neon-green exhibit was dedicated entirely to Tresiba (insulin degludec) - visitors were swarming reps to learn more about the benefits of the new ultra-long-acting basal insulin. On the SGLT-2 front, BMS/AZ marketed Forxiga (dapagliflozin) in an expansive booth, while Janssen's booth highlighted Invokana (canagliflozin). [As a reminder, Invokana received a positive opinion from the EMA's CHMP in late September, though has not been approved yet (read our coverage at <http://www.closeconcerns.com/knowledgebase/r/749d39a5>). Sanofi sported a much fuller booth than usual, a reflection of exciting new additions to its portfolio. The company prominently featured the new GLP-1 agonist Lyxumia (lixisenatide), and highlighted the ways it can complement treatment with Sanofi's bestselling basal insulin Lantus (glargine). We noticed an increased focus on Januvia's CV profile at the MSD (Merck) booth than we have seen in the past, with several prominent displays dedicated to the topic and MSD's CVOT of the agent, TECOS. The cardiovascular focus was also present in Takeda's booth, where signs highlighted the recently published alogliptin CVOT results from EXAMINE.

In our report below, exhibitors highlighted in blue are new additions to the report that were not included in our daily updates from Barcelona.

Exhibit Hall

- **Alere:** While the Alere booth was situated in a back aisle of the exhibit hall, the familiar purple-and-white logo rotating on the corner of the booth caught our eye. Upon entering, we were initially attracted to the large "X" made out of metal rods and containing nine numbered buttons - the game gave visitors 30 seconds to press as many buttons as they could in the order that they lit up (a harder challenge than expected!). Above the game was the phrase "co-ordination and reaction," reflecting the company's promise for "rapid results and improved outcomes". While we can't say that we were varsity players, the representatives still let us put our name on the leaderboard. Turning toward Alere's products, the booth featured devices relevant to diabetes, including the Afinion Lipid Panel

Test (an eight-minute point-of-care test to determine concentrations of total cholesterol, HDL, LDL, triglycerides, non-HDL, and Cholesterol/HDL ratio) and the Afinion A1c Test (a three-minute point-of-care A1c test, which representatives proudly noted was the fastest in the field). In the area where visitors were ushered for more information, Alere had a map denoting the more than 25 countries in which the company is based, a reminder of the global nature of the EASD meeting.

- **Bayer:** Bayer's booth focused entirely on its alpha-glucosidase inhibitor Glucobay (acarbose), with no information on their blood glucose meters. Although we also saw a focus on Glucobay at last year's EASD booth, it was notable not to see a single meter or mention of a meter in the booth. Bayer's booth was positioned along an outside edge of the exhibition hall, directly in front of the Animas/LifeScan and to the left of BD's booth. "Glucobay" was looped gently across the tops of most stations in mint green writing that complemented the similarly colored carpet. One Glucobay station sported the same game as last year, giving attendees 40 seconds to identify five differences between two pictures of a hamburger and french fries shaped like a tarantula; each missing item in the second picture represented something that would have raised a patient's post-prandial glucose level (for example, one french fry was missing). We thought it was a clever way to incorporate learning into the booth. Additionally, each picture described benefits of taking Glucobay, including phrases we saw last year like: "Protect them from the danger of glucotoxicity." Other phrases revolved around Glucobay's ability to lower the risk of CV events. After participants successfully completed the game, they exchanged their win for a USB with publications on the efficacy of the drug. There were large monitors with the results of two trials, one indicating that acarbose is a better add-on to metformin than glibenclamide, and the second highlighting the success of acarbose as an add-on to DPP-4 inhibitors (it decreases levels of GIP and increases levels of GLP-1). Bayer also had an espresso station and sitting area to relax during a busy exhibit hall.
- **BD:** The BD booth resembled the focus of ADA and AADE and was divided into three sections: its 4 mm needle, lipohypertrophy, and needle safety. On the far side, there was a live demonstration of lipohypertrophy with a real diabetes patient. A representative from BD Medicine described the dangers of lipohypertrophy and how to avoid it, which included using a 4 mm needle. The rep explained that the needle is short enough to avoid reaching muscle and is also small enough to provide extra area for insulin infusion - both aspects decrease the risk of lipohypertrophy. At the end of his presentation, the representative even demonstrated how to detect lipohypertrophy on the patient; after the official presentation had ended, the patient even offered to have members of the audience try to find lipohypertrophy on his abdomen (we saw at least two people take advantage!). For those not yet ready to palpate in an Exhibit Hall, attendees could also enter a raffle to win a lipohypertrophy educational briefcase. Attendees seemed excited after the live presentation, and we expect that even more visitors will be drawn to the demonstration in the next few days - the screen with a countdown to the next demonstration was smart marketing! Also near this side of the booth was a mannequin with a rubber abdomen, which one representative used to demonstrate how easy it is to hit muscle when using a needle longer than 4 mm; the floor immediately turned red, indicating that the needle had gone through the "subcutaneous tissue" of the mannequin. We've got to hand it to BD - they are one of the best at interactive booth demos! The other end of the exhibit was dedicated to needle safety, with descriptions and demonstrations of the company's dual protected needles. A rep noted that these are especially useful for patients with needle-phobia. In the middle of the booth, there was a large screen describing what BD does (since it is a US company), and also what they do and plan to do internationally. When we questioned reps on when there would be EasyFlow technology needle in Europe, they responded that they are "looking to keep moving forward" on that front.
- **BMS/AZ -** We were eager to see BMS/AZ's booth to see how the EU launch of their SGLT-2 inhibitor Forxiga (dapagliflozin) is progressing. A giant representation of a sugar dispenser with a spigot first caught our attention as we approached the booth. We then noticed Forxiga's logo (a picture of which can be seen at https://www.google.com/search?safe=off&q=Forxiga&bav=on.2,or.r_cp.r_qf.&bvm=bv.53077864,d.ZG4,pv.xjs.s.en_US.b5VD5atLOcw.O&biw

[animacion-Ilustracion-y-diseno%252F10619567%3B600%3B446](#)), which has a prominent downward arrow down the center, reflecting the agent's mechanism of action. Three brightly colored squares surround the arrow, which meandering through the booth we learned reflect Forxiga's lowering effect on A1c, weight, and blood pressure. Indeed, a survey of HCPs BMS/AZ were conducting on touch screens showed (at the time of our visit) that the two aspects HCPs who have tried Forxiga value most are 1) its delivery of effective A1c and 2) impact on weight loss and blood pressure. The other characteristics prescribers value (in order of decreasing ranks) are 3) its insulin independent mechanism, 4) that is it easy to understand and explain, and 5) its convenience for patients. We were slightly surprised that substantially fewer HCPs listed these latter two aspects as the item they value most when compared to the top three characteristics. HCPs who have not tried Forxiga yet indicated that they are also interested in the same characteristics of Forxiga, in approximately the same order. Overall, the booth was largely dedicated to Forxiga, however, BMS/AZ tied Forxiga into the rest of their portfolio (Bydureon, Byetta, Onglyza, and Kombiglyze) at screens throughout the booth, explaining to HCPs how they can individualize patient care using the Alliance's agents. Additionally, HCPs could "connect, shake, and inject" Bydureon under the tutelage of a representative at a stand in one corner of the booth.

- **Boehringer Ingelheim:** BI's booth was adjacent to the massive booth of its alliance partner Lilly. The space was brightly lit and was very open, giving it a cheery feel. The sound of chirping birds emanated from a Kinect motion-controlled video game, in which players flew around a simulated landscape as a bird (the mascot for BI/Lilly's Tradjenta and Jentadueto). Next to the game was a life-sized artificial purple tree, with bright yellow plastic birds constructing their own nests. Two modestly-sized banners stated that Tradjenta (spelled Trajenta in Europe) demonstrated sustained A1c reductions over two years of clinical study, and that some patients experienced reductions of up to 1.2%. The other half of BI's booth featured an educational campaign on SGLT-2 inhibitors, which did not mention any specific drug names (understandably so, as empagliflozin is still under regulatory review in the US and EU and thus cannot be marketed).
- **Cellnovo:** Cellnovo did not have a booth at EASD 2013, but met with us to provide an update on the progress of their insulin pump system. The company has been conducting patient studies in the UK, leading up to multi-center usability trials over the next few weeks. The company is still aiming for a UK commercial launch before the end of 2013, a roll out to other European countries following the UK launch, and a plan to file in the US in 2014. The company received a CE mark in Europe roughly a year ago. In recent weeks, the company has obtained third party data on pump accuracy and precision for basal and bolus delivery and for occlusion performance, and it compares well to other commercially available pumps. A strong differentiating feature of the system is remote monitoring and data management - it's possible to see all historic data from the handset and pump via an online web portal in near real-time. The touchscreen handheld has a cellular data connection, and notably, the system can also trigger text message alerts. We were also interested to hear about a new 'Before and After' analysis for meals - this should really help patients and HCPs optimize meal-specific bolusing. As a reminder, the Cellnovo system consists of four components - a pump/rechargeable battery unit, a disposable insulin cartridge, a color touchscreen handset with an integrated meter, and a cloud-based data management system. Cellnovo's system is more of a patch pump than a traditional pump, though it still requires a very short 0.4 inch (1 cm) infusion set.
- **CeQur:** Although CeQur was not present in the EASD Exhibit Hall, the company's corporate symposium reminded us of the benefits of the PaQ insulin delivery device for patients with type 2 diabetes. It was once again valuable to see the data from a two-week feasibility trial of PaQ, results that we originally saw at ADA 2013 (see page 99 at <http://www.closeconcerns.com/knowledgebase/r/94f937d8>). On the usability side, none of the trial's 18 participants had difficulty using PaQ, notable since there was only one hour of training - that simplicity is not to be underestimated in our view, particularly in the type 2 population. Participants listed "improved control" and "invisible to others" as some advantages of the product. CeQur also presented CGM data that demonstrated trends toward improved glucose control and less glycemic variability. As a reminder, CeQur recently

closed a \$27 million Series B round of financing, money that will be used to increase PaQ manufacturing as well as to fund activities related to US regulatory approval (presumably clinical trials, usability studies, user fees, etc.). PaQ received a CE Mark in November 2012 in Europe, and as we understand it, a focused EU launch is expected in late 2013 or 2014, with a broader launch in 2015. The device is three-day insulin patch pump with seven preset basal doses (16, 20, 24, 32, 40, 50, or 60 units per 24 hours) and two-unit on-device bolusing. We look forward to seeing this product launch in Europe and eventually the US, since simple and discreet insulin delivery is such an unmet market need in the type 2 diabetes arena and since the field needs new alternatives based on the high number of type 2 patients not at their glycemic targets (~45% in the US) and the significantly lower percentage not on insulin (under 30% on any insulin and even fewer on mealtime insulin).

- **Dexcom:** The Dexcom booth represented the company's smallest of the major 2013 conferences, to be expected given the more challenging reimbursement environment for CGM in Europe - that said, the placement of the booth was terrific and traffic was quite good. The exhibit's back wall reiterated the main news from Dexcom's ATTD 2013 booth: a CE Mark for use of the G4 Platinum CGM in patients as young as two years old. Dexcom has now begun marketing in this population, something it had not yet started at ATTD in February. At the booth's central table, attendees could talk to reps and see a demo of the G4 Platinum receiver. Along the left side, Dexcom's Studio software and pattern recognition were available for demo. Unlike ADA and AADE, the Dexcom Share remote monitoring product was not on display. Those looking for brochures could peruse them in five different languages, reflecting just a smidgeon of the 22 countries where Dexcom CGM is now available. This was very impressive. We asked the rep specifically about China, as it has been mentioned in recent earnings calls. His comments confirmed the comments by Dexcom management in the 2Q13 call - the key is deciding what product to go to China with, since the regulatory review takes more than two years and first requires an FDA approval. In line with one of Dexcom's marketing messages of the year, a sign declared, "CGM first - the first step for success." That marketing really targets a more traditional belief (by some) that pumps should come before CGM, a more simplistic view. In our view, the decision to adopt a pump, a CGM, or perhaps both should be left up to sound clinical judgment and patient needs and preferences - reimbursement, of course, will always weigh in.
- **Diasend:** The online data management company's booth had a clearly visible slogan as we entered: "Easy diabetes communication." Indeed, Diasend is now compatible with an 70+ devices, including several new additions: Insulet's second-generation OmniPod, Ypsomed's myLife Unio BGM, Dexcom's G4 Platinum, Bayer's Contour Next, and even pendiq's smart insulin pen. Diasend has also launched compatibility with mobile apps like Glooko and Sanofi's iBGStar. In addition to new devices, the platform's newest innovation allows users to compare pump setting changes over time. Looking to the future, Diasend hopes to include more pump features - one of the biggest pieces of user feedback has been a desire to see everything on one page. We asked about the standardized Ambulatory Glucose Profile report for CGM data (a major focus of Abbott's symposium on Day #2), and the rep told us it's "easy" to do on a technical front. The "hope" is to have this available on Diasend next year. Last, Diasend is deciding how to incorporate all the data from activity trackers - we think this would be a huge win for patients and providers, though the rep made it clear to us that the value of additional data must be balanced against information overload. As a result, Diasend is still brainstorming on how to best present this data. We'll stay tuned!
- **GI Dynamics:** Located toward the center of the exhibit hall, GI Dynamics' booth featured "EndoBarrier" in large letters on a central rectangular sign. Flanking both sides of the EndoBarrier sign were dual downward triangles - one orange and one purple - next to the words "weight loss" and "diabetes control." GI Dynamics' signage also had a faceless, computer-generated obese patient whose intestinal tract showed through a transparent body (a similar approach to that used by Vivus at recent US conferences). To educate attendees about the company's gastrointestinal liner, representatives were standing by two tables to demonstrate the EndoBarrier insertion procedure on

iPads. After we watched the informative video, we learned that in Germany, a national nutrition group is working to develop guidelines on what foods are well tolerated after EndoBarrier implantation. When we asked the representative what happens if the device does not settle correctly in its position just below the stomach, he responded that it is nearly impossible to misplace it due to the design of the released tubing. Outside of the exhibit hall, we also heard results from a 12-month study of the device in a technology-focused oral session. After 12 months of wearing the EndoBarrier (n=45), A1c declined by 1% (baseline: 8.5%) and mean total body weight loss was 10% (-26 lbs from a baseline of 245 lbs). Some questions and skepticism arose on the safety side, as there were a total of 13 device removals, nearly one-third of all patients in the study. Questions aside, we noted that the exhibit was swamped with curious visitors after the presentation, a reminder of the sincere interest in novel therapeutic approaches that improve diabetes control and weight.

- **Insuline:** Approaching Insuline's booth, we were immediately drawn in to a marketing video promoting the InsuPad, the company's wearable heated pad for MDI users. Clips featured HCPs and patients extolling the benefits of faster insulin absorption: 45% less hypoglycemia and 28% less prandial insulin (results from the just-reported 145-patient Barmer reimbursement study in Germany; see Dr. Andreas Pfutzner's presentation elsewhere in this report). As a reminder, the InsuPad includes a disposable adhesive pad (replaced every day) and a rechargeable heating unit. The whole on-body portion is quite slim and a bit smaller than the second-generation OmniPod. We appreciated a full demonstration of the device, which struck us as quite user friendly and unobtrusive. Patients apply the disposable pad once per day, which has a plastic hinged door that holds the heating unit. When it's time to inject insulin, patients open the door and inject their insulin into exposed skin through an oval-shaped opening. Upon closing the door, the heating unit warms the area to 40 degrees Celsius (104 degrees Fahrenheit) for 50 minutes. Though the temperature sounded quite hot to us, the device only felt warm to the touch. The heating unit needs to be recharged every 24 hours (based on four injections per day). Notably, the InsuPad will be launching in October in Germany with full reimbursement (i.e., no out of pocket costs for patients). For other countries, Insuline will have an online store -starter kit will cost 98 euros and include two heating units and five disposable pads. A 30-day supply of disposable pads will cost 49 euros (a nice recurring revenue stream!). Patients will be able to buy the device online only after obtaining a prescription - according to the rep, this includes the US, though we were somewhat skeptical this will be possible. We look forward to hearing real-world experiences with the device, as the market need for faster-acting insulin is so great.
- **Janssen's** booth occupied about one third of the overall J&J exhibit. Although the CHMP gave a recent positive opinion on J&J's SGLT-2 inhibitor, Invokana, the company still does not have actual approval. Upon entering the booth, visitors were greeted with a cross section of the renal system that surrounded an introductory video to the role of the kidney in type 2 diabetes management. The exhibit was mostly "self-serve" with regards to information: visitors could stand at one of several computer stations to sign up to receive more information on Invokana online, or visitors could walk themselves through interactive touch-screens with a few slides on SGLT-2 inhibition and the benefits of reversing glucotoxicity. We imagine J&J is excited to be bringing a product like Invokana to market - in the EU, reimbursement is a giant and everpresent challenge but the potential to help patients easily is great, especially with a drug with a unique mechanism of action.
- **J&J Animas:** At the end of sprawling LifeScan booth, there was a large picture of the Animas Vibe that highlighted its bolus options, bolus calculator, shortcuts, fine-tuned control, high-contrast screen, uninterrupted insulin delivery, waterproof nature, and accurate carb counter. One counter highlighted the Animas Vibe purely as a pump, and a second showed the device used in conjunction with the Dexcom G4 Platinum CGM. As a reminder, this combination was just approved in Canada at the beginning of September. As of the last update in Dexcom 2Q13, Animas had just received a round of written questions from the FDA regarding approval of the pump. We have not heard of an updated timeline but are excited for prospects in the US - we imagine Animas is as well so it can get

a pump with sensing on the market, particularly since it seems like integrated pump / CGM products will get the best reimbursement.

- **J&J LifeScan:** The J&J Animas/LifeScan booth had sleek white walls with dark blue accents, including lights radiating out from behind each display case. All of LifeScan's OneTouch products were displayed alongside each other and the slogan, "A World Without Limits for People with Diabetes." This has been in LifeScan's marketing for years and is such a compelling message for patients. The products in the booth included the OneTouch Delica lancing device and several meters: OneTouch SelectSimple (a buttonless meter targeted towards emerging markets), OneTouch Verio Pro+ (a hospital meter), OneTouch Verio IQ (pattern recognition, and the new OneTouch Verio. Representatives were pleased to welcome back the Verio IQ after it was removed from the market earlier this spring (see our report at <http://www.closeconcerns.com/knowledgebase/r/fe264e79>). The new OneTouch Verio meter was a focus of the booth's marketing - signage emphasized the meter's large high-resolution color screen, which gives lots of information without needing push any buttons: 1) the blood glucose level in large font; 2) a color-coded indicator circle for low, in-range, and high blood glucose results; and 3) automatic messages (e.g., "Your average over the last 7 days is 6.2 mmol/l"). We are especially big fans of the color coded results - we think the subtle psychology and context that color gives the numbers could really help patients visualize results and remind them when it is appropriate to intervene. Certainly, patients on the Dexcom G4 Platinum CGM have widely cited the color receiver screen as a big benefit of the product (read our test drive at <http://diatribe.org/issues/48/test-drive>). We also like the messages feature, which LifeScan has dubbed "Progress Notes" - very motivational! There were no reps on hand when we walked through the booth, though the [LifeScan UK website](#) suggests it can only be pre-ordered right now.
- **Lexicon** exhibited for the first time at a major diabetes meeting, which we found very exciting. The booth was simple, with a backdrop of the company's logo and slogan, "Discovering Breakthrough Treatments for Human Disease." Lexicon had copies available of the three posters it is presenting at EASD - two of them concerning positive phase 2b results on blood pressure, body weight, or triglycerides findings from the phase 2b study of LX4211 (the company's SGLT-1/SGLT-2 dual-inhibitor), and the third concerned preclinical data on the blood glucose-lowering effects of an SGLT-1 inhibitor (LX2761) in mice. Visitors could also take printouts with educational information on SGLT-1 and SGLT-2 inhibition as well as a list of the company's peer-reviewed publications on LX4211.
- **Lilly:** Similar to previous conferences, Lilly's exhibit was modeled after a home, with a different product or theme featured in each room of the house. Humalog was prominently featured in the "kitchen," where Humalog pens were displayed under glass casing. The dining room contained examples of Lilly's new Savvio Humalog pen, which is smaller than its predecessor (the Savvio is not yet available in the US). iPad displays in the "children's playroom" featured Lilly's innovative partnership with Disney to provide resources for children and teens with diabetes. The DPP-4 inhibitor Tradjenta (linagliptin) occupied a small corner of the booth, but when we asked about the drug, we were referred over to Boehringer Ingelheim's nearby booth, which had more information on the drug. A separate room featured the Diabetes Conversations toolkit, which was sponsored by Lilly and developed by Healthy Interactions in collaboration with IDF. The booth displayed examples of diabetes "conversation maps" that providers could use with patients of all ages to facilitate productive discussions on diabetes management. The maps were quite bright and full of information - we were impressed and assume that while they may present somewhat of an information overload for some patients, for others who are more "information seekers". On a positive note for attendees, Lilly also sponsored a fairly large internet terminal adjacent to its booth.
- **Medtronic:** Walking up to the Medtronic booth, it was impossible to miss the plasma screens and signage exclaiming, "Proven stellar results - only with the MiniMed Veo system." Prominent statistics boldly summarized the results of the ASPIRE in-home study of the Veo published in *NEJM* at ADA 2013: 38% less hypoglycemia exposure, 30% fewer hypoglycemia events, 0 severe events.

For complete coverage of this trial, see page 90 at <http://www.closeconcerns.com/knowledgebase/r/94f937d8>. Walking in to the booth, we were excited to see Medtronic's newest remote monitoring product, Connected Care, on display. This portable, hockey-puck-sized hub has a cellular chip in it that sends pump and CGM data directly to CareLink and a mobile app. As we understand it, the portable device's battery is rechargeable and the hub would not have to be plugged into a wall (i.e., it could be carried in a backpack and pump/CGM data would be wirelessly sent to CareLink). At ATTD 2013, it was only advertised on a video screen, so it was great to see it on the demonstration table for the first time. We arrived to the booth for the 10:30 am demo, but it was not working at the time. The rep told us there is no launch date as of yet, as the product is still in the prototype phase (the goal is to make it smaller). We think parents will love it. For some, it also may have an advantage over Dexcom Share, since Share will need to be plugged into the wall (though Dexcom's Gen 5 will send data straight from the transmitter to the smartphone). The last major update in the Medtronic booth came on the Enhanced Enlite sensor (called "Enlite 2" on Medtronic's F4Q13 earnings call) - the product received CE Mark within the last three weeks. It has two main innovations: an 80% reduction in implanted volume size over the Enlite and improved sensor-transmitter communication. The rep could not tell us if the size reduction translates into better accuracy, as that "has not been tested yet." Similar to the Enlite, Enlite Enhanced will still be six-day wear. Attendees seeking some competition could answer multiple-choice questions about Medtronic products, diabetes, or general knowledge questions - these were pretty hard! Results were displayed prominently on a large electronic leaderboard next to the popular European coffee station.

- **Mendor:** The Mendor display case was set against a sleek, black wall with a can't-miss TV screen - a video played a loop of a young adult using the all-in-one Mendor Discreet meter, which contains an integrated blood glucose meter, lancing device, and test strip cartridge (a bit like the Accu-Chek Mobile). The representative demonstrated how to use the device, which is approximately the size of an iPhone and as thick as a deck of cards. Between the sleek booth and the looping video, Mendor made a clear pitch for its target audience: young adults who desire a meter that is discreet to use. A representative also showed us Mendor's cloud-based software, Balance, which is compatible with 21 meters. This is great to see, since all too often, meter software is brand-specific (though this is changing with systems like Glooko, Diasend, and hopefully Dexcom's SweetSpot platform). Before we even had a chance to ask, the representative informed us that Mendor would *not* be filing with the FDA soon, primarily because of the long regulatory process. Exiting the booth, we also noticed that A. Menarini, Mendor's new partner, had an enormous ping-pong-table-sized model of Discreet meter (marketed as GlucoMen READY). While there was not much other information besides a pamphlet, it was nice to see the collaboration.
- **Merck Sharp & Dohme:** Located toward the center of the exhibit hall, the MSD booth had a stronger emphasis on Januvia's (sitagliptin) cardiovascular profile than the Merck booths at ADA and AADE, or the MSD booth at EASD 2012. Two of the most prominent displays detailed TECOS, Merck's CVOT of sitagliptin and results from a pooled analysis showing that Januvia did not increase the incidence of major adverse cardiovascular events (MACE). When we asked a MSD representative about what MSD is concluding from SAVOR-TIMI 53, BMS/AZ's CVOT for Onglyza (saxagliptin), he highlighted that the trial showed that saxagliptin has "no benefit; no risk. It is like taking a placebo - a lollypop." In contrast, he noted, early findings with sitagliptin "suggest it might have a benefit" and MSD is looking forward to seeing TECOS' results in 2014. In terms of glycemia, he remarked, MSD's competitors have conducted head-to-head trials of their agents versus sitagliptin, and have opted not to publish the data, since it is not in their favor. We believe this increased focus on CV safety is in line with a broader trend at EASD 2013, where CVOTs and CV profiles are one of the hottest topics.
- **Nipro Europe:** Nipro Europe occupied a medium-sized booth where we were able to learn about the company's meters, including two that are not available in the US. Nipro's traditional, full-featured meter is its TRUResult, which has seven, 14, and 30-day averaging capabilities as well as testing reminder capabilities. The TRUResult mini, which is not available in the US, has many of

the TRUEresult's capabilities but at a much smaller size - it looks more like a snazzy USB drive than a blood glucose meter. The exhibit also featured the TRUEresult twist (known as the TRUE2go in the US), and the TRUEresult twist 2. These are tiny, pocket-sized meters, strip containers, and lancing devices all in one. They come in three colors and are most popular with children. The TRUEresult twist 2 is an upgraded version of the TRUEresult twist, and is not available in the US. The TRUEresult twist 2 has increased memory capacity as well as averaging capabilities.

- **Novartis:** The Novartis booth had a large, lit-up billboard that highlighted the theme of the booth: "Diabetes and Me." Signs around the booth promoted the company's DPP-4 inhibitor Galvus (vildagliptin) and fixed dose combination with metformin (e.g., "Powerful 1.1% reduction in A1c - efficacy you can see." The focal point of the booth was an opportunity to meet "interactive patients" at several stands - these used a pair of headphones, an iPad, and a large screen with a virtual patient projected onto it. Booth-goers used the iPad to select different patients, ask them predefined questions, and hear their recorded answers. Patient 1 explained that even on metformin, her blood glucose levels remained uncontrolled. Patient 3, on the other hand, had impaired kidney function and fear of hypoglycemia. We thought it was a very cool way for attendees to interact with a broad spectrum of realistic patient case studies. The conversational experience was clearly targeted at HCPs, though we noticed that it did not overtly promote Novartis' products. Our only criticism of the experience came after learning from a rep that the "interactive patients" were actually actors reading scripts. In the future, we hope to see companies increasingly use real patients with diabetes in their marketing - we think doing so is more persuasive, shows that a company is patient focused, and reflects authentic marketing. Upon exiting the booth, signs for Lucentis, Novartis' diabetic macular edema drug, proclaimed, "See your success in the eyes of your patients."
- **Novo Nordisk's** exhibit was devoted entirely to Tresiba (insulin degludec) today - we hear that the exhibit will rotate themes each day such that, for example, that on day #4 it will be dedicated to Victoza, etc. Uncharacteristically, the long, rectangular booth was tucked away towards the back of the hall, but we could spot the neon green shirts of the sales representatives from a mile away. Apparently others could too because the exhibit was swarming with people while we visited. The sleek green and white booth's centerpiece was a giant, forest-green parachute anchored to heavy block letters reading "7.0%," suggesting Tresiba provided a smooth ride down to goal. Visitors could either learn about Tresiba's benefits at individual stations staffed with sales representatives and FlexTouch demo pens, or a 27-screen panel at the front of the booth. After filling out a worksheet asking questions such as "What are the three key benefits of Tresiba?" (correct answers: A1c reduction, reduction of nocturnal hypoglycemia, and flexible dosing), visitors earned a notebook to take home. A food station at the center served coffee and lunch wraps. Finally, at the back of the booth, visitors could meet members of Team Novo Nordisk, the cycling team made entirely of members with type 1 diabetes. Text on the exhibit walls politely reminded attendees in Spanish that Tresiba was not yet approved in Spain. Novo Nordisk had a second satellite booth devoted to the results of the DAWN2 study, which confirmed that physical, financial, and emotional burdens associated with diabetes are carried by patients' entire families. We were glad to see so much focus on the behavioral elements of diabetes.
- **Roche:** The Roche booth, prominently located upon entering the hall from registration, had a square in the middle surrounded by three circular areas. Each circle represented a different aspect of care: therapy optimization, patient engagement, and efficiency. Within each were two computers with representatives standing nearby to demonstrate how various Roche meters fit under each category. Under the 'therapy optimization' heading, reps showed attendees how the Roche data downloading works. In the 'patient engagement' circle, we saw how easy the FastClix lancing device is to use. The rep demonstrated it along with the Accu-Chek Compact Plus, noting how the integrated system reduces the burden on the patient to carry separate supplies around. Turning toward the center of the booth, one side of the square had a television screen rotating between advertisements of meters and key meter features, such as a better bolus calculator. A second side of the square touted that all Roche meters meet the new ISO standards - and even stricter standards.

Strategically, Roche prominently flashed this on the side of the booth facing the interior of the Exhibit Hall. With all of the discussion of BGM post-marketing surveillance and strip accuracy (in both the US and Europe), we think this was a smart move on Roche's part. The third wall showed a flow circle of "personalized diabetes management," moving from "structured education" to "treatment efficiency assessment" to "personalized treatment" to "analysis" to "data documentation and visualization" to "structured blood glucose monitoring" and back to the start. The last side of the wall housed one of the many coffee stands in the exhibit hall and a seating area, ready to give weary visitors a rest.

- **Sanofi:** The company's large booth enjoyed front-and-center placement, adjacent to the entrance most attendees used to enter the exhibit hall, and was abuzz with activity. As opposed to Sanofi booths we have seen at recent US conferences, which have been more low-key, its EASD booth was packed with displays - a testament to the number of new products Sanofi was showcasing. The front half of the booth was dominated by exhibits for Lyxumia (lixisenatide), the company's new once-daily GLP-1 agonist. Rather than standing alone, the Lyxumia portion of the booth was interspersed with information on Sanofi's bestselling basal insulin Lantus (insulin glargine). A series of displays titled "A Positive Addition" noted that Lantus primarily affects fasting glucose, Lyxumia primarily affects postprandial glucose, and therefore the two used in tandem can provide an effective and comprehensive way to lower patients' A1cs - this text was accompanied by an image of a Lantus pen and Lyxumia pen overlaid at right angles, forming a plus-sign. Perhaps because of the space required for the new Lyxumia display, Sanofi's rapid-acting insulin analog Apidra barely had any presence in the booth - after some searching, we managed to find one single display for the insulin off to one side. A great deal of space was dedicated to the company's new JuniorStar insulin pen, designed for younger diabetes patients (the JuniorStar is currently not available in the US). A series of large displays highlighted the device's design features, including the fact that it is lightweight yet robust, can administer half units of insulin, is easy to read, requires less pressure for injection, and can easily be dialed down. The pen was part of a featured campaign to "Lighten Lives" of type 1 diabetes patients. The MyStarExtra meter (made by AgaMatrix) was on display for the first time this year - the meter provides patients with a three-day fasting glucose average, a trend arrow, and even an A1c estimate! Sales representatives noted that the product is launching in Spain and Italy this year, with more countries to follow in 2014. This was one of the new products we were most excited to see. There will also be updates of meters coming for the newest iPhones, as we understand it, and there will be an Android system as well.
- **Takeda:** Takeda's booth focused on its trifecta of DPP-4 inhibitor-based therapies: Vipidia (alogliptin), Vipdomet (alogliptin/metformin), and Incresync (alogliptin/pioglitazone). The booth carried a bike theme throughout, with ample pictures of bicycle parts and themed slogans (e.g., "In type 2 diabetes every component matters"). The booth's central counter featured a coffee bar and iPads with a presentation on alogliptin. A sign on the side of booth proudly proclaimed the recently published alogliptin CVOT results (EXAMINE): "Vipidia is the first and only DPP-4 inhibitor to demonstrate proven CV safety in type 2 patients with recent acute coronary syndrome in a clinical trial" (White et al., *NEJM* 2013; see our complete coverage of EXAMINE at <http://www.closeconcerns.com/knowledgebase/r/2a8925c5>). A different side of the exhibit contained handouts on studies of pioglitazone: a meta-analysis to assess cardiovascular risk (Lincoff et al., *JAMA* 2007) and secondary prevention of macrovascular events (PROactive; Dormandy et al., *Lancet* 2005).
- **VPD:** As we passed by this small booth, we couldn't help but notice the glossy posters advertising the 2in1 Smart BGM that plugs into the headphone jack of an Apple iPhone/iPad/iPod and Samsung Galaxy SIII. Unlike Sanofi's iBGStar meter, the 2-in-1 meter does not function as a standalone device - to test blood glucose, it must be plugged into the headphone jack with the app open. The product has a CE Mark and is currently available in 12 countries in Europe (the rep specifically mentioned Norway, Sweden, Denmark, Slovenia, Slovakia, and Austria). Distribution varies in each country, and the rep assured us that the device has reimbursement. A sign advertised the "special exhibition

price" of 45 euros for the small thumbnail-sized meter and 100 test strips. In the US, the meter will be marketed under the brand "Gmate Smart." We asked the rep about FDA approval, and he told us that it was submitted to the agency, though "lots of questions" came back (we presume because it doesn't function as a standalone meter like the iBGStar). The rep lamented that very innovative products are challenging, as they fall outside the rules ("It's like Steve Jobs," he said). We previously wrote about this product in *Closer Look* on August 20, 2012. At the time, the South Korea-based company, Philosys, expected FDA approval of the Gmate Smart in 3Q12. Obviously, that has not panned out. We will certainly look for any news on the device, though are not optimistic approval is coming anytime soon. Still, we think the product is an encouraging and valuable idea - the meter is very tiny, the data upload is very easy, and patients nearly always carry their smartphones with them.

- **YOFiMeter:** Tucked in a small booth in the middle of the exhibit hall the YOFiMeter booth drew us in with the tagline, "First cellular all-in-one BGM" next to a Qualcomm partnership logo. In short, this seems to be the *ultimate* all-in-one meter - a single handheld contains a 20-strip cassette (Infopia strips), a lancing cassette, a color touchscreen, a cellular chip that automatically sends data to the cloud, and a built-in pedometer. All the rep would tell us was that it would be on the market "next September." It was unclear if this was EU, US, or both, though we'd assume EU to start. After watching a short video of various patients using the device (e.g., an elderly person, a teen skateboarding), we got a demo of the meter. It works as follows: 1) slide a plastic bar forward on the side of the meter to expose a test strip; 2) press finger against lancing port hole on the side of the device; 3) press lit up button to lance finger; 4) apply blood to strip; and 5) get result (it took about seven seconds by our count). The meter prominently displayed the result on the color touchscreen, offered extensive tagging capabilities (exercise, carbs, insulin, other medications, even leaving a voice note!), and automatically sent the blood glucose result to the cloud (we didn't see any demonstration of the system's backend or a web portal). Similar to Telcare's meter, a test is followed by a feedback message (we got a green thumbs up) and a time in range chart. All of it seems customizable as well (e.g., you can choose the picture that is displayed after a test). We found the system quite easy to use, especially the highly responsive touchscreen. We look forward to learning much more about the device, especially where and when it will launch. Intuity has been developing the all-in-one POGO device for quite a while (without the cellular chip or color touchscreen), though we understand it's been difficult to get through the FDA. YOFi's website (<http://www.yofimeter.com>) is just a single page right now with a company logo, two slogans ("Diabetic living made easier" and "Dawn of a new era in BGM technology"), and a contact email address: info@Yofimeter.com.
- **Ypsomed:** The sprawling bright green Ypsomed booth had a corner devoted to each of the company's areas of focus: ClickFine pen needles (new 4 mm x 32 gauge), the Insulet OmniPod, infusion sets, and the Unio blood glucose meter. We immediately talked to a rep about the new second-gen OmniPod, a major focus of the booth's marketing. **Notably, we learned that ~10,000 patients in Europe are on the OmniPod** (as of Insulet's 4Q12 call in February, the company had 45,000 patients on the OmniPod, up 50% from 30,000 at the end of 2012). We asked the rep where the OmniPod is not currently available in Europe - it sounds like France, Italy, and Spain though we are working to verify this. The rep emphasized that France is particularly challenging on the reimbursement front. We appreciated another demo of the Unio blood glucose meter system, which has a compactly designed, integrated case that conveniently positions the meter, strips, and lancet device for fast testing. Attendees looking for freebies could take their turn at a Play+Win slot machine-type game, while hungry booth-goers could grab green apples, chocolates, and pretzels.

-- by Adam Brown, Poonam Daryani, Hannah Deming, Jessica Dong, Hannah Martin, Manu Venkat, Vincent Wu, and Kelly Close