CLOSER LOOK

MEMORANDUM

## Lilly begins first feasibility study of its AID system with Dexcom CGM, its own pump, hybrid closed loop algorithm; launch still expected in ~2-3 years - December 14, 2017

# Executive Highlights

- **Lilly began dosing the first patient in a phase 1 safety/functionality study of its AID system** with Dexcom CGM, its own pump, and a hybrid closed loop algorithm acquired from Class AP in Montreal. Humalog (insulin lispro) will be used in the system for the purposes of the study. The study will wrap up in April.
- **The trial, now on CT.Gov, will study the system in 30 adults with type 1 diabetes (ages 18-65 years) over the course of 12-18 days.** Primary outcomes pertain to the system's response to challenges of hypoglycemia, hyperglycemia, and CGM re-connecting (presumably after losing connectivity).
- **Based on the listed outcomes,** we're not sure if the study will be completely inpatient (participant in clinic 12-18 days), if the participant will wear the system outside of the clinic and come in for tests, or if the participant will only put the system on a few times (when they are in clinic) during the 12-18 days. We're awaiting clarification from the company.
- **More clinical trials will begin in the coming months for the in-development integrated insulin management system,** combining a connected insulin pen with "glucose-sensing technologies" and software to personalize insulin recommendations.
- **We were thrilled to see that the press release was broadcasted from Lilly's main news stream,** signaling a deep commitment to the "Connected Diabetes Ecosystem."

Lilly recently announced that it has begun dosing the first patient with type 1 diabetes in a feasibility study of its automated insulin delivery (AID) system - right on time with the debut WSJ announcement to begin by the end of the year. This phase 1 AID trial, now posted on CT.gov, will test functionality and safety of the system with Humalog (insulin lispro) over a period of 12-18 days in 30 adults with type 1 diabetes (ages 18-65 years).

The actual design of the study is a bit hazy based on the provided description: Primary outcomes are (i) the number of participants who show a decrease/suspension of insulin delivery in response to hypoglycemia; (ii) the number of participants who show an increase of insulin delivery in response to hyperglycemia; and (iii) the number of participants who show a resumption of Auto Mode following restored CGM connectivity. Based on the listed outcomes, it seems like an inpatient study with periodic challenges. We've followed up with the company to find out if participants will wear the system at home, only put it on in the clinic, or possibly even spend 12-18 days in the clinic. The study is slated to wrap up in April.

The Lilly press release also mentions the integrated insulin management system in development, which combines a "connected insulin pen with glucose-sensing technologies and software applications to deliver personalized insulin dose recommendations." More clinical trials will begin in the coming months in insulin users with type 1 and type 2 diabetes - we assume the latter refers to the pen-based system, but we'd be fascinated to see closed loop with a pump tested in type 2s! The final line of the press release confirms the launch timing for both products we heard two weeks ago - "available to patients within two to three years, pending FDA approval - great to see this maintained and shared so publicly.

This Lilly-wide press release is a big deal, as it shows big commitment to the "Connected Diabetes Ecosystem" with algorithms driving smarter insulin dosing in both pumps and pens. As we covered previously, Lilly's AID system includes its own disk-shaped tubed pump, a hybrid closed loop algorithm (acquired from Class AP in Montreal), a wireless handheld controller, and Dexcom CGM. The pen system will be based on the disposable Kwik Pen platform (unclear if it is a cap or another attachment that enables dose capture), and the paired app will be capable of titrating, basal, bolus, and basal+bolus insulin. The use of "glucose-sensing technologies" (plural) may imply both BGM and CGM will be used in the pen system. We're also glad to see "automated insulin delivery (AID)" being used as a standard term now - far preferable to "artificial pancreas." We love it not only that Lilly is using it but that they made it a major component of the headline in the press announcement: "Lilly Initiates Clinical Trial to Evaluate the Functionality and Safety of its Automated Insulin Delivery System". Read our previous deep dive here for more on Lilly's Connected Care vision.

*-- by Adam Brown, Brian Levine, and Kelly Close*