FDA Approves Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants

The Associated Press

IRVINE, Calif.--(BUSINESS WIRE)--Feb 20, 2013--Allergan, Inc. (NYSE: AGN) today announced that the company has received approval from the U.S. Food and Drug Administration (FDA) to market the Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants for use in breast reconstruction, augmentation and revision surgery.

“The FDA approval of Natrelle® 410 shaped gel implants provides an important new alternative to traditional round implants for women considering breast augmentation, reconstruction or revision surgery,” said David E.I. Pyott, Allergan’s Chairman of the Board, President and Chief Executive Officer. “The Natrelle® 410 is the most selected shaped gel implant in markets where the product is already available, such as Europe and Canada. We are pleased that the FDA has recognized the benefits and safety of the Natrelle® 410, and has now made the product available as an additional option for women in the United States.” The Natrelle® 410 shaped gel implant is designed to mimic the slope of the breast and is filled with a highly cohesive silicone gel, which is intended to enable the implant to hold its shape over time while remaining soft to the touch.

The FDA approval of the Natrelle® 410 shaped gel implants was based on an extensive review of various studies and data, including pre-clinical device testing and clinical data from Allergan’s 10-year prospective, multi-center pivotal study, involving nearly 1,000 women who have undergone breast reconstruction, augmentation or revision surgery.

“For many patients, round silicone and saline breast implants are good options. For others, they may not provide the aesthetic outcome they desire,” said Scott L. Spear, M.D., FACS, Chairman, Department of Plastic Surgery, Georgetown University School of Medicine. “As well, patients may have minimal breast tissue remaining after the removal of a tumor or have lost breast volume over the years, so the option of a shaped breast implant designed with an anatomical shape that lasts over time is an important one as it may help these patients obtain the aesthetic look they are seeking.” Allergan requires surgeons to complete a certification program, which includes instruction on surgical techniques and patient selection, before they are able to offer the Natrelle® 410 shaped gel implant option to their patients. Please visit www.allerganacademy.com for more information and to complete the certification program. Women interested in seeking a consultation about the Natrelle® 410 breast implant can locate qualified surgeons by visiting the Natrelle® website at www.natrelle.com.

Conditions of approval - Submission of the final report for the 10-year clinical study.

Continued follow-up through 5 years of patients in the Continued Access Revision/Reconstruction Expansion (CARE) and Continued Access studies. A large study of newly enrolled patients followed for 10 years. Participation in developing the National Breast Implant Registry and contributing data from the large new enrollment study upon implementation of the registry. Completion of case-control studies on five rare disease outcomes. Completion of a focus group study to evaluate the patient labeling. Annual reporting of analyses conducted on all 410 devices explanted and returned to Allergan. Important Natrelle ® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant Safety Information Indications: Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. Breast reconstruction. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery. Contraindications Breast implant surgery should NOT be performed in: Women with active infection anywhere in their body. Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions. Women who are currently pregnant or nursing. Warnings There are many factors that can affect the outcome and appropriate timing of a breast reconstruction Many of the changes to breasts following implantation cannot be undone, and if the implants are removed without replacement, dimpling, wrinkling, or puckering may be experienced Breast implants are not lifetime devices, and additional unplanned surgeries will likely be necessary In order to screen for silent rupture, regular MRI screenings are recommended Precautions Safety and effectiveness have not been established in patients with the following: Autoimmune diseases (for example, lupus and scleroderma) A weakened immune system (for example, currently taking drugs that weaken the body’s natural resistance to disease) Planned chemotherapy following breast implant placement Planned radiation therapy to the breast following breast implant placement Conditions that interfere with wound healing and blood clotting Reduced blood supply to breast tissue Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait for resolution or stabilization of these conditions prior to undergoing breast implantation surgery. Adverse events The most commonly reported adverse events for Natrelle® 410 Breast Implants are: reoperation, implant removal (with and without replacement), implant rupture, and Baker grade III/IV capsular contracture.

Other potential complications include: swelling, implant malposition, pain, ptosis, infection, changes in breast sensation, nipple complications, seroma, delayed wound healing, hematoma, redness, scarring, asymmetry, wrinkling/rippling, extrusion, bruising, implant palpability/visibility, upper pole fullness, and necrosis.

Important: For full safety information please visit www.natrelle.com or call Allergan Product Support at 1-800-433-8871.

Caution: Natrelle® 410 Breast Implants are available by prescription only.

About Allergan, Inc.
Allergan is a multi-specialty health care company established more than 60 years ago with a commitment to uncover the best of science and develop and deliver innovative and meaningful treatments to help people reach their life's potential. Today, we have approximately 10,800 highly dedicated and talented employees, global marketing and sales capabilities with a presence in more than 100 countries, a rich and ever-evolving portfolio of pharmaceuticals, biologics, medical devices and over-the-counter consumer products, and state-of-the-art resources in R&D, manufacturing and safety surveillance that help millions of patients see more clearly, move more freely and express themselves more fully. From our beginnings as an eye care company to our focus today on several medical specialties, including eye care, neurosciences, medical aesthetics, medical dermatology, breast aesthetics, obesity intervention and urologics, Allergan is proud to celebrate more than 60 years of medical advances and proud to support the patients and physicians who rely on our products and the employees and communities in which we live and work. For more information regarding Allergan, go to: www.allergan.com.

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