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Revance Therapeutics Initiates Phase 2 Clinical Trial of Botulinum Toxin Type A Topical Gel to Treat Axillary Hyperhidrosis

Interim Data Expected by Year End 2015

NEWARK, Calif., Sept. 9, 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 with axillary hyperhidrosis (excessive underarm sweating) in a Phase 2 trial of its RT001 (now referred to as RTT150 (Botulinum Toxin Type A) Topical Gel) investigational drug product candidate. The Phase 2 trial is a randomized, double-blinded, dose-ranging, placebo-controlled study designed to evaluate the safety and efficacy of a single, bilateral application of RT001 topical gel for the treatment of primary axillary hyperhidrosis.

Revance expects to enroll a total of approximately 60 adult patients at multiple sites in the United States. The company plans to release interim data from this study by year end 2015.

"Hyperhidrosis, or excessive sweating, is a widespread condition in a highly underserved market, representing a significant therapeutic opportunity for topical RT001," said Dan Browne, President and Chief Executive Officer at Revance. "Botulinum toxin injections have been validated as an effective treatment, but not widely embraced. A big reason is the pain caused by the large number of required injections, up to fifteen per treated underarm. We believe our needle-free approach may provide a targeted, painless, and long-lasting alternative, without daily application or the systemic side effects observed in many other hyperhidrosis treatments. We also believe RT001 could dramatically expand the toxin market for excessive underarm sweating and bring new patients into the physician's office."

Mr. Browne continued, "Although this program's initial focus is on underarm hyperhidrosis, excessive sweating is often experienced in the palms, feet, and face. These represent potential future indications for us to pursue with RT001 topical gel."

Phase 2 Study Design

Revance's Phase 2, randomized, double-blind, dose-ranging, placebo-controlled trial will evaluate the safety and efficacy of RT001 topical gel for the treatment of primary axillary hyperhidrosis. A total of approximately 60 adult patients with a diagnosis of primary axillary hyperhidrosis will be enrolled at multiple sites in the U.S. The patients will be randomized into one of three parallel treatment groups (two doses of RT001 topical gel and one placebo topical gel). The product will be applied to both underarms.

An interim efficacy and safety analysis at Day 28 after treatment is planned. The primary efficacy endpoints are the proportion of subjects who are 2-point or greater responders from baseline using the Hyperhidrosis Disease Severity Scale (HDSS) and the absolute change from baseline in the gravimetrically measured sweat production. Secondary efficacy endpoints include the change from baseline in total Dermatology Life Quality Index (DLQI) scores.

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

About Hyperhidrosis

Hyperhidrosis, or excessive sweating, is a serious medical condition. In hyperhidrosis, the body's mechanism for cooling itself is overactive and can cause extreme sweating -- four or five times more than is necessary, or normal. According to the International Hyperhidrosis Society, hyperhidrosis afflicts millions of people around the world (approximately 3% of the population).

In the United States, hyperhidrosis affects approximately 9 million people, with about half suffering from axillary hyperhidrosis. Excessive sweating has debilitating psychosocial and emotional consequences, as well as significant medical and aesthetic dermatologic impact. Approved treatments for hyperhidrosis include topical applications, oral medications, laser therapy, and surgical interventions. Botulinum toxin has been shown to temporarily block the secretion of the chemical that is responsible for "turning on" the body's sweat glands. By blocking or interrupting this chemical messenger, botulinum toxin "turns off" sweating at the area where it has been injected. We estimate the global market for treating hyperhidrosis

with botulinum toxins was approximately $75 million in 2014.

RT001 and RT002 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 topical RT001 for aesthetic indications, such as crow's feet lines (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 injectable RT002 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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