COMPLETING ITS TRANSITION FROM GENESIS TO MATURITY, BIOCORP OPENS NEW HORIZONS

As Biocorp prepares for the market launch of its connected injector pen add-on, Mallya, Eric Dessertenne, Chief Operating Officer, and Arnaud Guillet, Business Development Director, share insights about key steps in the company's development and the opportunities that lie ahead. The article discusses the many partners Biocorp has entered into collaborations with, and includes a mini-interview with Sergio Monti, Plant Manager for one such partner, V.A.R.I.

It is well known that the world of the medical device moves at its own pace. Constrained by multiple standards to ensure the safety of patients, teams must comply with the necessary validations at each stage. Thus, after five years of hard work, Biocorp launches its first connected device this year. Many milestones have been achieved since 2014, thanks to foresight, agility and determination.

FROM GENESIS TO CE MARK AND DISTRIBUTION

Mallya is the add-on that turns any insulin pen into a smart device. The concept was born in 2014 when, based on the observation that some critical needs of patients with diabetes were not fulfilled, Biocorp challenged its team to find a way to achieve compliance for patients.

> "Mallya is indeed the first CE-marked class II-b medical device to be offered on the market."

The goal was to answer unmet needs in an immediate way and, considering that the timeline to develop an add-on is far shorter than for a whole connected product, an add-on approach was chosen. The idea was relevant, and the concept of Mallya was born, consisting of a connected smart cap compatible with any pen injector, recording and logging the exact dose dialled by the patient, along with the time and date, with the data being sent to a mobile app using Bluetooth technology.

Figure 1: Mallya is an add-on that turns any pen injector into a smart device.

Eric Dessertenne
Chief Operating Officer
T: +33 6 08 02 14 51
E: edessertenne@biocorp.fr

Arnaud Guillet
Business Development Director
T: +33 6 48 28 51 16
E: aguillet@biocorp.fr

Biocorp
Parc Technologique
Lavaur-La-Bèchade
63500 Issoire
France

www.biocorpsys.com

Since Mallya is an add-on, it can be used with existing products without any modification to their design (Figure 1), which saves a lot of time. Considering the market mainly offers disposable pens, adding connectivity becomes affordable thanks to Mallya, which is rechargeable (USB) and re-usable for up to two years. The diabetes field is widely adopting continuous glucose monitoring (CGM) and electronic blood glucose monitoring (e-BGM), so bringing the pen injector into the connected sphere is the last piece of the puzzle.

The device was first displayed at Pharmapack Europe 2016 (Paris, France, February 2016) where it won the Pharmapack Innovation Award. From the very beginning, the R&D team was committed to industrialisation capacity, designing Mallya from the outset to be produced on a large scale. Likewise, Biocorp has spent a lot of time ensuring that using the device is as seamless as possible for patients too, making it really easy to install Mallya on the pen and requiring no further steps to activate it and use the pen. All the formative and summative testing that Biocorp has been performing shows a high degree of acceptance of the system by patients of different age groups.

Mallya was originally developed for Eli Lilly's Kwikpen®, for the delivery of Humalog® (insulin lispro), and the CE marking file being finalised will be applicable for these pens. Mallya is also ready for SoloSTAR®, Sanofi's pen for the delivery of Lantus® (insulin gargine), and it will be finalised for Novo Nordisk pens by the end of 2019. Mallya is indeed the first CE-marked class II-b medical device to be offered on the market.

"We participated in the 2017 E-health awards at the E-health Summer University in Castres (France) and won First Prize for best connected Healthcare object, from a judging panel composed of pharmaceutical companies, HCPs, regulatory authorities and payers."

Figure 2: Inspair, a smart cap for inhalers that not only tracks medication use but also provides feedback on inhalation technique.

In 2016, Biocorp expanded its add-on approach to the respiratory field with Inspair (Figure 2), a smart cap for inhalers that not only tracks medication use but also provides feedback on inhalation technique. The development of this solution was based on the observation that many patients are unable to use their inhalers effectively, and critical errors are frequently observed, specifically for patients using pressurised metered-dose inhalers (pMDIs). These errors lead to lower drug deposition to the lungs, waste of medication and thus poor disease control, reduced quality of life, increased emergency hospital admissions and higher treatment costs.

"The Inspair platform showed a high degree of flexibility, in terms of integration, shape, functionalities, and adaptation to different device formats and technical constrains."

Based on preliminary technical specifications, an initial functional prototype of the solution was released at Pharmapack Europe 2017 (Paris, France, February 2017). Our first move was to seek the endorsement of various healthcare stakeholders. In that context, we participated in the 2017 E-health awards at the E-health Summer University in Castres (France) and won First Prize for best connected Healthcare object, from a judging panel composed of pharmaceutical companies, HCPs, regulatory authorities and payers.

Following this initial validation, we improved the device and moved its development forward through feasibility studies and customised programmes with pharmaceutical companies, on standard pMDIs and other types of respiratory device, either for clinical trials or commercial applications. Through these programmes, the Inspair platform showed a high degree of flexibility, in terms of integration, shape, functionalities, and adaptation to different device formats and technical constraints.

In parallel with these specific initiatives, Biocorp initiated the development of a standard off-the-shelf version of Inspair, with a defined set of unique functionalities. This version is now close to the verified prototype stage and will be industrialised in the coming months, at Biocorp's own facility in Issoire, France).

"Inspair guides patients to all steps necessary for correct use of the medication, from shaking the MDI to improving co-ordination between firing and inhaling the product. This gives a strong advantage versus all other smart devices currently on the market which only record when patients fire the drug."

Biocorp's strategy for Inspair will be the same as for Mallya, to obtain medical-grade classifications in Europe, the US and other markets, and follow the same development standards and requirements to guarantee the highest level of accuracy, repeatability, and robustness.

REACHING MATURITY

In parallel with exciting technical developments, Biocorp has built connections and signed partnerships with the most influential actors in the diabetes and respiratory markets, not only from a commercial perspective, but also to establish our solutions and guarantee high patient adoption and sustainable usage.

In the diabetes field, Biocorp has initiated collaboration strategies on many levels. Following the conclusions of leading diabetes experts, healthcare professionals and patients that combining glucose readings and insulin delivery data in a single platform could significantly improve diabetes management and control, Biocorp built connections with major glucose monitoring players (BGM and CGM) and insulin dose titration platforms, to provide comprehensive e-monitoring solutions.

In February 2019, we signed a distribution agreement with AgaMatrix (Dillingen, Germany), a major BGM player, and a collaboration agreement with DreaMed Diabetes (Petah Tikva, Israel), for its US FDA-approved insulin dose advisor software, DreaMed.

Mallya will feed our partners' platforms with exhaustive, reliable and 100% accurate insulin use data. Beyond these initial agreements, several technical evaluations and pilot studies are ongoing with other major diabetes players including pharmaceutical companies, CGM players and disease-management platforms, and further announcements are anticipated in the upcoming weeks.

On the scientific side, through collaborations with renowned hospital networks, institutions and key opinion leaders, clinical studies will begin soon in Europe, the US and the Middle East, to assess the impact of Mallya on adherence, diabetes control and treatment outcomes (specifically HbA1c levels). The outputs of these studies and evidence gathered will support our reimbursement strategy and our initiatives towards health plans and payers.

On the Inspair front, Biocorp has signed a global distribution agreement with Lindal Group company V.A.R.I., a leading player in the respiratory field. This deal will accelerate the technical development of the platform, in particular the "off the shelf" version of Inspair mentioned previously.

The agreement features exclusive distribution rights in some specific geographies (Asia, South America), merging the expertise of Lindal in the areas of valves and canisters with Biocorp's expertise in connectivity and sensing technologies. We recently talked with Sergio Monti, Plant Manager at V.A.R.I., about the benefits of this partnership and expectations over this collaboration, and this mini-interview appears in Box 1.

PROVEN EXPERTISE OPENING NEW HORIZONS

The success of Mallya and Inspair positions Biocorp as the reference player to develop add-on devices and bring connectivity to any type of drug delivery device, whenever there is a need to boost treatment adherence, monitor device use, or support patients in the management of their disease.

First, we can leverage our current add-on platforms. Our Mallya solution can be replicated to any pen injector in many therapeutic areas, specifically for self-managed and self-titrated diseases (e.g. fertility, multiple sclerosis, Parkinson's disease, psoriasis, and conditions requiring growth hormone). We have a reliable technology that was designed from the outset to be able to be readily adapted to the specific constraints and form factors of each pen. A similar approach could be considered for autoinjectors, to track compliance with device use-steps, and timely delivery by patients. Not to mention prefilled syringes, where key healthcare industry players are looking for solutions that are user friendly, easy to implement from an industrial standpoint, and economically viable.

In the respiratory field, Biocorp has already adapted its Inspair platform to various types of inhalers through feasibility studies and customised developments for clinical trial applications and, beyond MDIs, has been solicited for projects involving soft-mist inhalers, nebulisers and nasal delivery devices.

Beyond our traditional parenteral and respiratory fields, Biocorp has launched feasibility studies and development programmes in the ophthalmic, animal health and derma-cosmetic fields.

Through these initiatives, Biocorp has proven its ability to answer both the technical challenges (adapting to different form factors, sizes, and user requirement specifications) and the economic constraints specific to each project (design solutions from below €1 up to €100 in some cases).

Based on its experience and expertise in the field, all Biocorp's add-on developments follow five key principles:

- Seamless integration for maximum user convenience
- No interference with the existing drug delivery device user process or the formulation
- Minimal impact on existing drug delivery device industrial process
- Solutions with the highest level of accuracy, repeatability and robustness
- Compliance with economic criteria.

[Continued on Page 52...]

"Biocorp has launched an internal programme to develop a highly price competitive add-on solution for the injectable field which we believe will revolutionise monitoring of medication delivery in various therapeutic areas. Details will be disclosed this autumn."

BOX 1: INTERVIEW WITH...

SERGIO MONTI, PLANT MANAGER, V.A.R.I

Sergio Monti holds a Mechanical Engineering degree from Politecnico di Milano (Italy), an MBA from Northumbria University (Newcastle-upon-Tyne, UK) and Executives Education courses at London Business School. He began his pharma career in the Technical Service Team of ACS Dobfar, a major antibiotics manufacturer, heading all new projects and investments. Mr Monti joined Lindal Group in 2008 as Sales Director, contributing to the growth of its V.A.R.I. respiratory division. In 2017, he was promoted to Plant Manager of Lindal's Italian pharmaceutical facility.

Q **Mr Monti, could you briefly remind us what are the activities of Lindal Group?**

A Lindal Group is specialised in the design, development, manufacture and supply of aerosol dispensing packaging solutions tailored to meet a broad spectrum of customer needs and market applications. Our product offering includes a comprehensive range of valves, actuators, barrier packs and associated accessories that address the technical and aesthetic dispensing requirements.

V.A.R.I. is Lindal's wholly owned subsidiary focusing on respiratory applications. V.A.R.I. has been supplying valves and actuators for MDIs for more than 30 years and today we are one of the world's leading manufacturers in this field. Our main markets are the EMEA regions, Central and Latin American countries and Russia. We are growing significantly in Asia.

Q **Please describe the partnership you have in place with Biocorp?**

A Our partnership with Biocorp enables V.A.R.I. to commercialise Inspair to all our inhalation market customers we are supplying today and in all countries where we have strong market presence. Together, Biocorp and V.A.R.I. additionally offer a comprehensive service taking care of all technical aspects relating to the MDI devices.

Q **What are the benefits of this partnership for Lindal?**

A This partnership with Biocorp enhances Lindal's product portfolio with a highly innovative offering in a context where connected health is becoming more and more popular. Patients are very keen on collecting their health data to actively manage their therapy by sharing it with their doctor. This technology is particularly interesting for people with chronic diseases, like asthma or COPD, helping them to adjust their treatment easily and accurately.

Q **Do you see a strong demand for connected solutions among your key customers?**

A Yes, pharma companies are well aware of issues with adherence and device use, which is one of the historical weaknesses for MDIs. Our customers are looking for innovative solutions to help patients during their self-care. Inspair will help patients to get the dose at the right time and in the right way, with the ultimate objective of improving their quality of life.

Q **In your opinion, what are the key differentiators of Inspair versus competitive solutions?**

A Beyond tracking medication use and sending reminders, Inspair assess the quality of administration and the proper use of the device. Inspair guides patients to all steps necessary for correct use of the medication, from shaking the MDI to improving co-ordination between firing and inhaling the product. This gives a strong advantage versus all other smart devices currently on the market which only record when patients fire the drug.

Being an add-on is another important advantage of Inspair. This can significantly reduce the cost of smart devices. Inspair has a shelf life of two years and it can be used for several inhalers during this period.

Q **What made you choose Biocorp as your preferred partner to launch a connected offering?**

A Biocorp is well known for its innovations. As a pioneer in the field of connected solutions for drug delivery devices and with in-depth experience of the diabetes market, Biocorp was the best partner for Lindal to explore these new smart technologies. Right from the first contact, Biocorp impressed us with their knowledge of respiratory applications. Their flexibility and reactivity made all communications very easy. It has been a pleasure to start this collaboration and I really look forward to the first projects together.

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Underpinning this, Biocorp has the ability to aim for any medical-grade classification the project demands, and meet the highest development and regulatory standards.

In parallel with numerous initiatives based on specific client requests, in anticipation of emerging market demand, Biocorp has launched an internal programme to develop a highly price competitive add-on solution for the injectable field which we believe will revolutionise monitoring of medication delivery in various therapeutic areas. Details will be disclosed this autumn at the PDA Universe of Prefilled Syringes and Injection Devices, October 22-23, 2019, Gothenburg, Sweden.

ABOUT THE COMPANY

For 25 years, Biocorp has been designing, developing and manufacturing medical devices for the pharmaceutical industry, enhancing drug reconstitution, safety, packaging and delivery. Today, Biocorp continues to innovate in medical plastics, bringing new solutions to the market such as the Newguard™, an integrated passive safety system for PFS compatible with nest, and Biopass™, a reconstitution system with an integrated needle ready to inject.

Recognised for its expertise in device R&D, Biocorp has incorporated software development capacities to develop connected drug delivery systems, including the Datapen™, a reusable smart pen injector that automatically transmits data to a treatment mobile app, helping patients to manage their treatment, and a range of add-ons, smart sensors for existing drug delivery devices (pen injectors, MDIs).

In addition to its R&D activities, Biocorp also provides manufacturing services for plastic injection, process assembly and blister packaging.

ABOUT THE AUTHORS

Eric Dessertenne has worked for the pharmaceutical and medical devices industries for many years. He holds a pharmaceutical degree from the University of Clermont-Ferrand (France), an MBA from ESSEC Business School (Paris, France) and is a graduate of the Therapeutic Chair of Innovation at ESSEC Business School. He began his career in the pharmaceutical industry working for Servier in France in the Corporate Strategy department and then moved to the Chinese subsidiary in Beijing, where he handled positions in the marketing and sales force department. Mr Dessertenne then joined LEK Consulting where he worked as a consultant in the Life Sciences and Private Equity practices. In 2014, he brought his experience and insights on market opportunities to Biocorp as Head of Business Development & Commercial Operations.

Arnaud Guillet is Business Development Director at Biocorp, in charge of finding partnerships and license opportunities for Biocorp's range of connected devices. Previously, Guillet worked for a healthcare consulting firm with a strong focus on connected health strategies for pharma and insurance companies and has additional past experience in the pharmaceutical industry (with Sanofi) and the insurance industry (with AXA). He graduated from HEC Paris, a major European business school.

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MALLYA
DATAPEN
INSPAIR
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