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Revance Announces Positive 24-Week Duration of Effect in Interim Results from Phase 2 Cervical Dystonia Trial

- RT002 injectable appeared to be generally safe and well-tolerated -

- RT002 injectable displayed clinically significant impact on cervical dystonia signs and symptoms -

- Revance to host conference call at 4:30 pm ET today -

NEWARK, Calif.--(BUSINESS WIRE)-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing botulinum toxin products for use in aesthetic and therapeutic indications, today announced positive interim results from its U.S. Phase 2 open-label, dose-escalating clinical study of DaxibotulinumtoxinA Injectable (RT002) to treat moderate-to-severe isolated cervical dystonia in adults, a movement disorder of the neck.

The trial enrolled 37 subjects and follows three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial's first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the third cohort received from 300 to 450 units. Later-enrolled subjects in the second and third cohorts have yet to complete the trial's 24-week protocol. Today's results are therefore preliminary, with final results expected in the first half of 2017.

Interim Results from the Phase 2 Cervical Dystonia trial:

- **SAFETY**: In all three cohorts, RT002 injectable appeared to be generally safe and well-tolerated. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were transient and mild to moderate in severity, except for one case of neck pain reported as severe, with a duration of 2 days. The most common adverse events were dysphagia, or difficulty in swallowing (10.8%), injection site redness (8.1%), injection site pain (5.4%), muscle tightness (5.4%) and muscle weakness (5.4%). For reference, trials for botulinum type A products approved to treat cervical dystonia have adverse events for dysphagia ranging from 13% to 39%.
- **EFFICACY**: The trial's 4-week primary efficacy measurement was the improvement in dystonia symptoms as determined by reduction from baseline on the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)-Total score. RT002 injectable showed a clinically significant mean reduction of 16.9 from baseline, or 38%, across all three cohorts. In cohort one, with a mean dose of 174 units, the majority of the 44% reduction observed in the TWSTRS-Total score at Week 4 was preserved at Week 24, with a 33% mean reduction from baseline observed. Clinically meaningful mean reductions in the TWSTRS Severity, Disability and Pain subscales were consistent and observed at all follow-up visits in the first cohort. Later-enrolled subjects in the second and third cohorts have not yet reached the 24-week point. For reference, placebo-controlled trials with botulinum type A products approved to treat cervical dystonia had a reduction in the TWSTRS-Total score from baseline of 14% to 26% at Week 4.
- **DURATION OF EFFECT**: Duration of effect for this trial was defined as the number of weeks from treatment until the return of symptoms that warrant retreatment, based on the subject's target TWSTRS score. The median duration of effect was at least 24 weeks for subjects in cohort one (n=12), and at least 16 weeks for subjects in cohort two (n=11), using the complete 16 week follow up data. In cohort one, no subjects had returned to baseline at Week 24 and only one subject in cohort two, to date, has returned to baseline, which occurred at the Week 24 visit. In cohort one, RT002 achieved a median duration of at least 24 weeks based on three different assessments, including 1) the number of weeks from treatment until a subject reaches or exceeds their target TWSTRS-Total score, 2) improvement (score > 0) on the Clinician Global Impression of Change (CGIC), and 3) TWSTRS-Total score return to baseline. For reference, current treatment of cervical dystonia calls for injection of botulinum toxin approximately every 3 months, or 4 times per year.

"Patients with cervical dystonia suffer from painful, embarrassing twisting movements of the neck, often impairing their ability to work, drive and perform activities of daily living," said lead trial investigator Dr. Joseph Jankovic, Professor of Neurology, Distinguished Chair in Movement Disorders, Founder, The Parkinson's Disease Center and Movement Disorders Clinic (PDCMDC) Baylor College of Medicine, Houston, Texas. "The current treatment of cervical dystonia calls for injection of botulinum toxin about every 3 months, or 4 times per year, to provide patients with an improved quality of life. The

preliminary data in the Phase 2 trial appears quite robust, showing marked improvements in symptoms and signs. I am particularly encouraged that in this trial RT002 exhibited a safety profile at least as good as currently marketed neurotoxins. Furthermore, with a sustained median duration of at least 24 weeks, there is a possibility that patients will require injections only two times a year. Although further studies are needed, RT002 may represent a major advance in neurotoxin technology, which should translate into more meaningful treatment outcomes in patients with cervical dystonia."

"Cervical dystonia is an ideal therapeutic indication for testing the attributes of RT002 injectable," said Dan Browne, President and Chief Executive Officer at Revance. "We believe these results may have broad implications for the product profile of RT002, as we have now shown long duration in both low- and high-dose indications for small and large muscles. And we've also shown long duration of effect in two Phase 2 trials for the treatment of glablellar lines."

"Further, RT002 injectable, even at high doses, may deliver a strong safety profile possibly by limiting the spread of toxin, which could avoid life-altering adverse events such as general muscle weakness and difficulty swallowing," Browne continued. "We plan to share the final safety, efficacy, and duration results in 2017 once all cohorts have completed the 24-week assessment period. We then intend to seek regulatory advice from US and EU health authorities to determine the next steps in this clinical program."

The abstract for this Phase 2 clinical trial of RT002 injectable to treat cervical dystonia was submitted to the Toxins 2017 (January 18-21, Madrid, Spain) meeting and has been accepted for presentation. Study investigator Cynthia L. Comella, MD, Professor in the Department of Neurological Sciences at Rush University Medical Center, Chicago, Illinois, is scheduled to present.

Phase 2 Study Design

Revance's Phase 2 trial is an open-label, sequential, dose-escalating study to evaluate the safety, preliminary efficacy and duration of effect of a single treatment of DaxibotulinumtoxinA Injectable (RT002) for isolated cervical dystonia. Thirty-seven subjects with at least moderate cervical dystonia were enrolled at multiple sites in the United States. There are three treatment groups of 12, 12 and 13 subjects, respectively, each subject treated with one of three dose levels of RT002 injectable.

The primary efficacy endpoint of the Phase 2 study is an improvement in dystonia symptoms as measured by change (reduction) from baseline in Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score at four weeks. TWSTRS is a composite scale that covers different features of the cervical dystonia condition. The first part of the scale is based on the physical findings and severity of dystonia, the second part rates the patient's perceived level of disability, and the third part rates the pain. The study protocols also feature a number of secondary efficacy endpoints, including duration of effect and patient-rated quality of life as measured by change from baseline in Cervical Dystonia Impact Profile (CDIP).

All subjects are followed out to nine weeks, after treatment. Subjects with sustained improvement after this initial period of nine weeks continue to be assessed for duration of efficacy and other measures until they return to baseline or for up to a total of 24 weeks after treatment.

Conference Call

Revance management will host a conference call and webcast today at 4:30 pm ET. Individuals interested in listening to the conference call today, December 12, at 1:30 pm PT/4:30 pm ET may do so by dialing (855) 453-3827 for domestic callers, or (484) 756-4301 for international callers and reference conference ID: 37266728; or from the webcast link in the investor relations section of the Company's website at: www.revance.com. In addition, key data slides on the Phase 2 interim trial results will be discussed on the conference call and are posted to Revance's website on the INVESTORS tab in the *Presentations and Corporate Materials* section.

A replay of the call will be available beginning December 12, 2016 at 4:30 pm PT/7:30 pm ET through 7:30 pm ET on December 13, 2016. To access the replay, dial (855) 859-2056 or (404) 537-3406 and reference Conference ID: 37266728. The webcast will be available in the investor relations section on the Company's website for 30 days following the completion of the call.

About Cervical Dystonia

According to the Dystonia Medical Research Foundation, whose mission is to advance research, promote awareness and education, and support the needs affected individuals, cervical dystonia is a painful condition in which the neck muscles contract involuntarily, causing abnormal movements and awkward posture of the head and neck. The movements may be sustained (tonic), jerky (clonic), or a combination. Cervical dystonia (also referred to as spasmodic torticollis) may be primary (meaning that it is the only apparent neurological disorder, with or without a family history) or may be brought about by secondary causes (such as physical trauma). It can result in considerable pain and discomfort.

Treatments for cervical dystonia include oral medications, botulinum toxin injections, surgery, and complementary therapies. Botulinum toxin can help block the communication between the nerve and the muscle and may alleviate abnormal movements and postures. Current botulinum toxin treatments for cervical dystonia have a duration of effect of approximately three months. Cervical dystonia can occur at any age, although most individuals first experience symptoms in middle age. It affects several hundred thousand adults and children in the United States alone. Revance estimates the global market for treating muscle movement disorders with botulinum toxins, including cervical dystonia, was nearly $1 billion in 2015.

About Revance Therapeutics, Inc.

Revance, a Silicon Valley-based biotechnology company, is committed to the advancement of remarkable science. The company is developing a portfolio of products for aesthetic medicine and underserved therapeutic specialties, including dermatology, orthopedics and neurology. Revance's science is based upon a proprietary TransMTS® peptide technology, which when combined with active drug molecules, may help address current unmet needs.

Revance's initial focus is on developing daxibotulinumtoxinA, the company's highly purified botulinum toxin, for a broad spectrum of aesthetic and therapeutic indications, including facial wrinkles and muscle movement disorders. The company's lead drug candidate, DaxibotulinumtoxinA for Injection (RT002), is currently in development for the treatment of glabellar lines, cervical dystonia and plantar fasciitis with the potential to be the first long-acting neurotoxin. The company holds worldwide rights for all indications of RT002 injectable and RT001 topical and the pharmaceutical uses of the TransMTS technology platform. More information on Revance may be found at www.revance.com.

Forward Looking Statements

This press release contains forward-looking statements, including statements related to the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates, including but not limited to initiation and design of clinical studies for current and future indications, related results and reporting of such results; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects; and statements about our ability to obtain regulatory approval; and 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 risks that interim results are not indicative of final results and 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 4, 2016. 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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