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BD INNOVATION FOR SUBCUTANEOUS DELIVERY OF LARGE-VOLUME COMPLEX BIOLOGICS

In this article, Beth McBride DiLauri, Director, Portfolio Marketing at BD Medical – Pharmaceutical Systems, summarises the results of a clinical study on the BD Libertas™ Wearable Injector. The results position the device as a viable alternative to traditional intravenous administration.

From human factors engineers in the medical affairs organisation to line operators in the company's manufacturing facilities, everyone at BD recognises that there is a patient at the centre of everything they do.

The BD Medical – Pharmaceutical Systems business regularly conducts a combination of primary market research, human factors studies and clinical research studies to understand the patient experience better. These insights are applied to injection device design and combination product development.

BD is focused on high-growth therapeutic areas, such as obesity and diabetes, as well as other leading chronic diseases. The company aims to apply its organisational insights into the patient experience, together with its injection expertise, to support treatment of chronic diseases and transition to new care settings while positively impacting patients.

BD recognises that the patient experience can impact adherence and treatment outcomes, as highlighted by the US Association for Healthcare Research and Quality (AHRQ) and other leading organisations.[1,2] The BD Libertas Wearable Injector programme is an example of BD's work to enable the transition of care to new settings by shifting from intravenous (IV) to subcutaneous (SC) delivery.

To de-risk that transition, BD conducted interviews with patients and pharma companies, as well as multiple generative and formative human factors studies in an iterative cycle, to inform usability and the patient experience with a wearable combination product. The company also conducted its own clinical study* of the BD Libertas Wearable Injector,

Figure 1: The BD Libertas™ Wearable Injector is designed to deliver SC injections of large-volume and/or high-viscosity fixed-dose complex biologics.

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Figure 2: The 2–5 mL BD Libertas™ Wearable Injector.

the results of which were published in *Clinical Translational Science* in 2021.[3]

This study assessed key parameters, including subject tolerability and device acceptability, which can impact the patient experience. Among the findings was confirmation that 100% of subjects were likely to use the BD Libertas Wearable Injector, if prescribed.[3] We see this as a leading indicator of positive patient experience and compliance.

STUDY RESULTS IN DETAIL

The BD Libertas Wearable Injector (Figure 1) is designed to deliver SC injections of large-volume (2–5 mL or 5–10 mL) and/or high-viscosity (up to 50 cP) fixed-dose complex biologics in home or clinical settings. The 2–5 mL device (Figure 2) was evaluated in an early feasibility clinical study, using a viscous placebo, for its functional performance, tissue effects, pain tolerability and overall acceptability among 52 healthy participants.

The study demonstrated consistent device functionality and acceptability across the study population tested. Reliable targeted delivery was demonstrated by the fact that 98.6% of injections were successfully delivered within the targeted SC tissue – 93.2% completely SC and 5.4% predominantly SC. When it came to tolerability, the transient injection pain was well tolerated, with rapid resolution. On the safety front, no serious adverse events were reported.

Consistent and reliable functional performance was demonstrated by the study, confirming that 5 mL (±5%) of the placebo bolus was delivered to the SC tissue. Consistent performance was demonstrated across injection sites, gender, age and body mass index (BMI) categories tested, with and without movement during injection. Three BMI categories were tested – normal, overweight and obese – and two age groups, 18–64 years and ≥65 years. There was consistent injection delivery and duration – with a mean of 5.42 minutes. Reliable adhesive and needle actuation/retraction performance was also documented.

Pain and tissue effects reported during the study were transient, with rapid resolution and broad acceptability. The results showed that ≥94% of participants found the transient pain acceptable at the end of the injection, with 96% reporting the injection site appearance acceptable after receiving all four injections. In addition, ≥92% said the device was comfortable to wear during injection and ≥98% found the adhesive removal acceptable. When it came to the abdomen and thigh injection sites, the 52 study participants found both sites equally acceptable overall – with 25% preferring the abdomen, 26.9% preferring the thigh and 46.2% having no preference (Figure 3).

KEY BENEFITS

The key benefits of the BD Libertas Wearable Injector include the fact that the patient does not have to do any filling or assembly of the device. There is also automatic needle insertion and retraction, and the device is fully mechanical – with no software or electronics components.

Compared with the IV route, SC administration offers[3–5]:

- Increased patient autonomy and convenience
- Reduced treatment cost, time and systemic effects
- Self or caregiver administration outside hospitals in new care settings, such as at home.

Added to that, wearable injectors may be capable of delivering wider volume and/or viscosity ranges than other delivery system options currently on the market.

> "The study demonstrated consistent device functionality and acceptability across the study population tested."

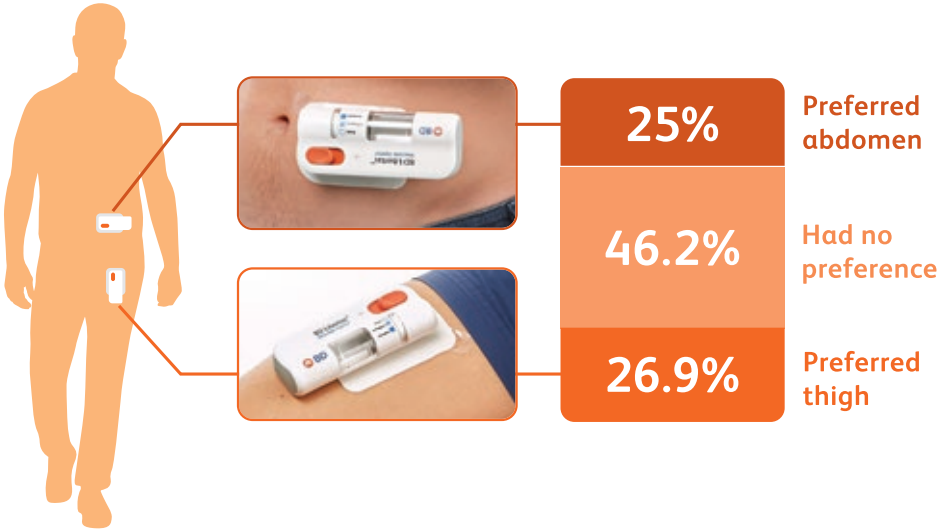

Figure 3: The 52 subjects found both injection sites equally acceptable.

"BD is committed to evolving its capabilities and portfolio to meet pharma companies' requirements, including supply chain stability, partner agility and sustainability."

BROAD PORTFOLIO

In addition to the patient experience, BD also recognises that there are multiple key decision criteria that inform pharma companies' choices when selecting the optimal device for a given combination product. BD is committed to evolving its capabilities and portfolio to meet pharma companies' requirements, including supply chain stability, partner agility and sustainability.

BD provides a broad portfolio of parenteral drug delivery systems, including glass and plastic prefillable syringes, safety and shielding systems and advanced drug delivery systems, including pens, autoinjectors and wearable and on-body injectors. The company also offers a wide range of combination product development testing services, leveraging its deep expertise partnering in combination product development.

BD Libertas™ Wearable Injector is a product in development; some statements are forward looking and subject to a variety of risks and uncertainties. BD Libertas Wearable Injector is a device component intended for drug-device combination products and not subject to FDA 510(k) clearance or separate EU CE marked certification.

**Early feasibility clinical study of investigational BD Libertas Wearable Injector evaluated 5 mL, non-Newtonian ~8cP SC placebo injections in 52 healthy adult subjects of ≥18.5 kg /m² BMI divided into two age groups (18–64 or ≥65 years) for functionality, tissue effects, subject tolerability and acceptability.*

ABOUT THE COMPANY

For 125 years, BD has pursued its purpose of *advancing the world of health™*. The company relentlessly commits to a promising future by developing innovative technologies, services and solutions, helping the healthcare community improve safety and increase efficiency. BD and its 77,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics.

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ABOUT THE AUTHOR

Beth McBride DiLauri is Director, Portfolio Marketing for BD Medical – Pharmaceutical Systems. Her responsibilities include developing portfolio strategies and leading commercialisation of drug delivery solutions for biologics. Ms McBride DiLauri has dedicated her career at BD to developing and executing portfolio strategies that impact patient care based on deep market and customer insights in pharma/biotech, medical devices, diagnostics and healthcare IT. She spent the early part of her career focused on structuring strategic partnerships, equity investments and acquisitions within BD and at Transcend Therapeutics, an early-stage biotechnology company that went public in 1997. Ms McBride DiLauri received a master's degree in Business Administration from the Tuck School of Business at Dartmouth College (NH, US) and a bachelor's degree in Psychology from Boston College (MA, US).