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FLASH REPORT: Smart Insulin Ready for Human Trials

During a recent investor briefing Merck announced that their “smart insulin” product is ready to progress from animal to human testing. This news generated some buzz in the type 1 community, especially after the JDRF released a “breaking news” email congratulating the accomplishment. Here we weigh in with a practical perspective on questions and challenges that face Merck’s development of smart insulin.

Smart insulin (a.k.a. glucose-responsive insulin or self-dosing insulin) promises to release insulin in response to changes in blood glucose. As currently envisioned, smart insulin would require only one injection a day. The insulin is combined with another molecule that would prevent it from being activated until glucose levels rise to a certain level. As blood glucose returns to a normal range, the release of insulin would stop until needed again. As a result, smart insulin would effectively reduce the incidence of hyperglycemia.

The Merck project appears to be the most advanced smart insulin initiative in development. It began as SmartCells, Inc., a 14-person company founded by an entrepreneurial MIT professor in 2003. In 2008 JDRF gave \$1 million to fund SmartCell’s work on smart insulin. In 2010 Merck acquired the firm for \$500 million. The high acquisition price suggests that Merck envisions smart insulin as a therapy primarily for type 2 diabetes and secondarily for the smaller type 1 marketplaces.

But a several major questions still need to be answered as the research progresses, including:

- Speed at which the insulin would begin control glucose after a release is triggered. Faster is better.
- Its ability to eliminate hypoglycemia with a high degree of confidence. As currently conceived, Smart Insulin should reduce low blood sugar frequency because less insulin will be released when blood sugars are lower. However, given the importance and risk of hypoglycemia, this needs to be fully validated and proven.
- Still requires monitoring of blood glucose levels.
- Dosing guidelines unclear. In theory, one would inject more insulin than required for the day ahead but not so much more that potential side effects occur.

Although Merck claims to be preparing to enter human trials, timing has not yet been disclosed. The JDCA placed several calls to determine the target timing for the trial and were told that this was “not publically available information.” We will continue to follow and report on the development of smart insulin as this project and others like it go into human trials.

While this new technology has the potential to meaningfully impact the treatment of type 1 diabetes, as currently conceived it is not a practical cure. There are still many key questions to address and substantial testing ahead, including successful completion of all human testing, which requires 7-10 years in the best of situations.