

Cellnovo provides update on 510(k) submission

Paris, France, September 8, 2017 – Cellnovo Group (“**Cellnovo**” or the “**Company**” CLNV:EN Paris), a medical technology company marketing the first mobile, connected, all-in-one diabetes management system, today provides an update regarding the review by the US Food and Drug Administration (FDA) of the Company’s 510(k) application for clearance of the Cellnovo Diabetes Management System.

Cellnovo filed a 510(k), a premarket submission that is required before a medical device can be marketed in the US, with the FDA on November 16, 2016. On August 8, 2017, Cellnovo responded to an initial series of questions from the FDA relating to the application. Cellnovo can report that since this submission, the FDA has responded requesting further information to supplement that already provided by the Company.

The Company expects this new step will extend the previously expected timeline for clearance of the device in the US and will continue to keep the market informed of progress.

Sophie Baratte, Chief Executive Officer of Cellnovo, commented: *“The Cellnovo Diabetes Management System is an innovative wearable insulin pump with a unique value proposition. Whilst we are disappointed with the extension of the approval process in the US, we are committed to working very closely with the FDA to ensure that Type I diabetes patients can benefit from the Cellnovo Diabetes Management System as quickly as possible and we will update the market on this progress as soon as we can.”*



About Cellnovo

An independent medical technology company specialising in diabetes, Cellnovo has developed and markets the first mobile, connected, all-in-one diabetes management system that helps make life easier for patients. Compact, intuitive and entirely connected, Cellnovo’s insulin pump comprises a mobile touchscreen controller with an integrated blood-glucose meter. This unique device allows optimal management of insulin injections whilst ensuring extensive freedom of movement and peace of mind for patients. Thanks to the automatic transmission of data, it also allows the patient’s condition to be continually monitored by family members and healthcare professionals in real time. Cellnovo is currently participating in several major Artificial Pancreas projects with Diabeloop, TypeZero and Horizon 2020 to develop automated insulin delivery systems.

For further information please visit www.cellnovo.com

About the Cellnovo Diabetes Management System

Compact, intuitive and entirely connected, Cellnovo’s insulin pump comprises a mobile touchscreen controller with an integrated blood-glucose meter. This unique device allows optimal management of insulin injections with drop-by-drop precision, whilst ensuring extensive freedom of movement and peace of mind for patients. Thanks to the automatic transmission of data, it also allows the patient’s condition to be continually monitored by family members and healthcare professionals in real time.

Cellnovo is listed on Euronext,
Compartment C
ISIN: FR0012633360 – Ticker: CLNV





The first connected all-in-one Diabetes Management System

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