



The First Connected All-in-one Diabetes Management System

Press Release

## Cellnovo files for 510(k) approval with the FDA for its mobile, connected, all-in-one diabetes management system

**Paris, France, 16 November, 2016** - Cellnovo Group ("Cellnovo" CLNV:EN Paris), a medical technology company marketing the first mobile, connected, all-in-one diabetes management system, announces today that it has filed for 510(k) approval with the US Food and Drug Administration (FDA) for marketing clearance of the Company's diabetes management system.

The 510(k) is a premarket submission that must be filled with the FDA before a medical device can be launched and marketed in the US.

Cellnovo can confirm that the submission is under review by the FDA, a process that the Company expects to last several months. In anticipation of 510(k) approval, Cellnovo will continue preparations to ensure readiness for launch of the system in the US, the world's largest single market for medical devices.

**Sophie Baratte, Chief Executive Officer of Cellnovo, commented:** *"We are pleased to have submitted our application to the US authorities. The United States represents an important future market for Cellnovo with 1.25 million children and adults with type 1 diabetes\*. Furthermore, market penetration of insulin pumps is higher in the US than anywhere else in the world. We believe that our diabetes management system, offering unrivaled levels of freedom and connectivity combined with high levels of accuracy, has the potential to perform strongly in the growing insulin-pump marketplace."*

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### 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, tubeless, 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's device has been shown in a recent peer-reviewed publication to offer superior accuracy in its delivery of insulin compared to other compact wearable systems. Cellnovo is also involved in research on the artificial pancreas with several partners.

For further information please visit [www.cellnovo.com](http://www.cellnovo.com)

### About the Cellnovo Diabetes Management System

Compact, tubeless, 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.

\*Source: American Diabetes Association



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