



BIOCORP: AARDEX® Group and BIOCORP recruited by Trials@Home - Decentralized Clinical Trial Centre of Excellence

- Combining BIOCORP's pen injector add-on Mallya® with AARDEX® Group's Software to improve adherence to medication in a Hybrid Phase IV Diabetes Study

Issoire (France), July 21st, 2022, 6:00 pm CET – BIOCORP (FR0012788065 – ALCOR / Eligible PEA-PME), a French company specialized in the design, development, and manufacturing of innovative medical devices, and Belgium-based AARDEX GROUP, the leader in tools for measuring and managing adherence to medication in clinical trials are proud to announce one of their first major joint initiatives that will come live in the upcoming months. Both companies today announced they have been recruited by Trials@Home to take part in a Phase IV study called RADIAL. Trials@Home is a center of excellence for Decentralized Clinical Trials (DCTs), whose members include notably Sanofi, J&J, Pfizer.

They will team up with Sanofi, a global leader in healthcare, to create a digital solution for optimized insulin management, 100 years after the first insulin injection in 1922.

Bernard Vrijens, CEO & Scientific Lead at AARDEX Group, comments: *"Our digital medication adherence tool, MEMS AS®, offers a powerful suite of tools to measure and manage adherence to medication. This project is an opportunity to leverage our extensive practical experience in diabetes, including our recognized scientific leadership in medication adherence to improve patient outcomes. We are also delighted to be progressing our strategic partnership with BIOCORP."*

The Phase IV RADIAL study will see BIOCORP's Mallya pen injector add-on collect data from Sanofi's Solostar® insulin pens. This will then be integrated with AARDEX Group's MEMS AS® (medication adherence software) to provide an optimal understanding of patient behaviors during the course of the study.

The RADIAL study aims to include around 600 patients with Type 2 Diabetes across 63 sites in six countries. Of those, 150 will be site-based, 150 will be hybrid and up to 300 will be participating fully remotely.

Eric Dessertenne, CEO at BIOCORP, says: *"Mallya is a smart dose monitoring solution for insulin pen injectors offering a seamless patient experience with automatic data collection. Secured real-time data is then transferred securely via Bluetooth allowing end-to-end validated medication data adherence and processing with MEMS AS® and Trials@Home's Clinpal digital platform. This project is an opportunity to create evidence of the user benefits and evaluate the clinical benefits of our solution within a real-world decentralized clinical trial setting."*

Improving medication adherence for patients with Type 2 Diabetes is crucial to improving outcomes. Non-adherence has a direct causal association with hospitalization and death.

Sanofi will contribute Toujeo® (insulin glargine 300 unis/mL) as the medicinal product to be used in RADIAL, Trials@Home's EU proof-of-concept study.

Anastasia Ukhova, Head of Medical Digital Healthcare General Medicine, notes: *"Bringing Toujeo® to the consortium and today Mallya cap with AARDEX MEMS AS® technology offers a unique opportunity to build evidence on the way that innovation in connectivity contributes to the improvement of diabetes management."*

Trials@Home projects are funded by the Innovative Medicines Initiative^[2] Joint Undertaking (H2020-JTI-IMI2) – a public-private partnership between the EU and the European pharmaceutical industry body EFPIA.

The aim is to reshape clinical trial design, conduct, and operations, by developing and piloting standards, recommendations, and tools for the definition and operationalization of DCTs in Europe.

Speaking about the project, **Gary Friedman (Pfizer representative on the Trials@Home project)** added *"The AARDEX and BIOCORP teams are outstanding collaborators, who anticipate the nuances of interventional decentralized clinical trials. They go to great lengths to provide the Trials@Home consortium with technology that is the sine qua non for study participants requiring precise insulin dosing and compliance monitoring."*

Philipp Bordes (Sanofi representative on the Trials@Home project) emphasized *"Monitoring medication adherence in remote patient settings is a pivotal piece of DCT design and is key to supporting both our patients' safety and optimal health throughout the Trials@Home RADIAL study. The use of innovative, connected digital health technologies such as the Mallya device and AARDEX AS application play a key part in the optimization and acceptability of DCTs as the DCT becomes more familiar across the industry"*.

ABOUT AARDEX

AARDEX Group is the global leader in digital solutions to measure and manage medication adherence. With operations in Belgium, Switzerland, and the U.S., AARDEX develops and markets digital solutions for adherence-enhancing strategies in clinical trials, research settings, and professional healthcare systems. AARDEX is the central actor of a complete ecosystem that combines its MEMS Adherence Software with a wide range of smart packages and devices that measure patient adherence across all routes of drug administration. AARDEX's vision is to continuously innovate in data-driven medication adherence solutions to enhance digital therapeutics and patient empowerment. www.aardexgroup.com

ABOUT TRIALS@HOME

Trials@Home, Centre of Excellence for Decentralized Clinical Trials, is working to reshape clinical trial design, conduct and operations, by developing and piloting standards, recommendations and tools for the definition and operationalisation of Decentralised clinical trials (DCTs) in Europe. The consortium follows a co-creative multi-stakeholder approach where academic partners, Small and Medium-sized Enterprises (SMEs), private foundations, and EFPIA partners will work together with other stakeholders from across the medical, technological, regulatory, ethical and social aspects of DCTs. For more information, please visit www.trialsathome.com

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 70 employees. BIOCORP is listed on Euronext since July 2015 (FR0012788065 – ALCOR).
For more information, please visit www.biocorpsys.com.

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