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Newsmakers

By Inga Hansen

Newsmakers: Reloxin

As clinical trials continue, Reloxin is revealing many similarities and a few key differences with future competitor Botox.

Despite a controversial entrance into the United States that included a bidding war and action from the Federal Trade Commission, Reloxin is continuing on its steady path toward Food and Drug Administration approval. Poised to be the first U.S. rival of Allergan's Botox, the highly anticipated botulinum toxin injection is currently in phase III clinical trials with some of the country's most experienced Botox injectors including David Bank, MD, director of The Center for Dermatology, Cosmetic and Laser Surgery, Mount Pisgah, New York (www.thecenterforderm.com).

"Both Botox and Reloxin are botulinum toxin type A so the differences between the two are not like apples to oranges," says Dr. Bank. "But there are some very subtle differences in the way that Reloxin handles and behaves compared to Botox."

Reloxin has been available outside of the U.S. for 20 years under the name Dysport. "What we've observed in some of the patients is that they're getting a wider or broader area of relaxation across the forehead than we typically expect to see using comparable amounts of Botox," says Dr. Bank. "This is something our European colleagues who've been working with this product for years have also noted."

With both Botox and Reloxin, the effects of the product spread in a circular pattern from the point of injection. "The diameter of the Reloxin circle seems a little larger than the Botox circle," says Dr. Bank. "A number of our patients have been very pleased with that because they feel they're getting larger areas of wrinkle reduction."

The slight differences in behavior mean there will be a learning curve to injection, and practitioners should be aware that broader relaxation could spell trouble, particularly in tight areas such as above the

eyelids. "A broader area of diffusion might be a plus in certain areas like the forehead but a negative in other areas," says Dr. Bank. "We have not seen any drooping of the eyelids during the clinical trials, but this effect is a theoretical concern if you're injecting very close to the eyelid muscles. You want to be aware that there is a broader area of diffusion so you can look at what the pattern of diffusion from your injection point will be and ask yourself, 'Do I want to relax all of the muscles within this circle?'"

Other slight differences include quicker and longer-lasting results in select patients. "What we're seeing in our practice is that Reloxin lasts three to four months on average, which is consistent with what we see with Botox," says Dr. Bank. "But we've also seen some patients who went six and even nine months before needing reinjections."

If the final phase III clinical trials are satisfactory, Reloxin should hit the U.S. market in 2007. It will be distributed through Medicus, which also distributes Restylane. The company purchased the rights to Reloxin after the Federal Trade Commission ruled that Allergan's initial involvement created a monopoly that would adversely affect American consumers.

On March 14, 2006, the *Federal Register* reported, "The entry of Reloxin, which is expected to be the second botulinum toxin product to receive FDA approval for the treatment of facial wrinkles, would increase competition and likely reduce prices to consumers. Accordingly, allowing Allergan to control both Botox and Reloxin would likely force customers to pay higher prices for cosmetic botulinum toxin."

"Provided the pricing is not significantly lower than Botox or vice versa, I predict Reloxin is going to gain a nice market share," says Dr. Bank. "Some physicians will prefer one over the other, but I believe many practices will offer both." ♦



▲ David Bank, MD

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