Dear Colleagues,

I am excited to share the following announcement with you:

**MEDTRONIC RECEIVES FDA APPROVAL FOR WORLD’S FIRST HYBRID CLOSED LOOP SYSTEM FOR PEOPLE WITH TYPE 1 DIABETES**

*The MiniMed® 670G System Features the Company’s Most Advanced SmartGuard™ HCL Technology to Date*

Featuring Medtronic’s most advanced algorithm – SmartGuard™ HCL technology – this new system is the latest innovation in Medtronic’s automated insulin delivery devices and the first hybrid closed loop system.

The MiniMed 670G system features the Guardian® Sensor 3, Medtronic’s newest and most advanced glucose sensor with enhanced accuracy and performance, and a longer 7-day life. This newest generation continuous glucose monitoring (CGM) sensor, the first and only sensor approved by the FDA for hybrid closed loop therapy, incorporates diagnostic technology that continuously monitors sensor health. Driven by the SmartGuard HCL technology, the system delivers a variable rate of insulin 24 hours a day based on the personalized needs of the patient, maximizing the time glucose levels are within the target range. It is designed to learn what an individual’s insulin needs are and take action to minimize both high and low glucose levels. As a result, the system requires minimal input – patients only need to enter mealtime carbohydrates, accept bolus correction recommendations, and periodically calibrate the sensor. The system is approved for the treatment of people with type 1 diabetes fourteen years of age and older with ongoing studies to expand the indication for additional patient populations.

This exciting breakthrough was done in partnership with you – our healthcare professional trailblazers -- clinical investigators, regulatory agencies, and respected advocates within
the diabetes community. It is only by working together that we are able to reach new heights in our shared goal of improving the lives of people with diabetes. The pivotal study results were recently published in JAMA,* The Journal of the American Medical Association.  http://jama.jamanetwork.com/article.aspx?articleid=2552454) and I am attaching summary slides for you to use in scientific presentations. If you would like more detailed slides, please let me know.

Know that Medtronic will initiate commercial release of the MiniMed 670G system in spring of 2017 with availability increasing over time. This timeline hopefully ensures payer coverage, as well as our ability to successfully train you and your patients on this new therapy.

As we move toward commercial release, rest assured that users of our MiniMed 630G system will be eligible for a Priority Access pathway program to the MiniMed 670G system, as their experience in using our newest hardware platform will facilitate an optimal transition.

I look forward to discussing this further with you, but wanted to share this exciting news with you immediately.

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*Please note that since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.
MINIMED® 670G SYSTEM
HYBRID CLOSED LOOP SYSTEM COMPONENTS

- New closed-loop algorithm, pump platform and CGM display
- New Guardian® Sensor 3 and Guardian Link 3 transmitter
- Sensors calibrated with the CONTOUR®NEXT LINK 2.4 blood glucose meter (not shown)

The sensor, transmitter, software, and insulin pump are currently limited to investigational use.
The pivotal study was conducted in 124 patients. There was a 2-week run-in period followed by a 3 month study period with 12,389 patient-days of Automated Basal Delivery use.

More patients achieved A1C <7% with Automated Basal Delivery: Run-in vs. Study Periods

Pivotal Trial Outcomes:

- Improvement in A1C: 1
  - A1C 7.4±0.9% at baseline and 6.9±0.6% at study end - (0.5% improvement)

- No Severe Adverse Events During Study: 1
  - No DKA and no severe hypoglycemia

- Reduction in Glycemic Variability: 1
  - Improvement in “time-in-range” 2
    (66.7% during run-in, 72.2% during study period)
  - 44% less low glucose* events comparing run-in to study periods

1Bergenstal RM, et al. JAMA. Published online September 15, 2016. 2Bergenstal R, Buckingham B., Garg S et al. Pivotal Trial of a Hybrid Closed-Loop System in Type 1 Diabetes. ADA 74th Scientific sessions June 10-14, 2016 *Data as measured by device sensor. Range defined as 71-180mg/dL during study period. Study of 124 adults and adolescents (ages 14-20) with type 1 diabetes. Diagrams rounded for illustrative purposes only. *Since this study did not include a control group, no claims regarding effectiveness can be made. However, the study does support that the device is relatively safe for use.
PIVOTAL TRIAL DATA FOR MINIMED 670G SYSTEM
ASSESSMENT OF DAILY GLYCEMIC VARIABILITY


- Reduced glycemic variability (high and low glucose* events) with Automated Basal Delivery in both adult and adolescent cohorts.

1Bergenstal R, et al. Pivotal Trial of a Hybrid Closed-Loop System in Type 1 Diabetes. ADA 74th Scientific sessions June 10-14, 2016  2Measured over study period. *Data measured by device sensor. Range defined as 71-180mg/dL during study period. Study of 124 adults and adolescents (ages 14-20) with type 1 diabetes. Diagrams rounded for illustrative purposes only.