

FDA Approves Sculptra® Aesthetic, A Facial Injectable for Correction of Nasolabial Folds and other Facial Wrinkles

Bridgewater, N.J., July 29, 2009 – Sanofi-aventis U.S. announced today that the U.S. Food and Drug Administration (FDA) approved Sculptra®Aesthetic (injectable poly-L-lactic acid) for the correction of shallow to deep nasolabial fold (smile lines) contour deficiencies and other facial wrinkles which are treated with the appropriate injection technique in healthy patients. Sculptra®Aesthetic works gradually to offer natural-looking results that can last up to two years.

"We are excited by the FDA approval of Sculptra®Aesthetic because it changes the landscape of what physicians can offer patients seeking natural and gradual looking results from an aesthetic injectable that is long-lasting," said Doris Day, M.D., Clinical Assistant Professor of Dermatology at New York University and in private practice in New York City. *"Sculptra®Aesthetic allows for a natural correction."*

The FDA approval of Sculptra®Aesthetic is based on results from a randomized, comparative, evaluator-blinded, parallel group, multi-center study of 233 patients. Patients received Sculptra®Aesthetic or an approved human derived collagen for the treatment of their nasolabial fold wrinkles.

Sculptra®Aesthetic was administered in a single treatment regimen, at three week intervals, for up to 4 treatment sessions for the correction of shallow to deep nasolabial fold contour deficiencies using a deep dermal grid pattern (cross-hatch) injection technique. The Sculptra®Aesthetic patients were followed for an additional 12 months. Sculptra®Aesthetic treatment effects were maintained up to 25 months after the last treatment session, while the human derived collagen was effective up to 3 months.

"Sculptra®Aesthetic showed effective correction of the nasolabial folds, which are considered to be the hallmark signs of facial aging," said Paul Chew, M.D., Chief Science Officer/Chief Medical Officer, sanofi-aventis U.S.

No serious adverse events were reported in this study for either treatment. Commonly occurring short-term injection site reactions were bleeding, tenderness or pain/discomfort, redness, bruising, itching or swelling and were reported in both treatment groups. Other adverse events reported during the 25 month trial included small bumps and lumps, some with a delayed onset and were mild or moderate in intensity. Most side effects resolved on their own; one small lump required treatment by the healthcare provider

Important Safety Information:

You should not use Sculptra Aesthetic if you are allergic to any ingredient of the product or have a history of keloid formation or hypertrophic scarring. Sculptra Aesthetic should not be injected while you have an active skin infection or inflammation in the treatment area and should not be injected into the red area of the lip. Use in the skin near the eyes is not recommended.

Side effects of Sculptra Aesthetic may include injection site discomfort, redness, bruising, bleeding, itching and swelling. Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration, have also been reported. In a key clinical study the numbers of small and larger lumps were low and most resolved without treatment.

For more information, including full Prescribing Information, please visit www.SculptraAesthetic.com or www.sanofi-aventis.us.

About sanofi-aventis

Sanofi-aventis U.S. is an affiliate of sanofi-aventis, a leading global pharmaceutical company that discovers, develops and distributes therapeutic solutions to help improve the lives of patients. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

For more information, www.sanofi-aventis.us or www.sanofi-aventis.com.

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