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Revance Therapeutics Announces Clinical Trial Results of RT001 Topical Gel Presented at the Annual Meeting of the American Society of Dermatologic Surgery

NEWARK, Calif.--([BUSINESS WIRE](#))--Revance Therapeutics, Inc. ("Revance") today announced that the results of two Phase 2b clinical trials on RT001, a topical botulinum toxin type A which is under investigation for the treatment of lateral canthal lines (crow's feet wrinkles) were presented at the annual meeting of the American Society of Dermatologic Surgery in Chicago. Both multi-center, double-blind, randomized, controlled studies showed that RT001 was well tolerated and demonstrated statistically significant efficacy versus controls. Adverse events were unrelated to study treatment as rated by the investigators and generally mild or moderate, and transient. There was no evidence of spread or diffusion away from the target muscle observed.

"The results of this study are very exciting"

The first study enrolled 90 subjects and utilized a primary composite endpoint that included ratings by both the investigator and the patient on validated wrinkle severity scales. To be a responder, each subject had to demonstrate a ≥ 2 -point improvement on both sides of the face as graded by the investigator's assessment and the patient's self-assessment. RT001 met the primary endpoint and all secondary endpoints with $p \leq 0.0001$. "A treatment that shows such promising results should appeal to a wide variety of new patients, many of whom do not like having a needle so close to their eyes and have been hesitant to come in for a cosmetic procedure," said Fredric Brandt, MD, a dermatologist in private practice in New York and Miami and the principal investigator of the study.

The second study had 180 subjects and was designed to compare the individual components comprising RT001. These components include botulinum toxin type A, the proprietary peptide carrier and the vehicle. RT001 met the primary endpoint of ≥ 2 -point improvement in lateral canthal line severity on both sides of the face as measured by the investigator. The results were statistically significant ($p < 0.0001$) compared to each component of RT001 individually and all the components combined. RT001 also met the more stringent composite endpoint of ≥ 2 -point improvement on both the investigator assessment and the patient's self assessment compared to controls ($p < 0.0001$). These results suggest that the peptide carrier is necessary for topically applied botulinum toxin to achieve positive results.

"The results of this study are very exciting," said Robert Weiss, MD, Director of the Maryland Laser, Skin & Vein Institute and Associate Professor of Dermatology at Johns Hopkins who was one of the investigators who presented data today. "These data confirm that large proteins such as botulinum toxin type A don't have the ability to cross skin by themselves."

Gary Monheit, MD, Clinical Associate Professor at the University of Alabama also presented the overall results of the Phase 2 program in a session dedicated to "Advances in Botulinum Toxins."

Revance has done extensive development work on RT001 for lateral canthal lines and has completed 11 clinical trials and treated more than 550 subjects. The company was originally scheduled for an end-of-phase 2 meeting with the FDA earlier this month. The meeting did not take place as the Agency continues the review of the end-of-phase 2 briefing package submitted in September.

“We are pleased by the results generated in the RT001 clinical program,” said Dan Browne, President and CEO of Revance. “We developed a robust testing program and RT001 continues to exceed our expectations. We will continue to provide information as the Agency requests in a timely manner as we move forward with the program.”

About RT001

RT001, Botulinum Toxin Type A Topical Gel, an investigational product whose first aesthetic indication is designed to reduce crow’s feet wrinkles by temporarily relaxing the muscle around the eye. Unlike other procedures that require several injections in the sensitive periorbital area, RT001 gel is applied by the physician and then wiped off using a simple proprietary cleansing procedure. Revance’s goal is to expand the market beyond other injectable treatments, which despite their popularity, have only captured about 10% of the potential market. The Company believes that offering a safe, efficacious and painless procedure could appeal to many of consumers who have considered treatment but are uncomfortable with the pain and bruising associated with injectables. RT001 is currently being studied for the treatment of lateral canthal lines (crow’s feet) and the therapeutic indication of hyperhidrosis (excessive sweating).

About Revance Therapeutics

Revance Therapeutics, Inc. (“Revance”) is a privately held specialty biopharmaceutical company which develops next generation products in dermatology and aesthetic medicine. Revance has developed a platform technology, TransMTS™ that enables local, targeted delivery of botulinum toxin and other potent macromolecules across skin without patches, needles or other invasive procedures.

Revance is backed by a blue chip roster of healthcare venture capital investors, including Essex Woodlands Health Ventures, Vivo Ventures, Technology Partners, Shepherd Ventures, Palo Alto Investors, Bio*One Capital and Pac-Link Ventures. Revance is currently seeking US and international strategic partnerships for its topical and injectable neurologic compounds and TransMTS delivery technology.

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