BD Extends Leadership in Advanced Tissue Regeneration Through Continued Clinical Innovation

STANCE trial surpasses a key enrollment milestone, advancing the clinical evaluation of GalaFLEX LITE™ Scaffold and generating evidence to support its use in breast revision surgery for capsular contracture

FRANKLIN LAKES, N.J., Aug. 27, 2026 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced a significant milestone in its advanced tissue regeneration strategy and expansion efforts with the STANCE clinical trial evaluating GalaFLEX LITE™ Scaffold in breast revision surgery for capsular contracture. The study has reached its first enrollment milestone, with 274 patients treated across 33 active U.S. sites, triggering the first planned interim analysis. This milestone places enrollment beyond 50% of the trial's maximum planned enrollment, expected to range from 250 to 530 patients under the adaptive design and prespecified criteria.

Implant-based breast surgery is among the most common plastic surgery procedures performed each year in the U.S., and capsular contracture is its most frequent complication. The condition occurs when scar tissue that naturally forms around the implant becomes unusually hard, potentially causing pain and anatomical displacement. Published estimates show overall incidence ranges from 10% to 20%[1–5], and when advanced capsular contracture is treated using conventional surgical techniques, the risk of recurrence may be as high as 54%[6]. This varies substantially by surgical technique, patient characteristics and follow-up duration.

"STANCE reflects our commitment to advancing innovation in soft tissue support and expanding the impact of advanced tissue regeneration in areas where patients continue to face significant clinical challenges," said Art Stephen, global R&D Leader of Surgery at BD. "By evaluating GalaFLEX LITE™ Scaffold in breast revision surgery for capsular contracture, we are generating clinical evidence that could help support a new indication while building on the established performance of our P4HB technology platform. We are grateful to the investigators, clinical sites and patients whose participation made this achievement possible."

"Capsular contracture remains a significant challenge in implant-based breast surgery, and robust clinical evidence is needed to advance patient care," said Caroline Glicksman, MD, FACS, MSJ, a board-certified plastic and reconstructive surgeon in Sea Girt, New Jersey, and the study's national principal investigator. "Enrollment has progressed consistently across participating sites, and we look forward to continuing participant follow-up through each scheduled study milestone as the study generates clinical data intended to support an FDA Premarket Approval application for a breast indication for GalaFLEX LITE™ Scaffold."

GalaFLEX LITE™ Scaffold is engineered to conform to the desired anatomical structure and provide strength and stability throughout the wound healing period[7]. It is composed of poly-4-hydroxybutyrate (P4HB), the only bioabsorbable and biologically derived polymer used for soft tissue support. P4HB has more than 10 years of clinical use supporting hernia repair and other plastic and reconstructive procedures where soft tissue weakness or deficiency exists.

STANCE Study
STANCE (NCT05945329) Clinical Trial 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).

For more information about GalaFLEX LITE™ scaffold, please visit galaflex.bd.com.

About BD
BD is one of the world's largest pure-play medical technology companies with a Purpose of *advancing the world of health™* by driving innovation across medical essentials, connected care, biopharma systems and interventional. The company supports those on the frontlines of healthcare by developing transformative technologies, services and solutions that optimize clinical operations and improve care for patients. Operating across the globe, with more than 60,000 employees, BD delivers billions of products annually that have a positive impact on global healthcare. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase clinical efficiency, improve safety and expand access to healthcare. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X @BDandCo or Instagram @becton_dickinson.

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7. Preclinical data on file. Results may not correlate to clinical outcomes.
8. Study of GalaFLEX LITE™ Poly-4-Hydroxybutyrate (P4HB)**S**caffold in **T**reatment of Capsular **C**ontracture after Breast Implant Augmentation (STANCE)

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