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Revance Announces Publication of Positive 24-Week Duration of Effect Results from Cervical Dystonia Phase 2 Trial in Movement Disorders Clinical Practice

- RT002 achieved high response rate, long-lasting effect across all treatment groups and doses -

- RT002 appeared generally safe and well-tolerated through Week 36 -

NEWARK, Calif.--(BUSINESS WIRE)-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing neuromodulators for use in treating aesthetic and therapeutic conditions, today announced that results of a Phase 2 study of DaxibotulinumtoxinA for Injection (RT002) to treat moderate-to-severe cervical dystonia (CD) have been published in the peer-reviewed journal *Movement Disorders Clinical Practice* (https://onlinelibrary.wiley.com/doi/epdf/10.1002/mdc3.12613).

These positive 24-week results from a Phase 2 open-label, dose-escalating study were announced in May 2017 and were formally presented at the 21st International Congress of Parkinson's Disease and Movement Disorders in June 2017. The previously reported findings demonstrate that RT002 injectable provided clinically significant improvement in the signs and symptoms of CD as determined by reduction of the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)-Total score from baseline. In addition, RT002 was found to be generally safe and well-tolerated.

KEY 24-WEEK RESULTS

• **DURATION OF EFFECT AT LEAST 24 WEEKS BY DOSE GROUP:** The study included 21 patients (Group A) who received 100 to 240 units of RT002 injectable and 16 (Group B) who received 300 to 450 units. Median duration of effect, defined as the number of weeks study participants maintained at least 20 percent of the treatment benefit achieved at Week 4 (Target TWSTRS Score), was greater than 24 weeks for both dose groups (25.3 weeks). This is consistent with the ≥ 24-week duration of effect previously reported in each of the trial's three pre-specified patient groups.

• **TWSTRS-TOTAL AND SUBSCALE SCORES:** RT002 injectable showed a clinically significant mean reduction in the TWSTRS-Total score from baseline at Week 4 - the primary efficacy endpoint - in both Group A (37 percent) and Group B (39 percent), with the majority of this benefit maintained through Week 24. In addition, clinically meaningful reductions in TWSTRS-Severity, Disability and Pain subscales were consistent and observed at all time points through Week 24.

• **RESPONSE RATES AND PATIENT-RATED QUALITY OF LIFE:** A high rate of response was observed in the study, with 94 percent of patients experiencing a reduction of at least 20 percent from baseline in TWSTRS-Total Score at Week 6, and 68 percent maintained this treatment benefit at Week 24. In addition, a mean reduction of 37 percent from baseline in the Cervical Dystonia Impact Profile (CDIP-58) score was observed at Week 6 for all patients, with the majority of this clinically meaningful benefit maintained through Week 24.

• **SAFETY FINDINGS:** As previously reported, RT002 injectable appeared to be generally safe and well-tolerated through Week 24 in all treatment groups. There were no serious adverse events and no dose-dependent increase in adverse events. The most common treatment-related adverse events were dysphagia (14 percent) and injection site erythema (8 percent), and these were generally characterized as mild to moderate and were transient, with one case of neck pain reported as severe (Day 10 onset; duration two days).

"Cervical dystonia is a movement disorder characterized by involuntary movements of the head and neck resulting in abnormal twisting postures of the head that is frequently associated with pain. The treatment of choice for cervical dystonia is botulinum toxin injections. Unfortunately, the drawback of this therapy, as currently available, is that patients must typically be re-treated at approximately three to four month intervals in order to maintain benefit," said trial investigator Joseph Jankovic, MD, Professor of Neurology and Distinguished Chair in Movement Disorders, Baylor College of Medicine. "The data from the now published RT002 study indicated that this new formulation of botulinum toxin serotype A may significantly improve symptoms of cervical dystonia and have an impressive duration of benefit of 24 weeks, which is almost twice as long as the toxins currently available. The Phase 3 ASPEN cervical dystonia program will ultimately determine if the results of this Phase 2 study published in *Movement Disorders Clinical Practice* are replicated."

In November 2017, the U.S. Food and Drug Administration granted RT002 orphan drug designation for the treatment of cervical dystonia. The FDA grants this designation to drugs intended to treat rare conditions that affect fewer than 200,000

people in the United States.

"The emergence of a new, differentiated neuromodulator is a potentially significant advance for physicians and their patients," said Revance President and Chief Executive Officer Dan Browne. "Acceptance in a peer-reviewed publication further validates the significance of our cervical dystonia clinical program and underscores the confidence we have in the long duration of effect of RT002 for treating a condition that takes such a toll on patient quality of life. We look forward to additional data from the upcoming ASPEN Phase 3 trials to further characterize the safety, efficacy and duration of effect of RT002 in this important orphan disease indication."

CD Phase 2 Study Design

Revance's Phase 2 trial was an open-label, sequential, dose-escalating study designed to evaluate the safety, preliminary efficacy and duration of effect of a single treatment of DaxibotulinumtoxinA Injectable (RT002) for isolated cervical dystonia. Thirty-seven patients with moderate-to-severe cervical dystonia were enrolled at multiple sites in the United States. The trial's first cohort of 12 patients received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 patients received between 200 and 300 units, and the third cohort of 13 patients received from 300 to 450 units.

The primary efficacy endpoint of the Phase 2 study was 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 validated composite scale that evaluates the severity of the condition based on the physical findings of dystonia as well as the patient's perceived level of disability and pain associated with the condition. The study protocol also featured a number of secondary efficacy endpoints.

Patients were followed for up to 24 weeks after treatment, or until return of symptoms that warrant treatment, at which time they could complete the study. Due to the long duration of effect seen in the first group, patients in the second and third groups were given the option to continue. Several patients elected to remain in the study and were followed for up to 36 weeks.

ASPEN Phase 3 CD Clinical Program

The ASPEN Phase 3 program with RT002 for the treatment of moderate-to-severe isolated cervical dystonia is planned to start in the second quarter this year. The program is expected to include a single pivotal trial, plus an open-label trial, totaling approximately 300 patients from the U.S., Canada and Europe.

Additional information about the ASPEN Phase 3 program, including patient eligibility criteria, will be available at www.clinicaltrials.gov.

About Cervical Dystonia

According to the Dystonia Medical Research Foundation, 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 the result of secondary causes (such as physical trauma), and can cause considerable pain and discomfort.

Treatments for cervical dystonia include oral medications, botulinum toxin injections, surgery, and complementary therapies. Botulinum toxin blocks the communication between the nerve and the muscle, relaxing the muscle, which alleviates abnormal involuntary 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. The condition affects a few 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 $1.1 billion in 2017.

About Revance Therapeutics, Inc.

Revance Therapeutics is a biotechnology company developing neuromodulators for use in treating aesthetic and therapeutic conditions, including muscle movement disorders and pain. 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 plans to initiate studies in upper limb spasticity and chronic migraine. RT002 has the potential to be the first long-acting neuromodulator. Revance has developed a proprietary, stabilizing excipient peptide technology designed to create novel, differentiated therapies. The company has a comprehensive pipeline based upon its peptide technology, including injectable and topical formulations of daxibotulinumtoxinA. More information on Revance may be found at www.revance.com.

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Forward-Looking Statements

This press release contains forward-looking statements, including statements related to Revance Therapeutics' long-term financial outlook and other financial performance, 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 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 May 9, 2018. 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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