

**Allergan-Issued Statement on
Rare Incidence of Anaplastic Large Cell Lymphoma (ALCL) in Patients with Breast Implants**

Over the past 15 years, there have been very rare, sporadic reports of anaplastic large cell lymphoma (ALCL), a rare subtype of lymphoma, occurring in women both with and without breast implants. Several studies have shown that the overall rate of lymphoma is no greater in patients with breast implants than in the general population. As opposed to systemic ALCL which can occur anywhere in the body, these rare cases have predominantly appeared in the scar tissue that forms around the implant, and when occurred, most of the patients have responded to a variety of treatments, including simple removal of the implant and surrounding scar capsule.

Reports of ALCL in patients with breast implants are extremely rare and are not to be mistaken for breast cancer. Of the estimated 5 to 10 million women who have breast implants worldwide, only 34 cases of ALCL have been identified and reported in peer-reviewed literature over nearly 15 years, since 1997.

As the FDA stated in its communication, based on available information, there is no data to support a causal relationship between breast implants and ALCL and the Agency reinforces that FDA-approved breast implants, when used as labeled, are safe and effective.

The data does indicate that the incidence of ALCL is very low, even in breast implant patients. In those sporadic reports of ALCL in breast implant patients, the etiology is unknown. Furthermore, it is not possible to identify a type of implant (silicone versus saline) or a reason for implant (reconstruction versus aesthetic augmentation) associated with a smaller or greater risk for this very rare occurrence of ALCL, as the rarely reported cases have involved textured and smooth surfaced, and both saline and silicone filled implants.

Allergan has been in ongoing dialogue with the FDA and all other regulatory authorities around the world about these rarely reported cases of ALCL in patients with breast implants. The company also sponsored a scientific advisory committee to independently evaluate reports of suspected ALCL in patients with breast implants and carefully assess and review each case. The members of this expert committee included Peter Boyle, PhD, DSc at the International Prevention Research Institute, George P Canellos, MD, at the Dana-Farber Cancer Institute, Bruce A Chabner, MD, at Massachusetts General Hospital Cancer Center, Gabriel N Hortobagyi, MD and Stephen Kronowitz, MD, at MD Anderson Cancer Center, and Marshall E Kadin, MD, at Boston University School of Medicine. All are available for commentary on this matter.

In addition, Allergan has provided ongoing communication to the medical community regarding these rare reports of ALCL in breast implants and created an online scientific web site for health care providers' access, summarizing all published public literature on the subject of ALCL.

Allergan supports the recommendations issued by the FDA today to physicians and patients, advising physicians to remain diligent in their monitoring of any symptoms of ALCL in breast implant patients, regardless of its rare occurrence, and not to recommend prophylactic breast implant removal in patients without symptoms or other abnormalities. In addition, Allergan agrees that patients with breast implants should not alter their routine medical care, and continue to undergo routine mammography screenings and speak with their physician if they suspect any abnormality.

Patient safety is Allergan's absolute first priority and we continue all efforts to collect and analyze further information about the very rare occurrence of ALCL in patients with breast implants. We are in ongoing dialogue with the FDA to evaluate the best course of action for health care providers and patients and adjust these recommendations as needed.

Allergan is deeply committed to providing important, up-to-date information about the safety and efficacy of our products to physicians and patients so they can make the most informed treatment decisions.

Breast implants are among the most studied medical devices in existence, with thousands of peer-reviewed and published reports on studies, including robust epidemiological studies supporting their safe use. The safety of Allergan's *Natrelle*[®] breast implants is supported by Allergan's extensive pre-clinical device testing, the use of breast implants in millions of women worldwide over the past 25 years. Complete safety information about *Natrelle*[®] breast implants can be found at www.natrelle.com.

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