

## **ALLERGAN ANNOUNCES U.S FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL OF LATISSE™ -- FIRST AND ONLY TREATMENT APPROVED BY THE FDA FOR HYPOTRICHOSIS OF EYELASHES**

### **New Prescription Product Increases Length, Thickness and Darkness of Eyelashes**

**(IRVINE, Calif., December 26, 2008)** – Allergan, Inc. (NYSE: AGN) today announced the U.S. Food and Drug Administration (FDA) has approved LATISSE™ (bimatoprost ophthalmic solution) 0.03% as a novel treatment for hypotrichosis of the eyelashes. Eyelash hypotrichosis is another name for having inadequate or not enough eyelashes. LATISSE™ is the first and only science-based treatment approved by the FDA to enhance eyelash prominence as measured by increases in length, thickness and darkness of eyelashes.

“LATISSE™ fulfills a significant and previously unmet need in the medical aesthetic marketplace with a product approved by the FDA that increases the growth of eyelashes, making them longer, thicker and darker,” said Scott Whitcup, M.D., Allergan’s Executive Vice President of Research and Development. “As the global leader in medical aesthetics, LATISSE™ exemplifies our continuing commitment to developing innovative treatments that are studied in well-controlled clinical trials, manufactured to pharmaceutical standards, appropriately labeled for use, and available to consumers as a prescription product.”

Available only through a doctor, LATISSE™ is a once-daily prescription treatment applied to the base of the upper eyelashes with a sterile, single-use-per-eye disposable applicator. LATISSE™ users can expect to experience longer, fuller and darker eyelashes in as little as eight weeks, with full results in 16 weeks. To maintain effect, continued treatment with LATISSE™ is required. If use of LATISSE™ is discontinued, eyelashes will gradually return to where they were prior to treatment over a period of weeks to months (average eyelash hair cycle).

Similar to Allergan’s other medical aesthetic offerings, the benefits of LATISSE™ are derived from scientific evidence, its quality formulation, and medical origin. LATISSE™ was clinically tested in a pivotal Phase III, multi-center, double-masked, placebo-controlled study to assess its safety and efficacy in which all endpoints (improved eyelash prominence, length, thickness and darkness) were met. In addition, like BOTOX® (botulinum toxin type A), which was first approved by the FDA as a medical treatment for eye disorders and was later found to have an aesthetic benefit, bimatoprost, the active ingredient in LATISSE™, was first approved in 2001 as a medical product to lower intraocular pressure in people with open-angle glaucoma or ocular hypertension. Patients treated with bimatoprost for this specific eye condition experienced eyelash growth as a side effect. The long-term safety of bimatoprost for therapeutic use has been recognized by the medical community and well established based on use in 32 clinical trials involving more than 5,700 glaucoma patients and more than 13 years of clinical trial experience. Given the existing and substantial clinical and post-marketing safety data with bimatoprost solution 0.03%, coupled with the positive results from the Phase III LATISSE™ study, LATISSE™ provides patients a clinically meaningful aesthetic benefit with a favorable safety profile.

Bimatoprost is the active pharmaceutical ingredient in the formulation of LATISSE™ and is a structural prostaglandin analog, a lipid compound derived from fatty acids designed to bind to prostaglandin (PG) receptors. PG receptors are present in hair, particularly in the dermal papilla and outer root sheath. Although the precise mechanism of action is unknown, PG receptors are thought to be involved in the development and regrowth of the hair follicle,<sup>i</sup> by increasing the percent of hairs in, and the duration of, the anagen or growth phase.

“As an oculoplastic surgeon who has treated both medical eye conditions as well as aesthetic needs, I have extensive knowledge of and experience with the established therapeutic safety profile for bimatoprost,” said Steven Fagien, M.D., F.A.C.S., in private practice at Aesthetic Eyelid Plastic Surgery in Boca Raton, Florida, and LATISSE™ clinical investigator. “In the clinical study with LATISSE™, I observed statistically significant differences in eyelash growth and resulting patient satisfaction. Now that LATISSE™ is FDA approved, I look forward to prescribing it to my patients who will enjoy the benefits of more prominent eyelashes while I remain confident in the treatment’s favorable safety profile.”

LATISSE™ will be available in the United States by prescription only and is subject to all U.S. guidelines applicable to dispensing a prescription product. Based on today’s FDA approval, Allergan expects to launch the product nationwide in the first quarter of 2009. Doctors and consumers are encouraged to visit [www.latisse.com](http://www.latisse.com) for further product and prescribing information.

Allergan estimates global peak sales of LATISSE™ could exceed \$500 million per year. As the exclusive U.S. and foreign patent owner, Allergan obtains the rights to the use of bimatoprost and other prostaglandins and prostaglandin analogs as a treatment to stimulate eyelash growth.

### **LATISSE™ Clinical Development Program**

In the pivotal Phase III study, 278 healthy adult patients with no active ocular disease and with baseline minimal or moderate eyelash prominence were randomized to apply either LATISSE™ or vehicle to both upper eyelid margins once daily for 16 weeks. The primary efficacy endpoint was overall eyelash prominence at the end of the 16-week treatment period as measured by a ≥1-grade improvement on a 4-point Global Eyelash Assessment Scale. Secondary efficacy endpoints were eyelash length, thickness, and darkness as determined by Digital Image Analysis of patient photographs taken in a standardized manner.

All of the endpoints in the LATISSE™ pivotal trial were met. By the end of the 16-week treatment period, patients treated with LATISSE™ experienced statistically significant greater improvement ( $p < 0.0001$  for each endpoint) than those in the vehicle group in the measurements of eyelash prominence, length, thickness and darkness. LATISSE™ was also well tolerated with the most commonly reported adverse events being non-serious and cosmetic in nature. Common adverse events observed in the clinical trial included eye redness (3.6%), itchy eyes (3.6%) and skin hyperpigmentation (2.9%).

### **Important LATISSE™ Safety Information**

LATISSE™ solution is intended for use on the skin of the upper eyelid margins at the base of the eyelashes. DO NOT APPLY to the lower eyelid. If you are using LUMIGAN® or other products in the same class for elevated intraocular pressure (IOP), or if you have a history of abnormal IOP, you should only use LATISSE™ under the close supervision of your doctor.

LATISSE™ use may cause darkening of the eyelid skin which may be reversible. Although not reported in clinical studies, LATISSE™ use may also cause increased brown pigmentation of the colored part of the eye which is likely to be permanent.

It is possible for hair growth to occur in other areas of your skin that LATISSE™ frequently touches. Any excess solution outside the upper eyelid margin should be blotted with a tissue or other absorbent material to reduce the chance of this from happening. It is also possible for a difference in eyelash length, thickness, fullness, pigmentation, number of eyelash hairs, and/or direction of eyelash growth to occur between eyes. These differences, should they occur, will usually go away if you stop using LATISSE™.

The most common side effects after using LATISSE™ solution are an itching sensation in the eyes and/or eye redness. This was reported in approximately 4% of patients. LATISSE™ solution may cause other less common side effects which typically occur on the skin close to where LATISSE™ is applied, or in the eyes. These include skin darkening, eye irritation, dryness of the eyes, and redness of the eyelids.

If you develop a new ocular condition (e.g., trauma or infection), experience a sudden decrease in visual acuity, have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, you should immediately seek your doctor's advice concerning the continued use of LATISSE™ solution.

Full prescribing information is available at [www.latisse.com](http://www.latisse.com) and [www.allergan.com](http://www.allergan.com).

### **Important BOTOX® and BOTOX® Cosmetic (Botulinum Toxin Type A) Information**

BOTOX® is approved for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.

BOTOX® is approved for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.

And BOTOX® is approved for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

BOTOX® Cosmetic is approved for the temporary treatment of moderate to severe frown lines between the brows in people ages 18 – 65.

### **Important Safety Information**

#### **Who should not be treated with BOTOX® and BOTOX® Cosmetic**

BOTOX® injections should not be given to people who have an infection where the physician proposes to inject. They should not be given to people who are known to be sensitive to any ingredient in the BOTOX® product.

## **Warnings**

Serious heart problems and serious allergic reactions have been reported rarely. If you think you're having an allergic reaction or other reaction, such as difficulty swallowing, speaking, or breathing, call your doctor immediately.

Patients with certain neuromuscular disorders such as ALS, myasthenia gravis, or Lambert-Eaton syndrome may be at increased risk of serious side effects.

Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia (difficulty swallowing) and respiratory compromise from typical doses of BOTOX<sup>®</sup> and BOTOX<sup>®</sup> Cosmetic.

Dysphagia (difficulty swallowing) is a commonly reported adverse event following treatment of cervical dystonia patients with all botulinum toxins. In these patients, there are reports of rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube.

## **Precautions**

Patients or caregivers should be advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

## **Side Effects**

Localized pain, infection, inflammation, tenderness, swelling, redness and/or bruising may be associated with the injection.

In cervical dystonia, the most common side effects following injection include difficulty swallowing (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

In blepharospasm, the most common side effects following injection include ptosis (20.8%), inflammation of the cornea (6.3%), and eye dryness (6.3%).

In strabismus, the most common side effects following injection include ptosis (15.7%) and vertical deviation (16.9%).

In severe primary axillary hyperhidrosis, the most common side effects (3-10% of patients) include injection-site pain and bleeding, non-underarm sweating, infection, sore throat, flu, headache, fever, neck or back pain, itching and anxiety.

The most common side effects following BOTOX<sup>®</sup> Cosmetic injections include temporary eyelid droop and nausea.

Please see full product information at [www.botox.com](http://www.botox.com) and [www.botoxcosmetic.com](http://www.botoxcosmetic.com).

## **Forward-Looking Statements**

This press release contains "forward-looking statements," including the statements by Dr. Whitcup, Dr. Fagien and other statements regarding the safety, effectiveness, approval and market potential associated with LATISSE<sup>™</sup>, BOTOX<sup>®</sup> and BOTOX<sup>®</sup> Cosmetic. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Allergan's expectations and projections. Risks and uncertainties include, among other things, general industry, biologic and pharmaceutical market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and

regulatory processes; inconsistency of treatment results among patients; potential difficulties in manufacturing; general economic conditions; and governmental laws and regulations affecting domestic and foreign operations. Allergan expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Additional information concerning these and other risk factors can be found in press releases issued by Allergan, as well as Allergan's public periodic filings with the Securities and Exchange Commission, including the discussion under the heading "Risk Factors" in Allergan's 2007 Form 10-K and subsequently filed Forms 10-Q. Copies of Allergan's press releases and additional information about Allergan are available on the World Wide Web at [www.allergan.com](http://www.allergan.com) or you can contact the Allergan Investor Relations Department by calling 1-714-246-4636.

### **About Allergan, Inc.**

Founded in 1950, Allergan, Inc., with headquarters in Irvine, California, is a multi-specialty health care company that discovers, develops and commercializes innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential - to see more clearly, move more freely, express themselves more fully. The Company employs more than 8,500 people worldwide and operates state-of-the-art R&D facilities and world-class manufacturing plants. In addition to its discovery-to-development research organization, Allergan has global marketing and sales capabilities with a presence in more than 100 countries.

Allergan Medical, a division of Allergan, Inc., offers the most comprehensive, science-based, aesthetic product offerings under its *Total Facial Rejuvenation*<sup>™</sup> portfolio, including BOTOX<sup>®</sup> Cosmetic; hyaluronic acid and collagen-based dermal fillers; and physician-dispensed skin care products. Allergan Medical also offers the industry's widest range of silicone gel-filled and saline-filled breast implant options for reconstructive and aesthetic breast surgery, and leading minimally invasive devices for obesity intervention treatment.

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<sup>i</sup> Tosti et al., 2004