New Clinical Trial Data Demonstrates BD Libertas™ Wearable Injector as a Drug Delivery System

FRANKLIN LAKES, N.J., Dec. 9, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced publication of the results from a 52-subject human clinical trial with the BD Libertas™ Wearable Injector. The subcutaneous drug delivery system, currently in final phases of development, is designed as ready to use and to deliver drugs such as biologics with viscosities up to 50 cP in 2-5 mL and 5-10 mL configurations.

This research to evaluate the performance of the 5 mL BD Libertas™ device in human subjects, including tissue effects, skin reactivity and patient acceptance, confirms that the BD Libertas™ device delivered within an acceptable time period 5 mL of 8 cP injections to the abdomen and thigh regardless of subject age, gender, or BMI and with/without patient movement.

The application, use, and removal of the injector were found to be acceptable and 100% of subjects were likely to use the BD Libertas™ Wearable Injector if prescribed. No severe wheal, erythema, or bleeding was observed, and no unacceptable pain was noted at 24 hours post-injection.

The study represents the most recent in a series of over 50 BD-conducted pre-clinical and clinical studies intended to inform the design and measure the performance of the BD Libertas™ Wearable Injector, demonstrate feasibility of 2-10 mL biologic injections into subcutaneous tissue and characterize tissue response to large volume injections in human and animal subjects.

"These results show that BD Libertas™ Wearable Injector effectively delivers dose volumes up to 5 mL subcutaneously and may be leveraged by our pharmaceutical partners as a reliable platform for large volume delivery," said Eric Borin, Worldwide President, BD Pharmaceutical Systems. "BD is committed to working with our customers and the broader pharmaceutical market to meet their needs by enabling an expanded drug delivery design space. We are excited to share these results further with our partners and the broader market, to help accelerate and de-risk combination product development."

Biologics for subcutaneous delivery in larger dose volumes (>2mL) are now being developed by pharmaceutical companies to support life cycle management of therapies, including migration from intravenous to subcutaneous routes of administration. BD undertook this study, recognizing that limited clinical evidence exists in the public domain to support injection feasibility and tolerability with wearable injector solutions to deliver larger dose volumes (up to 5 mL).

A detailed analysis of the BD independently sponsored and conducted study has been published in *Clinical and Translational Science* (5 Dec 2020).

BD Libertas™ Wearable Injector is a product in development; some statements are forward looking and are 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.

About BD

BD is one of the largest global medical technology companies in the world and is *advancing the world of health* by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 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. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com.

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