



# **NEWS RELEASE**

## **MEDIA CONTACTS:**

**Mark Marmur**

Assoc VP, Communication and Public Relations

Allergan Inc.

[mark.marmur@allergan.com](mailto:mark.marmur@allergan.com)

T. +44 7725 758 677

**Cassandra Collier**

Allergan Australia Pty Ltd

[cassandra.collier@allergan.com](mailto:cassandra.collier@allergan.com)

T. 0488 118 256

## **Allergan Australia Provides Statement on Therapeutic Goods Administration (TGA) Proposed Regulatory Action on Textured Breast Implants**

**Sydney, Australia -- July 11, 2019 --** Allergan Australia today commented on the Therapeutic Goods Administration (TGA)'s proposed regulatory action on textured breast implants.

“Patient safety remains Allergan’s highest priority. The Company is actively reviewing the TGA’s proposed regulatory action on Natrelle BIOCELL® textured breast implants and tissue expanders, as well as its invitation to submit response to the proposed action as a matter of priority. Allergan continues to stand behind the benefit/risk profile of its breast implants, including BIOCELL® textured breast implant products.

Whether mammoplasty, breast reconstruction or breast augmentation procedures, breast implants play a vital role in a patient’s physical and psychological health. Surgeons need a variety of implant types to address the variable nature of breast anatomy and pathology to meet the needs of individual patients. With every medical procedure, there are benefits and risks, and Allergan continues to believe the benefit/risk profile of BIOCELL® textured breast implant products remains positive.”

The proposed regulatory action is the result of a TGA review of all textured breast implants included in the Register. The review involved surface testing of breast implants along with statistical and clinical analyses concerning the incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

**There continues to be no recommendation from any health authority, including the TGA, for asymptomatic patients to have their textured breast implants removed or replaced prophylactically.**

Australian patients with questions or concerns about BIOCELL® textured breast implant products should, in the first instance, consult with their healthcare professional. Patients and healthcare professionals can also contact Allergan's Medical Information team at [medinfo.australia@allergan.com](mailto:medinfo.australia@allergan.com) or by phone at 1800 252 224.

### **About Allergan plc**

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a global pharmaceutical leader focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world. Allergan markets a portfolio of leading brands and best-in-class products primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. As part of its approach to delivering innovation for better patient care, Allergan has built one of the broadest pharmaceutical and device research and development pipelines in the industry.

With colleagues and commercial operations located in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at [www.Allergan.com](http://www.Allergan.com).

### **Forward-Looking Statement**

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective on existing trends and information as of the date of this release. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; the impact of uncertainty around timing of generic entry related to key products, including RESTASIS®, on our financial results; risks associated with divestitures, acquisitions, mergers and joint ventures; risks related to impairments; uncertainty associated with financial projections, projected cost reductions, projected debt reduction, projected synergies, restructurings, increased costs, and adverse tax consequences; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2018 and Allergan's Quarterly Report on Form 10-Q for the period ended March 31, 2019. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.