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Revance Announces Positive Phase 2 Results for RT001 Botulinum Toxin Type A Topical Gel to Treat Axillary Hyperhidrosis

Both Doses of RT001 Topical Show Measurable Reduction in Underarm Sweating Following a Single Application at the Time of Treatment

NEWARK, Calif., Dec. 23, 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 interim efficacy and safety results from its Phase 2 trial of its RT001 topical botulinum toxin type A investigational drug product candidate for the treatment of axillary hyperhidrosis (excessive underarm sweating). The trial was designed to evaluate safety and efficacy of two doses of RT001 applied on a single day of treatment. Although the trial sample size was not chosen to meet statistical significance, using quantitative gravimetric measurements, the data was positive and showed that a single treatment of RT001 topical gel achieved clinically meaningful efficacy at Week 4. Using the qualitative Hyperhidrosis Disease Severity Scale (HDSS), RT001 showed a strong efficacy trend for both 1-point and 2-point improvement. Both doses of RT001 appear to be safe and well tolerated.

"We are very pleased with the Phase 2 interim results, which provide strong clinical evidence establishing RT001's ability to safely deliver botulinum toxin topically to reduce the severity and quantity of underarm sweat production," said Dan Browne, President and Chief Executive Officer at Revance. "Quantitatively, the gravimetric data shows clinically meaningful sweat reduction for both doses of RT001 and, at the higher dose, RT001 was statistically significant versus placebo. While the qualitative self-assessment by HDSS showed a notable placebo effect between Week 2 and Week 4, we believe that, overall, the RT001 data in this study are highly meaningful from a clinical standpoint."

Mr. Browne added, "We plan to advance RT001 into a larger, well-powered hyperhidrosis Phase 2 study in 2016, which will be designed to confirm a final dose. Upon successful completion, we will then meet with the FDA to take RT001 into Phase 3 studies."

Key Interim Results

- At Week 4, on the primary quantitative assessment of average reduction from baseline in gravimetrically-measured sweat production, the results ranged from 214.2 mg to 165.7 mg (p=0.003 for the higher dose) per five minutes for RT001, compared to 66.3 mg per five minutes in patients who received placebo. These ranges corresponded to 81.1% to 79.6% change for RT001, compared to 54.6% for placebo.
- On the primary qualitative efficacy assessment of a 2-point or greater responders from baseline using the HDSS, at Weeks 1 and 2 the results ranged from a 23.8% to 13.3 % improvement for RT001 compared to a range of 17.6% to 11.8% improvement for placebo. By Week 4, there was a 14.3% to 13.3% improvement for RT001, compared to a 29.4% improvement in patients who received placebo.
- RT001 appears to be safe and well tolerated at both doses. Adverse events were generally mild, localized and transient. There were no serious adverse events or evidence of any systemic exposure for either of the two doses evaluated. The most common treatment-related adverse events reported were application site erythema (redness), folliculitis (razor bumps) and application site pain.

"It is very encouraging to see the consistent level of sweat reduction RT001 provided subjects in this study, particularly in multiple cases who presented with profound baseline sweating and showed dramatic reduction following a single treatment," says Richard G. Glogau, MD, a recognized dermatologist, Clinical Professor of Dermatology, University of California, San Francisco, and a pioneer for the clinical research of botulinum toxin to aid in excessive sweating of hands and underarms. "Most noninvasive treatments for hyperhidrosis provide only temporary relief at best, with very little relief for severe cases. In my current practice, I use injectable botulinum toxin to successfully treat hyperhidrosis, but the high number of injections required is a significant barrier to patient acceptance. I believe more patients would seek treatment if there were an easy-to-apply topical treatment that allows them to achieve improved dryness for months at a time."

Phase 2 Study Design

This 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, also known as RTT150 (Botulinum Toxin Type A Topical Gel), for the

treatment of primary axillary hyperhidrosis. A total of 67 adult patients with a diagnosis of primary axillary hyperhidrosis were enrolled at multiple sites in the U.S. The patients were randomized into one of three parallel treatment groups (two doses of RT001 topical gel and one placebo topical gel). The product was applied to both underarms. Patients are followed out to Week 8.

Additional information about the trial is posted at www.clinicaltrials.gov under identifier NCT02565732.

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 (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). 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 drug 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 RT001 topical and RT002 injectable 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 "Risk Factors" of our quarterly report on Form 10-Q filed November 10, 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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