BIOCORP obtains 510(k) FDA clearance for Mallya®

- Already CE marked, the FDA's authorization reinforces BIOCORP's technological leadership in the smart pens market.
- Supported by key players in the diabetes field (SANOFI, ROCHE, and NOVO NORDISK), access to the American market opens up new opportunities for industrial partnerships

Issoire (France), December 7, 2022, at 7:30 am CET – BIOCORP (FR0012788065 – ALCOR / Eligible PEA-PME), a French company specialized in the design, development, and manufacturing of innovative medical devices, announced today that they have received 510(K) clearance from the U.S. Food & Drug Administration (FDA) to market Mallya, its smart medical device that connects insulin pens.

Eric Dessertenne, CEO of BIOCORP, said: *"This approval is a major achievement for BIOCORP and all of our employees who have been heavily involved in this regulatory process. This approval marks a historic achievement for BIOCORP as it allows the commercial launch of our Mallya device in the United States and illustrates BIOCORP's ability to meet the highest regulatory requirements. This news has been eagerly awaited by all our industry partners to commercialize Mallya in the world's largest diabetes market and we are delighted that U.S. patients will soon be able to benefit from Mallya's services. This regulatory milestone will have a positive impact on our sales outlook in 2023 and positions BIOCORP as a leader in the field of smart pens.*"

The Mallya medical device is a smart sensor that is directly attached to insulin pen injectors, making them connected devices. Mallya automatically collects and records key treatment information (selected insulin units, date, and time of injection) and transmits it to a dedicated digital application. Mallya becomes the first system approved in the U.S. capable of automatically connecting different types of insulin & GLP-1 drugs, with an initial version of Mallya compatible with SANOFI's Solostar pen injectors.

Mallya is already the only device in its class to be CE marked as a Class IIb medical device. It offers the possibility to connect to different types of injection pens and thus to follow a patient in a multitherapy notably with a use of basal and rapid insulin.

BIOCORP has already signed major partnerships in the field with leaders of the diabetes space such as NOVO NORDISK, SANOFI AND ROCHE Diabetes Care.

BIOCORP's 510K approval will accelerate the submission of Mallya's future generations in the diabetes field and in other therapeutic areas where the company has signed partnerships.

ABOUT BIOCORP

Recognized for its expertise in the development and manufacture of medical devices and delivery systems, BIOCORP has today acquired a leading position in the connected medical device market thanks to Mallya. This smart sensor for insulin injection pens allows reliable monitoring of injected doses and thus offers better compliance in the treatment of patients with diabetes. Available for sale from 2020, Mallya spearheads BIOCORP's product portfolio of innovative connected solutions. The company has 80 employees. BIOCORP is listed on Euronext since July 2015 (FR0012788065 – ALCOR).
For more information, please visit www.biocorpsys.com.

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