Boston Scientific

Boston Scientific and BioForm Medical Announce FDA Approval of Coaptite® Injectable Implant

NATICK, Mass. and SAN MATEO, Calif, May 10 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) and BioForm Medical, Inc. today announced United States Food and Drug Administration approval of BioForm Medical's Coaptite Injectable Implant for the treatment of female stress urinary incontinence. The companies also announced that they have signed an agreement giving Boston Scientific exclusive distribution rights for the Coaptite Injectable Implant in the United States. The product is expected to launch in the U.S. immediately.

"Boston Scientific is excited to distribute this next-generation bulking agent," said Eric Goorno, President of the Urology and Gynecology businesses at Boston Scientific. "This agent is designed to offer the durability of a synthetic product in addition to procedural ease-of-use. Coaptite is a natural strategic fit for our women's health business and rounds out our product offering for the treatment of stress urinary incontinence."

"Approval for Coaptite Injectable Implant and our new relationship with Boston Scientific are important milestones for BioForm Medical," said Steven Basta, President and Chief Executive Officer of BioForm. "We believe that Boston Scientific is the ideal distributor for the Coaptite Injectable Implant. Their strong presence and experience in offering the market different treatment options for female stress urinary incontinence will be instrumental in positioning Coaptite Injectable Implant as a leader in the bulking market."

The Coaptite Injectable Implant is a next-generation bulking agent. Clinical trial results indicated fewer re-injections and less material volume versus other approved bulking agents while maintaining the durability characteristics of a synthetic product. The combination of calcium hydroxylapatite particles and the sodium carboxymethylcellulose carrier gel form a scaffold that promotes tissue infiltration. The Coaptite Injectable Implant particles are composed of the same components that are found in bone and teeth and are biocompatible.

Clinical trial results

BioForm Medical also announced results from a multi-center clinical study for the treatment of stress urinary incontinence comparing the use of Coaptite Injectable Implant versus bovine collagen. Coaptite Injectable Implant demonstrated that 63 percent of patients treated with Coaptite Injectable Implant were improved at 12 months. Coaptite Injectable Implant also demonstrated that total implant volumes were significantly less ($p<0.0001$) versus the control group (4 ml vs. 6.8 ml).

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: http://www.bostonscientific.com/.

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with clinical trials, the regulatory approval process, reimbursement policies, commercialization of new technologies, litigation, the Company's overall business strategy and other factors described in the Company's filings with the Securities and Exchange Commission.

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