Press release June 13, 2019

Update on the CE-certification process for Actiste.

Due to extensive interest in Brighter's ongoing certification process, we are issuing a status update as follows:

Brighter has been working in parallel on the certification of our quality management system under ISO 13485 (the framework for medical technology products), and on the CE-marking of Actiste. Both processes are carried out in collaboration with a Notified Body, which issues the relevant certifications.

ISO 13485 is a standard that ensures Brighter meets quality requirements for the design, development, manufacture and marketing of medical devices and services. The certification also enables Brighter to self-certify products in the future.

The CE-mark for the Actiste device facilitates clinical use, and means that Brighter can proceed with the commercialization of Actiste® Diabetes Management as a Service – our unique solution for diabetics and caregivers. The digital infrastructure and mobile applications included in the service received their CE-mark during H2 2018.

In the ISO 13485 certification process, a "pre-audit" was carried out in 2017. This was subsequently followed by an "off-site audit" and an "on-site audit". The "on-site audit" was carried out as part of the CE-marking of the physical product, with representatives from the notified body spending two days at the company's head office in Kista during Q1 2019, with very good results. The same notified body issues both the ISO 13485 certificate and the EC certificate for the Actiste device (CE-marking).

The company has a good relationship and frequent contact with the notified body. Brighter's employees have also visited the notified body to support its work. As the certification is an iterative process, timetables are preliminary and uncertain, which has led to Brighter being able to communicate only relative time indications. However, the process has progressed continuously and is in its final phase.

Comment from Brighter's CEO, Henrik Norström:

Brighter's Actiste is a complex product that, through its multi-functionality, is classified under both the Medical Device Directive ("MDD") and the In-Vitro Diagnostics Directive ("IVDD"). This means that the certification process is more extensive than if it were just a single directive.

The complexity is partly due to the fact that we have created a unique and ground-breaking solution where comparable products for the certification work are lacking. Although it is frustrating that the process has taken time, we have full understanding of and respect for this being a challenge for the notified body.

The duality of the product also requires additional resources from the notified body, which, like the other notified bodies in Europe, is struggling with the implementation of new regulations, and is overloaded by companies and products that are in line to be certified. The complexity of our case has meant that the time aspect has been very difficult to assess. Thus, the time assessments that we have had to adapt to, have unfortunately not always been accurate.

To optimize the process Brighter has been very proactive in supporting and providing feedback directly on any issues that have arisen in the certification work. I feel very confident that the Actiste device will be certified, and I look forward to being able to proceed with the commercialization of our service. The entire company is inspired, and I am grateful we have such strong commitment from our shareholders.

About Actiste.

Brighter's solution Actiste® handles most of the self-monitoring and treatment of insulin-treated diabetes in a single easy-to-use device. Measurement of glucose levels, insulin injections, automatic logging, and timing of all activities are performed from a single unit. Actiste is connected via an autonomous and

secure mobile connection, and information can be automatically shared with selected recipients through The Benefit Loop®, Brighter's open cloud-based service where data is collected, processed and analyzed with patient consent.

Validated user-generated data, such as glucose levels or insulin doses, can be automatically transferred electronically to many different constituents. The patient selects when and how data is shared and who will have access to it. Through The Benefit Loop, different services can motivate patients with chronic illnesses to change their behavior, which can save lives, reduce relatives' concerns, and release enormous healthcare resources. https://actiste.com/

About Brighter AB (publ).
Brighter is a Swedish-based company that, from a unique IP portfolio, creates smart solutions for one of healthcare's biggest challenges: changing patient behavior. Chronic diseases such as diabetes are rapidly increasing, and account for an increasing share of healthcare costs globally. Brighter's Business Model and Multi-Sided Market Platform - The Benefit Loop®- is based on the fact that many special interests create value for each other. By increasing access to valid health data, Brighter creates value for all stakeholders in the care chain: patients and their close associates, healthcare providers, research institutes, the pharmaceutical industry, and society as a whole. https://brighter.se/

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