Widely anticipated, a topical neurotoxin treatment for crows’ feet may be moving closer to the clinic. Phase 3 clinical trials of investigational drug product candidate RT001, a topical gel formulation of botulinum toxin type A (Revance Therapeutics), are commencing. The notion of topical neurotoxin therapy fuels the imagination. Ahead, we speak with an investigator, Coral Gables-based dermatologist Joely Kaufman, MD, FAAD, to learn the facts about RT001.

1. TOPICAL TOxin DEPENDS ON TECHNOLOGY

Describing RT001 as a “breakthrough technology,” Dr. Kaufman notes that topical formulation was a daunting proposition. “As we all know, botulinum toxin type A is a large molecule,” she says, “making delivery through the skin a challenge. RT001 uses a TransMTS® peptide delivery platform that is able to carry that large molecule through the skin and then release it to the targeted area. Patented technology carries the toxin through the skin and releases it very specifically at the muscular level.”

Dr. Jacob Waugh, CSO at Revance, explains that the carrier peptide is ionically bound to the surface of the toxin until it reaches the intended target. He says that localized spread of toxin has not emerged as a concern: “Lateral spread and spread in depth is equal to about the depth from the stratum corneum to the mid-dermis.”

2. TREATMENT IS IN-OFFICE

Some physicians worry about a topical toxin being improperly applied. “RT001 will be applied in-office by a trained professional and will be placed on skin for 30 minutes before it’s removed,” Dr. Kaufman says. Once the gel is removed, delivery ceases.

“Potential adverse effects would be expected to be the same as for botulinum toxin,” Dr. Kaufman notes. “In 13 clinical trials so far, we haven’t seen any severe adverse events related to the toxin or peptide. Therefore, when applied and used correctly, RT001 appears to be very, very safe.”

3. DOSING WILL BE PREDETERMINED

RT001 will be available in pre-filled doses, Dr. Kaufman says. “There is a hand-held applicator pre-dosed for application,” she explains.

4. IT’S NOT JUST FOR NEEDLE-PHOBIC PATIENTS

Needle-phobic patients are one small part of this patient population, Dr. Kaufman says. “I think the bigger reach for the topical toxin is those patients who are worried about looking frozen.” She says that compared to injectable neurotoxin, the topical gel may provide a “softer” effect. In trials to date, she emphasizes, the primary endpoint was wrinkle reduction at rest rather than at full smile. Ideally, she says, we want to “not change facial expression at all while still improving wrinkles.”

Treatment must remain in place for 30 minutes. However, Dr. Kaufman points out, when you consider the time to numb and inject a patient, topical application may not take significantly longer than injectable toxin. And there are other potential topical applications, such as for hyperhidrosis. “People are excited about having another alternative.”

5. THERE COULD BE AN UNTAPPED MARKET

“We all realize that the number of women using toxin injections is small in comparison to those considering it,” Dr. Kaufman observes. A new delivery system has the potential to expand the market, she says. And treatment could be a gateway to other cosmetic procedures—some treatments that could be provided while the topical toxin is in place. “Topical RT001 potentially opens the door to other procedures,” she says.

For more from Dr. Waugh and a diagram of the peptide delivery, download the Modern Aesthetics® app.