DIABETES CLOSE UP

Diabetes Close Up, January, 2005
No. #43
Early 4Q04 Earnings/2005 JP Morgan Conference Update/ Pfizer's DPN FDA Approval

T h e s h o r t e r v e r s i o n

It's a busy 2005 so far! *In this newsletter, we offer updates on early industry earnings announcements, the recent JP Morgan investment conference in San Francisco, a Pfizer diabetic peripheral neuropathy approval that arrived on December 31, and a most excellent new Roche Accu-Chek Compact TV ad.*

1. **Earnings of Note**
   - **Novartis**: Musings on LAF237 and a new metabolic disease compound, LBM642.
   - **Pfizer**: Management says it is moving toward a preferred outcome with Sanofi-Aventis.
   - **Abbott**: Abbott Diabetes Care posts close to $800 million for 2004 and forecasts over $1.0 billion in sales for 2005.
2. **JP Morgan Healthcare Conference, 2005, January 8-11, San Francisco, CA**
   - **Medtronic**: Expects release of Guardian RT in fiscal year 2006.
   - **Amylin**: 2005 is here and we're looking forward to approvals of Symlin and Exenatide.
   - **Animas**: The company increased guidance for 4Q04 and announced approval of the IR1250.
   - **Lilly**: Awaiting Exenatide …
   - **Merck**: MK-431 (DPP-IV inhibitor) NDA filing expected next year.
   - **Inamed**: Lap-Band continues on a roll.
   - **Matria**: Data on disease management sounds very interesting …
   - **Alkermes**: Inhaled insulin two-year safety study to start this year. We look for potential '08-'09 approval.
3. **Pfizer's New DPN Drug**: Lyrica received FDA clearance for diabetic peripheral neuropathy on New Year's Eve – hurrah! We think drugs for complications like this will be important moving forward. Type 2 patients with complications represent such an underestimated (read: very large) portion of the $92 billion in direct costs of diabetes.
4. **Media Watch – Excellent new Roche Accu-Chek ad:** Roche continues on a roll with its newest Accu-chek Compact ad.

T h e l o n g e r v e r s i o n

1. **Fourth Quarter Earnings of Note**
   - **Novartis:** LAF237 (vildagliptin) and an early stage compound, LBM642, were the diabetes-related items of note on Novartis' call on Thursday, January 20. As a reminder, LAF237 is a first-in-class DPP-IV inhibitor (an incretin enhancer) for the treatment of type 2 diabetes.
     - Phase III development as a monotherapy and in combination with other medicines remains "on track" and Phase III data are expected at the end of 2005, with submission planned for early 2006. Management reiterated that LAF237 had been shown in Phase II trials to be effective in lowering A1c levels. We are eager to see Phase III data and to see A1c differences from baseline.
     - Novartis highlighted that among its priority early-stage projects is LBM642, a novel agonist of both PPAR-alpha and PPAR-gamma (peroxisome proliferator-activated receptor) for the treatment of metabolic syndrome.
     - LBM642 was shown to be more efficacious in lipid lowering than fenofibrate in a first proof-of-concept trial. Proof-of-concept data in diabetes are expected in mid-2005.
     - We see metabolic syndrome (a group of risk factors that includes obesity, insulin resistance, elevated cholesterol and high blood pressure) receiving more attention recently. As we have noted, if the 12 million-plus (U.S.) diagnosed type 2 patients represent a sizable, undertreated market, certainly the 40 million-plus (U.S.) estimated population with metabolic syndrome represent a very attractive market as well. This is particularly true when we consider that the majority of the $92 billion in diabetes related direct expenses each year stems *not* from pharmaceuticals and medical devices but rather for treatment for a relatively *smaller* group of patients who have the highest costs – i.e., patients with microvascular and macrovascular complications. Given that such complications can be prevented – with positive public health implications – we agree with thought leaders who have been saying this for year – it makes *so* much sense in our view to treat patients earlier and more aggressively.
   - **Pfizer:** The 4Q04 Pfizer call was mostly uneventful from a diabetes perspective, though there were a couple of interesting Q&A exchanges. See below for news on recently-approved Lyrica, for diabetic peripheral neuropathy (DPN).
     - Management was asked about a U.S. filing for Exubera, and the answer was basically *'we're working on it...'*
     - An analyst also asked about the ongoing dispute with Sanofi-Aventis over Exubera rights. Pfizer management responded that they're moving toward a "*preferred outcome*" – they wouldn't specify in any greater detail what that meant. Whatever happens, they will be able to characterize it as according to plan. We don't think after all the investment to date that it is likely that Pfizer will pull out of the drive for an inhaled insulin submission and approval. Pfizer said in late '04 that it planned to submit for FDA approval this year.
     - Pfizer said that the litigation process was moving forward but that they believed both parties would prefer to settle it outside of court. As readers may recall, late last year Sanofi-Aventis management characterized Exubera as "*charming at first glance.*" Kelly still loves that phrase and goes out of her way to use it whenever possible!
     - The same analyst asked about whether the DEA would ease restrictions on Lyrica (see detail below on approval/controlled substance status). Pfizer didn't go into depth on this but suggested they would see some sort of DEA decision in three to four weeks.
   - **Abbott:** We were impressed that Abbott hit nearly $800 million in blood glucose monitoring sales for 2004, on the strength of TheraSense. This represents increased year-over-year sales for Abbott Diabetes Care of 46%. When management reported 4Q03 sales (see DCU V3, #2 – January 16, 2004, on http://www.closeconcerns.com/dcu/V3-2%20-

%20Diabetes%20Close%20Up.pdf), it projected an increase of 30% for the business, which we had characterized as conservative. Great news on the performance.

- Results: 4Q U.S. sales reached $117 million, up 135%, while international sales came in at $125 million, up 37%, for global growth of 71%. For 2004, U.S. sales reached $378 million, up 85%, while international sales of $413 million rose 23%, for global sales of $791 million, up 46%.
- Management did not disclose incremental sales from TheraSense, but noted that TheraSense had outperformed expectations and that Abbott is committed to using the TheraSense platform. It also forecast that Abbott Diabetes Care would surpass $1 billion in sales in 2005 – excellent! This would suggest growth over 26% for 2005, a healthy rate - some of 2005 will obviously still reflect incremental sales coming from TheraSense, since the acquisition closed late in the first half of 2004. Management noted that combined market share has increased by 2% and we would forecast continued share gains. Competition is tough, but the combined entity has an excellent product, in particular, in Flash, and definitely is benefiting from more feet on the street.
- In terms of Navigator, management said the device correlates well enough to justify a replacement claim. The company will conduct additional continuous studies, and a launch in 2006 was forecast.

--by Stephen D. Simpson and Kelly L. Close

2. **JP Morgan Healthcare Conference, 2005, January 8-11, San Francisco, CA**

- **Medtronic**:
  - The company expects to release its continuous monitor Guardian RT in fiscal year 2006 – i.e., sometime after April 2006. This product, management noted, will have alarms with real-time values, updated every five minutes. As a reminder, this was submitted to the FDA in August, 2004.
  - MiniMed has launched its 515/715 pumps and said it was "pleased with acceptance" – it continued to mention CareLink and we will be eager to hear more about progress on this front, given CareLink success in Medtronic's cardiovascular rhythm management business. Management said there will be incremental pump launches each year.
  - Medtronic again stated it would have a closed loop product on the market in FY08. We are hopeful about industry strides, but see two major barriers: the long road to algorithms that *really* work (no failure) and the necessity of dual-chambered pump with a counter-regulatory hormone (glucagon). While we're sure industry can achieve success on both fronts, we aren't sure about the timing for this closed loop product. We do know the hospital will be an important place to test closed loop and certainly this plays to Medtronic's strengths. We also still question accuracy at hypoglycemic levels and will be eager to see more data on this front.
  - While we are certainly excited about prospects on the continuous/open/closed loop front, we are cautious on timing. Continuous monitoring product prospects hold enormous excitement for us; still, we feel very strongly that patients' expectations should not be raised further until significant more data is published. As such, we don't think any of these products should be discussed with patients or should be part of marketing until they are available. Given delays to date, we suspect three years for a closed loop, given that patients have been hearing about the closed loop for literally decades, is aggressive.
  - *Notably, we do envision modified open loop as significantly more "doable" and importantly, as a major, major milestone for patients, families and friends of patients, healthcare providers, and ultimately payors*. Which patients? Certainly type 1 intensively managed patients for a start, type 2 patients on insulin, particularly those needing titration help, pregnant patients (gestational and type 1), patients with various

problems/complications (especially hypoglycemic unawareness, severe hypoglycemia, and gastroparesis), and children of all ages.
    - Medtronic believes pump penetration will go to 35% (from 20% today) by 2009. We could definitely see this happening. We think that in particular, once real-time continuous glucose monitoring is available and reimbursed and covered, pump penetration will increase. In our view, continuous monitoring will result in patients becoming ever-more engaged in their diabetes care. They will have tools that will actually help them in real time – real innovation, in other words, when it emerges.
- **Amylin**: The Amylin presentation, led by CEO Ginger Graham, was packed – clearly excitement is growing over the potential launch this year of Exenatide. We're also excited, certainly more than Wall Street appears to be, over a Symlin launch – we hope, according to PDUFA dates, to see approval for Symlin by late March and Exenatide by late April. Although there was not *new* news at this talk, we highlight what we characterized as notable items mentioned:
    - 60% of patients on oral meds are not achieving A1c targets. We know you all know that. But think of it! Sixty bleepin' percent! We completely buy into the potential for Exenatide to represent a new "space" – we think that patients will welcome the idea of, when failing oral meds, as not needing to move straight to insulin. Obviously there are multiple opinions on how much patients will be willing to inject, but we do feel strongly that at least those who are willing to inject would rather inject a drug like Exenatide than insulin – insulin spells failure. On the weight front, Exenatide is more attractive than insulin, particularly in terms of weight loss durability – not only was weight loss sustained, but patients lost more weight over time. LAR holds very exciting prospects.
    - Many of the patients who are not reaching their A1c goal are on insulin. It will be interesting to see how patients already taking insulin perceive Exenatide. While Amylin is not pursuing an indication to delay insulin initiation for such patients at this stage, and reiterated in Q&A that there was no proof for this yet, we would see this group as an obvious eventual target and we believe there will ultimately be patient demand here.
    - Observed restoration of first-phase insulin response was mentioned – we think this is exciting and are eager to see evolution on this front.
    - 350-400 additional personnel (sales and support, we believe) are expected to be hired if and when we see Exenatide approval. Amylin will aggressively target possible overlaps between Exenatide and Symlin.
    - Re: Symlin, Amylin mentioned that the healthcare provider target market will be far more targeted for Symlin than for Exenatide – primarily endocrinologists, and likely high-prescribing endos. Interestingly, we speak often to a number of healthcare providers who themselves have diabetes, and we note particular excitement across this group for Symlin. Although most of them have excellent A1cs, many still suffer greater variability of blood glucose levels than they would like. Enter, Symlin!
    - On AC137, Amylin is now prepping for Phase 2B dose-ranging study. It will look for optimal dose and dose frequency for this use of pramlintide in obese patients. Management reiterated that weight loss appears independent of nausea.
    - For AC2592, Amylin's GLP-1 compound for congestive heart failure, a 10-week, 180 patient Phase 2 trial for patients with severe congestive heart failure (Class III or Class IV[1]) was initiated in the fourth quarter of 2004. The primary endpoint will be peak oxygen consumption; results should be available in late 2005 or early 2006.

[1] For those unfamiliar with the functional classification system developed by the New York Heart Association, healthcare professionals often assess degrees of heart failure according to this system, which is well delineated on www.abouthf.org/questions_stages.htm: 1) Class I: No limitation of physical activity. No shortness of breath, fatigue, or heart palpitations with ordinary physical activity. 2) Class II. Slight limitation of physical activity. Shortness of breath, fatigue, or heart palpitations with ordinary physical activity, but patients are comfortable at rest. 3) Class III. Marked limitation of activity. Shortness of breath, fatigue, or heart palpitations with *less than* ordinary physical activity, but patients are comfortable at rest. 4)

- The breakout session was jam-packed and management could barely enter the room! Q&A highlights:
  - Re: Lilly partnership: Management emphasized that they chose Lilly – this makes complete sense, since at the time of the Lilly deal (second half of 2002), big pharma had awoken to power of Exenatide and we imagine that companies were in line to partner with Amylin. That Amylin chose Lilly makes complete sense to us given the power of the Lilly relationships with PCPs and GPs.
  - Re: Incretin memetics/GLP-1 visibility among healthcare professionals: Management mentioned its belief that more and more HCPs had received exposure/education on this front. We concur, given the packed symposia at major 2004 meetings (AACE, ADA, AADE, EASD). GPs and PCPs are almost never as well-informed as specialists, but undoubtedly this group will start to receive more and more exposure as well.
  - Re: the LAR develop pathway: This will be shaped by current studies and the upcoming multidose study. FDA guidelines on appropriate trial lengths have not been crystallized.
  - Re: blood glucose monitoring changes following pending Exenatide approval: Management gave a careful answer to this question, saying that it expected no change. We would say that although patients failing oral meds are by no means the largest group using blood glucose monitors, type 2 patients on insulin are more frequent users (though still far less frequent than, for example, type 1 intensively managed patients) – and perhaps if such populations move to Exenatide, we could envision less frequent blood glucose monitoring from this group, particularly assuming hypoglycemia becomes less of an issue. On the other hand, given our view that some patients do not test because they do not like seeing poor scores, we also could see some patients testing *more* often.
  - Re: time it would take from pending Exenatide approval to launch: "several weeks" for labels, shipping, etc.
  - Re: beta cell markers: work is ongoing studying and tracking potential markers of beta cell function; we feel this is important because while a "restores beta cell function" claim could be powerful marketing mojo for Exenatide, it could otherwise be difficult to prove.
  - Several studies are attempting to track markers of beta cell function. At present, it is very difficult to measure insulin secretion *in vivo*.
  - Re: need to raise capital: Amylin noted that it has sufficient cash for drug launches, although it did announce after the conference that it would raise more fund, perhaps to move forward its earlier stage pipeline. The company announced January 21 a public offering priced at $22/share-we view this as an excellent deal.
- Amylin reports fourth quarter results on March 2.

- **Animas**: Animas was in great form at the conference – it had increased guidance for the fourth quarter that morning, announced FDA approval of its IR1250 insulin pump, and given initial guidance for 2005 of $80-$82 million. It seems clear to us that Animas' operating leverage is continuing to improve. CEO Kathy Crothall led the well-attended talk, with the following items of note:
  - Re: market size for pumps and disposables: $780 million worldwide and $580 million in the U.S., with a growth estimate of approximately 20%.

Class IV. Severe to complete limitation of activity. Shortness of breath, fatigue, or heart palpitations with *any* physical exertion and symptoms appear even at rest.

- Re: Animas pump market share: roughly 30% of new U.S. pump placements, and ~ 13% overall. We think even with Disetronic coming back on the market in 2005, this will only continue to increase. To boot, Animas should benefit from industry expansion.
- Re: Animas pump penetration estimates: Approximately 25% in the U.S. and 7% penetration in Europe.
- Re: IR1250 launch – this launch is expected over the next several months.
- Re: reimbursement: Internationally, pumps are reimbursed at roughly two thirds the rate of the U.S., with disposables reimbursed at close to 100%.

- **Lilly**: John C. Lechleiter, Executive Vice President – Pharma Operations, outlined Lilly's late stage pipeline as well as recent FDA submissions and recent drug launches.
  - In September the FDA approved Cymbalta, a neuroscience drug used in treatment of depression, as the first treatment for diabetic peripheral neuropathic pain (DPN). Lilly estimates that two to three million patients with diabetes in the U.S. have this condition (in line with Pfizer's estimate – see below for more information on the recent Lyrica approval). Today, about 10% of Cymbalta scripts are for DPN. Lilly is promoting this indication with specialist prescribers for now, but plans to expand the promotion to PCPs in the future. The drug is currently under review for this indication in Europe (where it was approved for the depression-related indication in December).
  - Lilly is awaiting an FDA decision on Exenatide, the first of a new class of drug candidates called incretin mimetics (co-developed with Amylin for treatment of type 2 diabetes). The companies expect an FDA decision by the April 30 PDUFA date. Exenatide will be indicated for use in patients with functioning beta cells. Three studies have provided the following positive results:
    - Exenatide stimulates the secretion of insulin only in the presence of elevated blood glucose. It provides self-regulating glycemic control and substantially lowers the risk of hypoglycemia.
    - In a fixed-dose, twice-a-day regimen, exenatide does not require patients to adjust doses to accommodate changes in their daily activities and meals.
    - Exenatide reduced patients' body weight.
  - The PKC-beta inhibitor Ruboxistaurin is a treatment for DPN. DPN is a leading cause of foot ulceration and amputations in patients with diabetes. Phase III studies of Ruboxistaurin are expected to conclude this year. Pending the results of the trials, Lilly expects to file regulatory submission in the U.S. during the second half of 2005.
  - Zyprexa, Lilly's schizophrenia drug, has received negative attention for causing weight gain and hypoglycemia risks. In response, Zyprexa sales reps are providing information about diabetes-management to doctors, and teams of treatment specialists are discussing weight gain and diabetes with nurses and social workers in community mental health centers.
- **Merck**: CEO Ray Gilmartin's presentation was entitled "Focused on Future Growth" and outlined the late stage pipeline as well as recent FDA submissions and recent drug launches.
  - In his introductory comments, Gilmartin highlighted Merck's entrance into new therapeutic categories such as diabetes and obesity. Merck put forward that new categories are being approached in a substantive way with multiple mechanisms explored at once.
  - Merck has three obesity compounds and one diabetes drug in Phase 2 development.
  - MK-431 is a type 2 diabetes DPP-IV (dipeptidyl peptidase IV) inhibitor in Phase 3 late stage development and NDA filing is expected in 2006. The mechanism of action was described as having the potential to provide benefits including effective glucose lowering alone and in combination; improved safety profile; no weight gain and potential for weight loss; no edema; and minimal risk of hypoglycemia. We look forward to seeing more data on this drug. Recall that DPP-IV inhibitors also have some major safety

questions. Merck also put forward that stimulation of beta cell growth has the potential to stabilize or reverse the disease process – this would obviously be a major advantage if it were proven.
    - Gilmartin's presentation also highlighted muraglitazar, jointly developed and commercialized with Bristol-Myers Squibb. This drug to treat type 2 diabetes was submitted to the FDA in December 2004. Muraglitazar is expected to be the first entrant in a new class of dual-acting, PPAR-alpha/gamma agonists (glitazars). The target profile put forward for muraglitazar included durable glycemic efficacy comparable to or better than TZDs, direct and substantial improvements in HDL and triglyceride levels commonly seen in type 2 patients, and favorable safety profile. We have the most questions on the last – safety – given that all other PPARs are in the midst of rodent studies.
- **Inamed**: Lap-Band is clearly driving obesity growth, big-time, with IGB (BioEnterics Intragastric Balloon – a non-surgical short-term treatment) doing well in Europe. Items of note:
    - Management reminded listeners that Lap-Band is the least invasive obesity surgery option on U.S. market. Inamed noted estimates that Lap-Band is ten times safer than gastric bypass surgery.
    - Inamed is currently studying results of pilot IGB U.S. study – IGB is a non-surgical short term treatment - a four to six month option that is placed and removed with a scope.
    - Re: the 2005 Lap-Band strategy: Inamed is focused on driving the number of surgeries at existing sites - it is not patient demand that is the limitation to growth, it is more a matter of getting surgeons trained. This is a good problem in our view. Also on the surgeon front – Inamed is committed to helping build practices (we imagine lots of logistics here).
    - Re: pricing and reimbursement: Other procedures are 1.6 - 1.8 times as expensive as Lap-Band. Medicare reimbursement could be very important; the November CMS meeting was characterized as "quite positive."
- **Matria** had several pieces of interesting commentary:
    - Re: how Matria is distinguished from managed care: A proactive rather than reactive approach – certainly, many (most? virtually all?) diabetes patients need to be more proactively managed in our view. Given high average A1Cs, we are happy to see more focus on this front and would love to see data.
    - Re: "favorite" patients for Matria to work with: management claims they're especially good at working with patients who have compliance problems – again, certainly the diabetes population qualifies in spades.
    - Re: areas of strength in the business: foreign diabetes distribution business has been growing particularly well.
- **Becton Dickinson**: This discussion was focused almost solely on cell biology (their most profitable business) and diabetes was not mentioned.
- **Alkermes**: Diabetes was mentioned well after alcohol dependence and schizophrenia.
    - Re: AIR (inhaled insulin): two-year safety study to begin in '05. This is a rate-limiting study that's key for the NDA.
    - Re: data: look for Phase 2 data on type 1 patients to be presented at ADA in San Diego in June by Lilly. Alkermes is moving forward with Phase 2 dosing studies, which will examine A1C impact.
    - Re: timing: timing for anticipated approval was not mentioned but we would imagine 2008-09 would be a reasonable estimate if trials go well.
    - Re: other: 1) AIR insulin waveform is said to be identical to Humulin; 2) A facility in Chelsea, MA has been built for commercial manufacturing.

--by Stephen D. Simpson, Sara S. Dauber, and Kelly L. Close

3. **Pfizer approval – Lyrica**

- On New Year's Eve, Pfizer announced it had received FDA approval for Lyrica (pregabalin) for management of neuropathic pain associated with diabetic peripheral neuropathy (DPN). See above for more information on Lilly's also recently-approved competing compound Cymbalta.
- Lyrica will be available to physicians and patients in the "near future" – the company stated when the drug was approved that they expected it to be classified as a controlled substance (albeit in a category with lower potential for misuse or abuse relative to controlled substances in other categories). Pain associated with DPN is said to be intense, involving burning and sharp pain in the hands, feet, arms, and legs.
- Pfizer received an approvable letter for the DPN indication last September. At AADE last August, there had actually been a separate *booth* for a new Pfizer drug that reps couldn't name – literally all the booth really said was "new Pfizer drug for diabetes coming soon." Since the drug had been approved for DPN in July in the EU, we suspected this was the drug; although it seems approval had been hoped for earlier in 2004, it was nice to see the quick action after the approvable letter receipt.
- Pfizer's PR at the time of approval noted that "nearly half" of the 18 million Americans with diabetes would develop some form of DPN during the course of their disease. Since there are actually only 13 million diagnosed patients with diabetes in the U.S. estimated at present, we thought it was a little bit much to cite the 18 million figure, but overall it's probably a quibble: first, those numbers will be updated soon; second, we do hope to see earlier diagnoses – and earlier treatment – with better screening.
- Pfizer tested Lyrica efficacy in three double-blind, placebo-controlled trials involving patients with DPN. The company said the drug gave fast, meaningful pain relief in a "significant" portion of patients, sustained in studies out to 12 weeks. We were surprised not to see longer trials.
- As noted, last July, Pfizer received European Commission approval to market Lyrica in the European Union for peripheral neuropathic pain. Clearly, Pfizer has invested significantly from a regulatory perspective; in the EU alone, Lyrica's approval reflected submission of 10 clinical trials involving over 9,000 patients at 10 sites.
- Pfizer estimates that one in six diabetes patients experience DPN – this would be over 2 million patients with diabetes in the U.S. An illustrative point only – we have no idea what pricing will be – but we do note that for the drug to have a billion dollar potential market, it would only need to be priced at ~$500/year. Emphasis – this is illustrative only! The drug will undoubtedly be priced far higher and undoubtedly not every patient would receive the drug – and undoubtedly, since it is a controlled substance, healthcare professionals will be extra careful about prescribing it. Our main point – it's not a small market.

--by Melissa P. Ford and Kelly L. Close

4. **Media Watch – New Roche ad:** There's another excellent Roche Compact ad out that we have seen on CNN – have you seen it?! It's two hip-looking 17-ish-year-old twins who convey in 30 seconds that they are best friends, they're savvy, they love jazz, love cars, hate pain, and are cool. To boot, one mentions ever-so-blithely that they test ten times a day with the Roche Compact – "because it's *so* not a pain." We love seeing the definition of intensive expand – while intensive used to mean four tests a day, one simply can't tell *that* much from only pre-prandial tests, so anything that moves the notion of more tests per day into the mainstream is great by us (we both routinely test that frequently). So back to the ad - the announcer *then* mentions that patients don't have to test on fingertips with Compact and the ad moves back into super-sharp focus on the twins, showing one testing on her palm. Who knew when Amira was founded in 1996 that this would be the start of alternate-site testing – or that when TheraSense commercialized FreeStyle in 2000 that AST would really move into the mainstream? Kudos to these pioneers for putting forward more options, and to Roche (who purchased Amira in 2001) for putting forward a lot of education in one short ad. We believe these commercials help industry as *well* as Roche and we expect to see more direct-to-consumer ads for

diabetes moving forward. We hope the effort that goes into them will be on the scale of Roche's effort – they have cracked it.

--by Melissa P. Ford and Kelly L. Close

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