

Galderma Presents Results From Phase 4 Clinical Studies of *Restylane*[®] Refyne and *Restylane*[®] Defyne at the 15th Aesthetic & Anti-aging Medicine Annual World Congress

Clinical outcomes from Phase 4 data are first of their kind to be shared by Galderma in hyaluronic acid dermal fillers, measuring natural-looking results achieved through XpresHAN TechnologyTM

Fort Worth, TX – (April 06, 2017) – Galderma, a global leader focused on medical solutions in skin health, announced today the results from two Phase 4 clinical studies of its most recent additions to the *Restylane*[®] family of products in the U.S., *Restylane*[®] Refyne and *Restylane*[®] Defyne.* Results from these studies will be presented during the Galderma Symposium at the 15th Aesthetic & Anti-aging Medicine Annual World Congress (AMWC) taking place from April 6-8 in Monaco. The Natural Expression study found that naturalness in facial expressions was at least maintained in 95% (60/63) of subjects (primary objective).^{1**} Additionally, results from the Dynamic Strain study found that 83% (25/30) of subjects had enhanced attractiveness, looked younger and at least maintained naturalness, post *Restylane*[®] Refyne and *Restylane*[®] Defyne injections.^{1**}

Restylane[®] Refyne and *Restylane*[®] Defyne were recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of nasolabial folds (NLF) or “laugh lines,” in patients over the age of 21.^{2,3} *Restylane*[®] Refyne was approved for the treatment of moderate to severe facial wrinkles and folds, such as NLF, and *Restylane*[®] Defyne for the treatment of moderate to severe, deep facial wrinkles and folds, such as NLF. These scientifically-advanced gels are manufactured with XpresHAN Technology^{TM†} (pronounced *ex-’spre-shən*), creating gels that offer a range of flexibility and support for varied patient needs.^{1,4}

“*Restylane*[®] Refyne and *Restylane*[®] Defyne were designed to remain flexible and integrate with the tissue so they could be used in animated areas of the lower face, such as the nasolabial folds, and still allow for natural expression in motion,”¹ said consulting investigator, Wolfgang Philipp-Dormston, MD, Cologne-based dermatologist. “The Natural Expression study was designed to measure the perception of facial expressions through a series of evaluation techniques to confirm that natural expression could be maintained as the face animates. Until now, proven results through a combination of these techniques and innovative methods for measurement have not been reported.”¹

“These Phase 4 clinical studies in aesthetic and correctives truly embody our long-term commitment as a leader in innovative skin solutions and demonstrate our continued effort to collaborate with healthcare professionals to develop products that raise the bar on clinical outcomes in every skin health category in which we operate,” said Johannes J. Baensch, Chief Scientific Officer of Nestlé Skin Health, Galderma’s parent company. “The data from the Natural Expression and Dynamic Strain studies are the first of its kind and provide scientific evidence that our XpresHAn Technology™ addresses a major concern for patients who fear looking unnatural by delivering natural-looking results that are maintained during everyday and dynamic expressions.”¹

The Phase 4 clinical studies include:

Title	Presenter	Date & Time
AMWC Galderma Symposium Information		
Natural Expression: A Multi-Center, Non-Comparative Study to Evaluate the Perception of Facial Expressions Following Correction of Wrinkles and Folds in the Lower Face using <i>Emerve</i> ® Classic Lidocaine and <i>Emerve</i> ® Deep Lidocaine** – Main Study	Alexandra Ogilvie, MD	Thursday, April 6, 2017 at 14:00-17:30 PM CET
Dynamic Strain: A Multi-Center Study to Evaluate the Perception of Facial Expressions Following Correction of Wrinkles and Folds in the Lower Face using <i>Emerve</i> ® Classic Lidocaine and <i>Emerve</i> ® Deep Lidocaine	Nowell Solish, MD	Thursday, April 6, 2017 at 14:00-17:30 PM CET

“Results of the Dynamic Strain study are impressive as they confirm published findings from previous clinical studies on dynamic strain. The new data offer clear and objective evidence that dermal fillers may help patients achieve a more youthful appearance when treating facial areas prone to volumetric effects of aging such as the nasolabial folds and marionette lines,”¹ said consulting investigator, Ivona Percec, MD, PhD, Philadelphia-based plastic surgeon. “The precise quantitative data collected illustrate the intricacies of facial dynamics and age-related soft-tissue changes.¹ By transforming this complex dynamic anatomy into simple, visually-interpretable patterns, these studies will deliver benefits in treatment planning, evaluation and training.”

About the Natural Expression Study¹

Topline clinical data from the multi-center, non-comparative study evaluated the perception of the naturalness of facial expressions in motion following correction of wrinkles and folds, such as NLF, in the lower face following treatment (primary objective). Overall the study demonstrated that naturalness was at least maintained in 95% (60/63) of the treated subjects**, fulfilling the primary objective. The study also demonstrated that attractiveness was enhanced in 89% (56/63)

of subjects, and 79% (50/63) of the subjects looked younger. By introducing facial contraction patterns, static and in movement, useful tools were presented to assess the impact of facial treatment of the lower face.

About the Dynamic Strain Study¹

Topline clinical data from the multi-center, non-comparative study evaluated the naturalness of facial expressions following correction of wrinkles and folds, such as NLF, in the lower face, as well as the dynamic strain in facial expressions using 3D stereophotogrammetry (Canfield Scientific, Inc) to objectively quantify surface soft-tissue strain associated with various facial expressions. Thirty (30) treated females (40-65 years old) showed a statistically significant reduction in mean peak dynamic strain in the facial regions, for various standardized expressions, one-month post-treatment, compared to baseline ($p \leq 0.05$).^{**} Results found that 83% (25/30) of subjects had enhanced attractiveness, looked younger and maintained naturalness. These data demonstrated both subjectively and objectively that treatment with *Restylane*[®] Refyne and *Restylane*[®] Defyne provided a more attractive and youthful appearance, without compromising naturalness in facial animation of the lower face.

For these Phase 4 studies, initial treatment injection site responses (redness, swelling, bruising, lump/bump formation, pain/tenderness) were predominantly mild or moderate in intensity, temporary (typically with a duration of one to two weeks), and similar to the NASHA[™] (Stabilized Non-Animal Hyaluronic Acid) Technology *Restylane*[®] products.^{1,5}

About Restylane

With over 30 million treatments worldwide and counting,⁶ the *Restylane*[®] family of hyaluronic acid fillers is used to help smooth away wrinkles and folds, such as nasolabial folds (*Restylane*[®]-L, *Restylane*[®] Refyne, *Restylane*[®] Defyne and *Restylane*[®] Lyft with Lidocaine), create fuller and more accentuated lips (*Restylane*[®] Silk and *Restylane*[®]-L), and add lift and volume to the cheeks (*Restylane*[®] Lyft with Lidocaine). All *Restylane*[®] products work to enhance facial features and give long-lasting, yet non-permanent results.

To learn more about the *Restylane*[®] family of products, visit www.RestylaneUSA.com.

About Galderma

Galderma, Nestlé Skin Health's medical solutions business, was created in 1981 and is now present in over 100 countries with an extensive product portfolio to treat a range of dermatological conditions. The company partners with health care practitioners 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® Gel, Epiduo® Forte Gel, Oracea® Capsules, Clobex® Spray, Mirvaso® Gel, MetroGel® Gel, Soolantra® Cream, Vectical® Cream, Tri-Luma® Cream, Cetaphil®, Differin® Gel OTC, Restylane®, Restylane® Silk, Restylane® Lyft with Lidocaine, Restylane® Refyne, Restylane® Defyne, Dysport® and Sculptra® Aesthetic.

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

To earn exclusive rewards, bonuses and discounts on Galderma's aesthetic treatments, join the ASPIRE Galderma Rewards program. To learn more about ASPIRE, visit www.aspirerewards.com.

**Restylane® Refyne and Restylane® Defyne were first CE-marked in EU in 2010 under the brand names Emervel® Classic Lidocaine and Emervel® Deep Lidocaine, respectively.*

***Combined treatment results for Restylane® Refyne and Restylane® Defyne subjects.*

† XpresHAn Technology™ is also known as Optimal Balance Technology (OBT)™ outside the U.S.

Contact

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Important Safety Information

The *Restylane* family of products includes *Restylane*®, *Restylane-L*®, *Restylane*® Lyft with Lidocaine, *Restylane*® Silk, *Restylane*® Refyne, and *Restylane*® Defyne.

APPROVED USES

Restylane® and *Restylane-L*® are for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. *Restylane*® and *Restylane-L*® are also indicated for injection into the lips in patients over the age of 21.

Restylane® Lyft with Lidocaine is for deep implantation into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for cheek augmentation and for the correction of age-related midface contour deficiencies in patients over the age of 21.

Restylane® Silk is for lip augmentation and for correction of perioral wrinkles in patients over the age of 21.

Restylane® Refyne is for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

Restylane® Defyne is for mid-to-deep injection into the facial tissue for the correction of

moderate to severe deep facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

Are there any reasons why I should not use products within the Restylane® family? (Contraindications)

To ensure a safe procedure, your doctor will talk to you about your medical history to determine if you are an appropriate candidate for treatment. You should not use products within the Restylane family if:

- You have severe allergies with a history of severe reactions (anaphylaxis)
- You are allergic to lidocaine or to any of the gram-positive bacterial proteins used to make hyaluronic acid
- You are prone to bleeding or have been diagnosed with a bleeding disorder

Are there other precautions that I should discuss with my doctor?

- Tell your doctor if you are breastfeeding, pregnant, or trying to become pregnant. The safety of these products for use during pregnancy, or in women who are breastfeeding, has not been studied
- *Restylane*, *Restylane-L*, *Restylane® Lyft with Lidocaine*, *Restylane Refyne* and *Restylane Defyne* are intended to treat facial wrinkles and folds, such as nasolabial folds. *Restylane* and *Restylane-L* are also intended for lip enhancement. Treatments in other areas of the face have not been evaluated in clinical studies.
- The safety and effectiveness of *Restylane® Silk* for areas other than the lips and perioral area have not been evaluated in clinical studies
- Tell your doctor if you have any history of scarring, particularly thick and stiff scars, or any pigmentation (skin color) disorders. These side effects can occur with hyaluronic acid fillers in general.
- Tell your doctor if you are planning other laser treatments or a chemical peel, as there is a possible risk of inflammation at the treatment site if these procedures are performed after treatment
- Patients who experience skin injury near the site of injection with these products may be at a higher risk for side effects
- Tell your doctor if you are on any medications to decrease your body's immune response (immunosuppressive therapy). Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- Tell your doctor if you are using any "blood thinners" such as aspirin, warfarin, or any other medications that affect bleeding. Using these medications may increase your risk of bruising or bleeding at the gel injection site.
- The use of these products on gel injection sites with skin sores, pimples, rashes, hives,

cysts, or infections should be postponed until healing is complete. Use of product in these areas could delay healing or make your skin problems worse.

What are the possible side effects?

The most commonly observed side effects are swelling, redness, pain, bruising, headache, tenderness, lump formation, and itching at the injection site. These are typically mild in severity and typically resolve in less than 7 days in nasolabial folds and less than 14 days in lips. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis at the injection site.

One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

As with all skin injection procedures, there is a risk of infection.

To report a side effect with any of the Restylane products, please call Galderma Laboratories, L.P. at 1-855-425-8722.

The *Restylane* family of products is available only through a licensed practitioner. Complete Instructions for Use are available at www.RestylaneUSA.com.

¹ Data on file. Fort Worth, TX: Galderma Laboratories, L.P.

² Galderma. *Restylane*® Refyne Important Safety Information. Fort Worth, TX: Galderma Laboratories, L.P., 2016.

³ Galderma. *Restylane*® Defyne Important Safety Information. Fort Worth, TX: Galderma Laboratories, L.P., 2016.

⁴ †Segura S, Anthonioz L, Fuchez F, et al. A complete range of hyaluronic acid filler with distinctive physical properties specifically designed for optimal tissue adaptations. *J Drugs Dermatol*. 2012; 11(1):s5-s8.

⁵ Data on file. Galderma at a Glance. Fort Worth, TX: Galderma Laboratories, L.P., 2016.

⁶ Data on file. Global Launch Learnings. Fort Worth, TX: Galderma Laboratories, L.P., 2016.