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Revance Therapeutics Initiates Phase 3 Clinical Trial of Botulinum Toxin Type A Topical Gel to Treat Lateral Canthal Lines

RT001 Targeted to be the First Topically Applied Neurotoxin Treatment

NEWARK, Calif., Sept. 28, 2015 (GLOBE NEWSWIRE) -- Revance Therapeutics, Inc. (NASDAQ:RVNC), a specialty biopharmaceutical company developing botulinum toxin products for use in aesthetic and therapeutic indications, today announced it has commenced dosing patients in the Phase 3 pivotal study to evaluate the safety and efficacy of its RT001 investigational topical drug product candidate for the treatment of lateral canthal lines, or crow's feet. The Phase 3 trial will evaluate the safety and efficacy of a single, bilateral administration of RT001 topical gel compared to placebo in patients with moderate to severe crow's feet. The company plans to release interim results from this Phase 3 study in the first half of 2016.

"Transporting large molecules, such as botulinum toxin, through the skin has the potential to offer many clinical benefits. We anticipate it will be easier for medical professionals to administer a topical product and that patients will be able to avoid the pain, bruising and downtime associated with needles," said Dan Browne, President and Chief Executive Officer at Revance. "Topical delivery has the potential to transform the $3 billion global neurotoxin market and change the way many other drugs are administered in the future. We've invested significant capital and resources to refine our proprietary TransMTS® technology platform, generate and publish meaningful clinical data, build manufacturing capabilities and develop cutting-edge performance analytics. We believe these have positioned Revance to become the first and only company to move into Phase 3 clinical trials with a topical botulinum toxin approach.

"Our market research indicates that consumers want natural-looking improvement in wrinkles, not the 'frozen face look' that many people associate with injectable toxins. Success in treating crow's feet would set the stage for potential future indications of RT001 topical gel across other areas of the face and body."

Phase 3 Trial Design

The Phase 3 trial is a randomized, double-blind, parallel-group, placebo-controlled study to evaluate the safety and efficacy of RT001, also referred to as RTT150 (Botulinum Toxin Type A) Topical Gel, for the treatment of moderate to severe lateral canthal lines. A total of up to 450 adult patients will be enrolled at multiple sites in the United States and will be randomized 1:1 to a single treatment of either RT001 topical gel or placebo. The product will be applied to lateral canthal lines on both sides of the face using Revance's proprietary applicator.

The primary efficacy endpoints are composites based upon the Investigator's Global Assessment of Lateral Canthal Lines (IGA-LCL) assessment and the Patient Severity Assessment (PSA) between baseline and 28 days after treatment. One composite endpoint includes those patients with a 2-point or greater improvement as graded by the investigator's assessment and the patient's self-assessment. The other composite endpoint includes those patients who experience a 1-point or greater improvement in the investigator's and patient's assessments. Patients will also be assessed at Day 28 for muscle paralysis (or paralytic effect) using electromyography (EMG).

Additional information about the trial, including patient eligibility criteria, will be posted shortly at www.clinicaltrials.gov.

About Lateral Canthal Lines

Lateral canthal lines, or crow's feet, are the spider-like fine lines around the outside corners of the eyes that become more obvious when someone smiles. These lines (also referred to as periorbital wrinkles, laugh lines or smile lines), fan out across the skin from the outer corner of each eye. Sometimes they extend down across the cheekbones to the lower cheeks. Repetitive motions, such as squinting and smiling, can lead to the increase of wrinkles and contribute to the severity and onset of crow's feet. Age and exposure to sun also play significant roles in development of these lines, which can deepen over time. Current treatments include anti-wrinkle eye creams and moisturizers, topical tretinoins, botulinum toxin injections, dermal fillers and laser treatments.

Revance estimates that the global market for aesthetic treatments with neurotoxins represented about a $1.4 billion market

in 2014. According to the American Society for Aesthetic Plastic Surgery, botulinum toxin treatment is the number one nonsurgical cosmetic procedure in the U.S.

RT001 Topical Gel and RT002 for Injection Product Candidates

Revance is currently developing two botulinum toxin type A investigational drug product candidates. RT001 is a topical formulation, which has the potential to be the first commercially available non-injectable dose form of botulinum toxin type A. Revance is studying RT001 topical gel for aesthetic indications, such as crow's feet (wrinkles around the eyes) and therapeutic indications such as axillary hyperhidrosis (excessive underarm sweating). RT002 is a novel, injectable formulation of botulinum toxin type A designed to be targeted and long lasting. Revance is studying RT002 for injection for aesthetic indications, such as glabellar (frown) lines, and therapeutic uses, such as muscle movement disorders (cervical dystonia and upper limb spasticity). Both products could have the potential to expand into additional aesthetic and therapeutic indications in the future.

About Revance Therapeutics, Inc.

Revance is a specialty biopharmaceutical company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications. The company is leveraging its proprietary portfolio of botulinum toxin compounds combined with its patented TransMTS® peptide delivery system to address unmet needs in the large and growing neurotoxin markets. Revance's proprietary TransMTS technology enables delivery of botulinum toxin A through two novel drug product candidates, a needle-free topical form and an injectable form that may localize the drug to the site of injection resulting in a targeted and potentially long-lasting delivery. Revance is pursuing clinical development for drug product candidates topical RT001 and injectable RT002 in a broad spectrum of aesthetic and therapeutic indications. The company holds worldwide rights for all indications of RT001, RT002 and the TransMTS® technology platform. More information on Revance Therapeutics can be found at www.revance.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements about our investigational drug product candidates, including but not limited to statements about our business strategy, clinical development, timeline and other goals and market for our anticipated products, plans and prospects and statements about potential benefits of our drug product candidates and our technologies.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: the outcome, cost and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; our ability to obtain funding for our operations; our plans to research, develop and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; our ability to successfully commercialize our drug product candidates and the timing of commercialization activities; the rate and degree of market acceptance of our drug product candidates; our ability to develop sales and marketing capabilities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in Revance's periodic filings with the Securities and Exchange Commission (the "SEC"), including factors described in the section entitled described in the "Risk Factors" section of our quarterly report on Form 10-Q filed August 7, 2015. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

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