

# FDA Approval of Reloxin Predicted Within Year

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DESTIN, FLA. — Approval of Reloxin, a botulinum toxin type A product marketed in Europe as Dysport, is expected in the United States within the next 8-12 months, Dr. Patricia Farris said at a meeting sponsored by the Alabama Dermatology Society.

The product, which is similar to Botox, has been proved safe and effective in various trials worldwide, including in recently completed phase III U.S. trials, she said.

"The phase III clinical trial data for Reloxin in this country have not all been collated at this point, but I thank [Medicis

Pharmaceutical Corp.] for sharing a little bit of it with me," said Dr. Farris, referring to the company that will develop and market Reloxin in the United States and which sponsored her talk at the meeting.

The 150-day, double-blind, placebo-controlled trial, which was designed to determine the efficacy of a single 50-unit dose for the treatment of glabellar lines, involved 300 patients. Response at 30 days in the 200 patients treated with Reloxin was excellent. "Slightly less than 90% of treat-

ed patients, compared with 0% of placebo patients, responded," said Dr. Farris of the department of dermatology at Tulane University, New Orleans.

Patients were considered responders if they improved from a score of 2 or 3 to a score of 0 or 1 on a 4-point scale, with 0 indicating no frown lines, 1 indicating mild frown lines, 2 indicating moderate frown lines, and 3 indicating severe frown lines.

Investigators used a 5-point injection technique, with two 10-unit injections in

each of the corrugator muscles, and a single 10-unit injection in the procerus muscle. The 50-unit dose was shown in previous studies to be optimal. Median time to onset was 2 days, and by day 7 about 80% of patients had responded. Median duration was 117 days, Dr. Farris noted.

The product also proved to be safe. The most common adverse event was headache, and there were some ocular events, including two cases of probable Reloxin-related ptosis, she said. ■

## Cosmetic Result Analysis Depends On the Evaluator

GRAPEVINE, TEX. — The outcomes of cosmetic dermatologic procedures are in the eyes of the beholders.

The mindset of expert evaluators and their level of blinding can play critical roles in how the results of a cosmetic procedure are judged, Dr. David Horne said at the annual meeting of the American Society for Laser Medicine and Surgery.

He tested this hypothesis in a "Rashomon"-like study in which the same set of before-and-after clinical images from a noninvasive dermatologic procedure performed on about 10 patients was presented to five different groups of evaluators. In each case, the evaluators reached different conclusions about the treatment's efficacy.

The first group of evaluators comprised enthusiasts for the procedure who were unblinded as to which images were taken before treatment and which were taken after. These experts judged the results as impressive, with all patients having at least 25% improvement, said Dr. Horne of New York-Presbyterian Hospital.

The experts in the second group were ambivalent about the procedure and were unblinded. They rated the images as showing modest benefit, with selected patients getting up to 25% improvement, he said.

The third group included experts who were skeptics of the procedure and were unblinded. They rated the images as showing minimal improvement, with several patients showing no response.

The fourth group was the same set of ambivalent experts as in group 2. They were reshown the images 3 months after their first assessment, but they were completely blinded as to which images were taken before treatment and which were made after treatment and this time they said that most patients were not changed by their treatment, and in some cases the treatment seemed to worsen their appearance.

The fifth group, the patients themselves, said that they all had at least a 20% improvement in appearance, with an average improvement of 50%, said Dr. Horne.

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Reference: 1. Thiboutot D, Thieroff-Ekerdt R, Graupe K. Efficacy and safety of azelaic acid (15%) gel as a new treatment for papulopustular rosacea: results from two vehicle-controlled, randomized phase III studies. *J Am Acad Dermatol*. 2003;48:836-845.

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