



GALDERMA DELIVERS INNOVATION IN DERMAL FILLERS WITH THE LAUNCH OF TWO FIRST-IN-CLASS FDA PIVOTAL PHASE III TRIALS

Significant R&D Investments Support Fast-growing Restylane® Silk and Restylane® Lyft Dermal Filler Brands

FORT WORTH, Texas - February 26, 2015 – Galderma, a global leader focused on medical solutions in skin health, today announced that it will be initiating two pivotal Phase III trials focused on fast growing Restylane® brands. The trials will evaluate the safety and efficacy of Restylane® Lyft for hand augmentation and volume loss in the back of the hands and the safety of Restylane® Silk when administered via a cannula for lip enhancement and the treatment of lines around the mouth.

“Galderma is committed to advancing skin health and wellness while driving innovation to enable healthcare providers to advance patient care,” said Kelly Huang, Ph.D., Vice President and General Manager of Aesthetic and Corrective business for Galderma USA. “With 20 years of research and millions of treatments worldwide, the Restylane® family of products continues to evolve and deliver effective and proven aesthetic solutions to both healthcare professionals and their patients.”

Restylane® Silk Cannula Study

The pivotal Phase III trial is a multi-center U.S. study designed to assess the safety and tolerability of Restylane® Silk when delivered via a microcannula.

“With the demand for injectable lip fillers on the rise, we are constantly looking for innovative tools that will enable us to deliver safe results while minimizing side effects,” said Dr. Arthur Swift, Plastic Surgeon, Montreal, Canada.

Restylane® Lyft Hand Rejuvenation Study

The pivotal Phase III trial is a randomized, controlled, multi-center U.S. study designed to assess the safety, tolerability and efficacy of the use of Restylane® Lyft to treat loss of volume in the hands. Galderma will be the first company to conduct a study on the use of the hyaluronic acid filler in the hands. Currently Restylane® Lyft is FDA approved for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as nasolabial folds, and for subcutaneous to supraperiosteal implantation for cheek augmentation and correction of age-related midface contour deficiencies in patients over the age of 21. If successful, this trial could lead to the third major indication for Restylane® Lyft.

“As a participant in this new clinical trial for Restylane® Lyft, I look forward to being one of the first to explore and contribute to the future of aesthetic treatments,” said Dr. Ellen Marmur, Dermatologist, New York City.

About Restylane® Silk and Restylane® Lyft

After its recent launch in January 2015, Restylane® Silk has quickly become a relied-upon aesthetic solution for healthcare professionals nationwide. Restylane® Silk is the first and only FDA approved

product exclusively designed for subtle lip enhancement and the treatment of lines and wrinkles around the mouth in people over the age of 21. Restylane® Lyft (formerly marketed as Perlane-L®) is the first and only FDA approved filler indicated to provide fullness to the midface area (cheeks) and nasolabial folds ("smile lines").

For more information about Restylane® Silk, please visit www.RestylaneSilk.com

For more information about Restylane® Lyft, please visit: www.RestylaneLyft.com

About Galderma

Dating back to 1961, Galderma is now present in 100 countries with an extensive product portfolio to treat a range of dermatological conditions. The company partners with health care professionals around the world to meet the skin health needs of people throughout their lifetime. Galderma is a leader in research and development of scientifically-defined and medically-proven solutions for the skin, hair and nails.

Strategic brands in the U.S. include Epiduo®, Oracea®, Clobex®, Differin®, Mirvaso®, MetroGel®, Soolantra®, Vectical®, Tri-Luma®, Cetaphil®, Benzac® Acne Solutions, Restylane®, Restylane® Silk, Restylane® Lyft, Dysport® and Sculptra® Aesthetic.

For more information, please visit www.galderma.com and www.galdermausa.com.

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Dysport is a prescription injection for temporary improvement in the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults less than 65 years of age.

Important Safety Information

What is the most important information you should know about *Dysport*?

Spread of Toxin Effects: In some cases, the effects of *Dysport* and all botulinum toxin products may affect areas of the body away from the injection site. These effects can cause symptoms of a serious condition called botulism. Symptoms of botulism can happen hours to weeks after injection and may include swallowing and breathing problems, loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, or loss of bladder control. Swallowing and breathing problems can be life threatening and there have been reports of death.

The risk of symptoms is probably greatest in children and adults treated for muscle spasms, particularly in those patients who have underlying medical conditions that could make these symptoms more likely.

The toxic effects have been reported at doses similar to those used to treat muscle spasms in the neck. Lower doses, in both approved and unapproved uses, have also caused toxic effects. This includes treatment of children and adults for muscle spasms.

These effects could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

Do not have *Dysport* treatment if you: are allergic to *Dysport* or any of its ingredients (see the end of the Medication Guide for a list of ingredients), are allergic to cow's milk protein, had an allergic reaction to any other botulinum toxin product, such as Myobloc[®] or Botox[®], or have a skin infection at the planned injection site.

The dose of *Dysport* is not the same as the dose of any other botulinum toxin product. The dose of *Dysport* cannot be compared to the dose of any other botulinum toxin product you may have used.

***Dysport* may not be right for you if:** you have surgical changes to your face, very weak muscles in the treatment area, your face looks very different from side to side, the injection site is inflamed, you have droopy eyelids or sagging eyelid folds, deep facial scars, thick oily skin, or if your wrinkles can't be smoothed by spreading them apart.

Tell your doctor about all your medical conditions, including if you have: a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis, or Lambert-Eaton syndrome), allergies to any botulinum toxin product or had any side effect from any botulinum toxin product in the past, a breathing problem (such as asthma or emphysema), swallowing problems, bleeding problems, diabetes, or a slow heart beat or other problem with your heart rate or rhythm, plans to have surgery, had surgery on your face, weakness of your forehead muscles (such as trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks. Patients with a disease that affects muscles and nerves who are treated with typical doses of *Dysport* may have a higher risk of serious side effects, including severe swallowing and breathing problems.

Human Albumin

This product contains albumin taken from human plasma. Steps taken during donor screening and product manufacturing processes make the risk of spreading viral diseases extremely rare. In theory, there is also an extremely rare risk of contracting Creutzfeldt-Jakob disease (CJD). No cases of spread of viral diseases or CJD have ever been reported for albumin.

Allergic Reaction to Injecting in the Skin

It is not known if an allergic reaction can be caused by injecting *Dysport* into the skin. The safety of treating excessive sweating with *Dysport* is not known.

Common Side Effects

The most common side effects are nose and throat irritation, headache, injection site pain, injection site skin reaction, upper respiratory tract infection, eyelid swelling, eyelid drooping, sinus inflammation, and nausea.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using *Dysport* with certain other medicines may cause serious side effects. **Do not start any new medicines while taking *Dysport* without talking to your doctor first.**

Especially tell your doctor if you: have received any other botulinum toxin product in the last four months, have received injections of botulinum toxin, such as Myobloc[®] (rimabotulinumtoxinB) or Botox[®] (onabotulinumtoxinA) in the past (be sure your doctor knows exactly which product you received), have recently received an antibiotic by injection, take muscle relaxants, take an allergy or cold medicine, or take a sleep medicine.

Use in Specific Populations

Dysport should not be used in children or in women who are pregnant or breastfeeding.

Ask your doctor if *Dysport* is right for you.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see *Dysport* Full Prescribing Information including Medication Guide at www.dysportusa.com.

Important Safety Information

Indications: The *Restylane* family of products includes *Restylane*[®], *Restylane-L*[®], *Restylane*[®] *Silk*, *Restylane*[®] *Lyft with Lidocaine*, and *Perlane*[®]. *Restylane*, *Restylane-L*, *Restylane Lyft with Lidocaine*, and *Perlane* are indicated for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. *Restylane* and *Restylane-L* are indicated for mid-to-deep dermal implantation. *Perlane* and *Restylane Lyft with Lidocaine* are indicated for implantation into the deep dermis to superficial subcutis. *Restylane Silk* is indicated for submucosal implantation for lip augmentation and dermal implantation for correction of perioral rhytids in patients over the age of 21. *Restylane Lyft with Lidocaine* is also indicated for cheek augmentation and for the correction of age-related midface contour deficiencies in patients over the age of 21. *Restylane* and *Restylane-L* are also indicated for submucosal implantation for lip augmentation in patients over the age of 21.

Products in the *Restylane* family contain traces of gram-positive bacterial protein and are contraindicated for patients with allergies to such material or in patients with severe allergies that have required in-hospital treatment. These products should not be used by patients with bleeding disorders or by pregnant or breastfeeding women. *Restylane* and *Restylane-L* for lip enhancement and *Restylane Silk* should not be used by people under 22 years. *Restylane-L*, *Restylane Silk* and *Restylane Lyft with Lidocaine* should not be used by anyone with a known allergy to lidocaine. Products should not be injected anywhere except the dermis, superficial subcutis (*Perlane* and *Restylane Lyft with Lidocaine* only), or lip submucosa (*Restylane*, *Restylane-L*, and *Restylane Silk* only).

Use of products in the *Restylane* family at the site of skin sores, pimples, rashes, hives, cysts, or infection should be postponed until healing is complete. The most commonly observed side effects are swelling, redness, pain, bruising, headache, tenderness, and itching at the injection site. These are typically mild in severity and typically resolve in less than 7 days. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis at the injection site. Do not implant into blood vessels. Use with caution in patients recently treated with anticoagulant or platelet inhibitors to avoid bleeding and bruising.

The *Restylane* family of products is available only through a licensed practitioner. Complete Instructions for Use for *Restylane*, *Restylane-L*, *Restylane Silk*, and *Perlane* are available at [www. RestylaneUSA.com](http://www.RestylaneUSA.com). Complete Instructions for Use for *Restylane*[®] *Lyft with Lidocaine* is available at www.RestylaneLyft.com

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