BD Announces Milestone in Clinical Trial for Use of Bioabsorbable GalaFLEX LITE™ Scaffold in Breast Implant Revision Surgery

FRANKLIN LAKES, N.J., March 20, 2025 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the first patient treated in an Investigational Device Exemption (IDE) clinical trial intended to advance BD's efforts to achieve Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) for the use of GalaFLEX LITE™ Scaffold in decreasing capsular contracture (CC) recurrence during breast revision surgery.

Implant-based breast surgery is among the most common plastic surgery procedures performed each year in the U.S., and capsular contracture, a condition where the scar tissue naturally forming around the implant becomes unusually hard, causing pain and anatomical displacement, is its most frequent complication, with overall incidence ranging from 10% to 20%[1-5]. At advanced stages, CC necessitates treatment through surgical intervention, and when performed using conventional techniques, the risk of recurrence may be as high as 54%[6]. This multi-center Study of GalaFLEX LITE™ Poly-4-Hydroxybutyrate (P4HB) **S**caffold in **T**reatment of Capsular **C**ontracture after Breast Implant Augmentation (STANCE) is a pivotal study that aims to evaluate whether GalaFLEX LITE™ Scaffold, when used in breast revision surgery, decreases the likelihood of CC and or malposition. The trial further positions BD as a leader in advanced biomaterial science – driving transformative change in how tissue is reconstructed.

"This milestone marks a significant advancement in our efforts to achieve FDA Premarket Approval for our first breast indication for GalaFLEX LITE™ Scaffold and reinforces the company's commitment to improving patient outcomes through innovative technologies that reduce surgical complications," said Rian Seger, worldwide president of the BD Surgery business. "Our team has worked closely with the FDA to help address a critical medical complication arising from implant-based breast surgery, and the first patient treated brings us closer to delivering a much-needed solution."

GalaFLEX LITE™ Scaffold is engineered to conform to the desired anatomical structure and provide immediate strength and stability throughout the wound healing period[7]. It is made from P4HB, a fully absorbable, biologically-derived polymer with more than 10 years of clinical use supporting hernia repair and other plastic and reconstructive procedures where soft tissue weakness or deficiency exists.

"Participating in this trial underscores our commitment to innovation and providing the best evidence-based care for patients suffering from capsular contracture, offering them hope and solutions for the future," said Dr. Shawna Kleban, the board-certified plastic surgeon who performed the inaugural procedure. "This trial allows participants to help identify a solution for themselves and for future patients."

Dr. Caroline Glicksman, the study's National Principal Investigator from Sea Girt, New Jersey added, "As an early adopter of the P4HB technology, we are excited to see the potential benefits of GalaFLEX™ LITE Scaffold in improving patient outcomes in breast revision surgeries. This study is crucial in providing the data FDA requires for a specific breast indication that will advance our ability to deliver better solutions for breast surgery patients."

The following five sites are currently enrolling patients:

- **HKB Cosmetic Surgery** (Various Locations, North Carolina) – Principal Investigator: Dr. Bill Kortesis; Sub-Investigators: Dr. Gaurav Bharti, Dr. Shawna Kleban, Dr. Brett Baker
- **Billington Plastic Surgery** (St. Petersburg, Florida) – Principal Investigator: Dr. Alicia Billington
- **The Practice Plastic Surgery** (Beverly Hills, California) – Principal Investigator: Dr. Kelly Killeen; Sub-Investigator: Dr. Lisa Cassileth
- **Plastic Surgery Institute of New York** (New York, New York) – Principal Investigator: Dr. Matthew DelMauro; Sub-Investigator: Dr. Adam Schaffner
- **Newport Plastic and Reconstructive Surgery Associates** (Newport Beach, California) – Principal Investigator: Dr. Hisham Seify
- **Essential Medical Research** (Tulsa, Oklahoma) – Principal Investigator: Dr. John Tedesco

The trial is expected to enroll at least 250 patients across 40 investigative sites and aims to demonstrate the device's safety and efficacy in breast implant revision surgery to treat capsular contracture. BD is committed to scientific rigor and patient safety and aims to continue proactive FDA engagement in developing products that enhance women's health care.

STANCE Study
STANCE (NCT05945329) Study is an ongoing prospective, randomized, controlled, multi-center study to assess the safety and

efficacy of GalaFLEX LITE™ scaffold in revision surgery for reduction of capsular contracture recurrence and/or malposition in implant-based breast augmentation patients versus patients undergoing conventional revision surgery with no supportive matrix or acellular dermal matrix (ADM). Patients will be randomized 2:1 to receive either GalaFLEX LITE™ Scaffold or standard care (no ADM or matrix placement).

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 more than 70,000 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 or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X (formerly Twitter) @BDandCo or Instagram @becton_dickinson.

Forward-Looking Statements

This press release contains certain forward-looking statements regarding the Premarket Approval clinical trial for GalaFLEX LITE™ Scaffold. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, including, without limitation, clinical trial outcomes and progress, obtaining regulatory clearance and approval, including achieving FDA Premarket Approval for the first breast indication for GalaFLEX LITE™ Scaffold, competitive factors, including the development of new technologies or products by other companies, changes in healthcare practices and patient preferences, future regulatory and market conditions, or other factors listed in BD's 2024 Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. BD expressly disclaims any undertaking to update any forward-looking statements set forth herein to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

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7. Preclinical data on file. Results may not correlate to clinical outcomes.

For more information about GalaFLEX LITE™ scaffold, please visit www.galateasurgical.com.

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