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FDA News

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FDA Approves Sculptra for HIV Patients

After an expedited review, the Food and Drug Administration (FDA) today approved an injectable filler to correct facial fat loss in people with human immunodeficiency virus (HIV) infection.

The filler, called Sculptra, is the first such treatment approved for a condition known as lipoatrophy, or facial wasting, a sinking of the cheeks, eyes and temples caused by the loss of fat tissue under the skin. Lipoatrophy is common among HIV patients. FDA expedited review of the product because of its importance to people with HIV/AIDS.

Sculptra was shown to produce significant increases in skin thickness, adding volume to facial tissue and restoring shape in areas of the face with fat loss. After an initial treatment series, repeat treatments may be needed to maintain the correction. Studies reported an improvement in the quality of life among those treated and less of the anxiety and depression often associated with lipoatrophy.

Sculptra is an injectable form of poly-L-lactic acid, a biodegradable, biocompatible synthetic polymer from the alpha-hydroxy-acid family that has been widely used for many years in dissolvable stitches, bone screws, and facial implants.

"Change in facial appearance is one of the emotionally devastating and stigmatizing side effects of HIV/AIDS and the drugs used to treat it," said FDA Acting Commissioner Dr. Lester M. Crawford. "The AIDS community has been awaiting a product like this that can give patients a smoother, fuller face."

FDA approval of Sculptra was based on a review of clinical studies of safety and effectiveness submitted by the manufacturer, Dermik Laboratories, of Berwyn, Pa.

Dermik reported on the use of Sculptra in 278, HIV-positive patients with severe facial lipoatrophy. The patients, who were all being treated with antiretroviral drugs, were primarily white males, mostly ages 41 to 45. Patients were given three to six injections of Sculptra at two-week intervals and were followed for two years.

The studies showed that the product was safe and significantly improved facial appearance. Most adverse events were related to the injection itself and included nodules, redness, swelling and bruising in the injection area.

Sculptra should only be used in patients with HIV by health care providers who are fully familiar with the product training materials provided by Dermik and the entire product package insert. The use of the product for other indications, such as to treat wrinkles, has not been approved by FDA.

As a condition of approval, Dermik has agreed to conduct an open-label registry study of 100

patients for five years to evaluate Sculptra's long-term safety. The study will include at least 30 females and 30 people with dark skin types.

It is estimated that 900,000 to 1 million people in the United States are HIV-positive, although about one third are not diagnosed. Some 50 percent will develop lipoatrophy. An estimated 150,000 to 350,000 patients could potentially benefit from the new treatment.

For more information on HIV and AIDS go to <http://www.fda.gov/oashi/aids/hiv.html>

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