Revance Doses First Patient in ASPEN Phase 3 Clinical Program of RT002 Injectable for the Treatment of Cervical Dystonia

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- RT002 Injectable has potential to be first long-acting neuromodulator for treatment of a debilitating involuntary muscle movement disorder -

NEWARK, Calif.--(BUSINESS WIRE)--Jun. 21, 2018-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing neuromodulators for use in treating aesthetic and therapeutic conditions, today announced initiation of patient dosing in the company's ASPEN Phase 3 clinical program for its investigational drug candidate DaxibotulinumtoxinA for Injection (RT002) for the treatment of cervical dystonia (CD), a movement disorder of the neck.

"In our Phase 2 study, treatment with RT002 resulted in patients realizing clinically meaningful relief from the pain and disability associated with cervical dystonia for at least 24 weeks," said Roman Rubio, MD, Senior Vice President of Clinical Development at Revance. "Current botulinum toxin injections for cervical dystonia are administered at approximately 12-week intervals. With the potential for twice yearly administration, RT002 could represent a meaningful advancement in treatment, providing significantly prolonged improvement of symptoms in patients."

"The initiation of our pivotal program is an important milestone for Revance as we advance our novel long-lasting neuromodulator RT002 in this important therapeutic indication," said Dan Browne, President and Chief Executive Officer at Revance. "The FDA granted Orphan Drug Designation for the use of RT002 in the treatment of cervical dystonia, and we believe that RT002 can deliver improved patient outcomes not only in cervical dystonia therapy, but in a number of other muscle movement disorders as well."

Positive results from the company's open-label, dose-escalating Phase 2 clinical study of RT002 injectable in the treatment of cervical dystonia were recently published in *Movement Disorders Clinical Practice*. The trial demonstrated a median duration of effect of at least 24 weeks for each of the three dose cohorts studied. For reference, current treatment of cervical dystonia calls for injection of botulinum toxin approximately every three months (12 weeks), or four times per year.

The Phase 2 trial achieved its primary efficacy endpoint, demonstrating a clinically significant mean reduction of 38 percent in the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) - Total score from baseline at Week 4 across all three cohorts. This mean reduction continued to increase to 50 percent at Week 6, was 42 percent at Week 12, and was maintained at or above 30 percent through Week 24. For reference, placebo-controlled trials for botulinum toxin type A products approved to treat cervical dystonia had a reduction in the TWSTRS – Total score from baseline of 21 percent to 26 percent at Week 4 and 13 percent to 16 percent at Week 12.

Regarding the Phase 2 study's key secondary endpoint – percentage of responders showing improvement on Clinician Global Impression of Change (CGIC) – 97 percent of all patients experienced an improvement in cervical dystonia symptoms at Week 4. In all three cohorts, RT002 injectable appeared to be generally safe and well-tolerated through Week 24. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were generally transient and mild to moderate in severity, with one case of neck pain reported as severe. The most common adverse events were dysphagia, or difficulty in swallowing (14 percent), of which all cases were mild in severity, injection site redness (8 percent), injection site bruising (5 percent), injection site pain (5 percent), muscle tightness (5 percent) and muscle weakness (5 percent).

The global neuromodulator opportunity for muscle movement disorders in 2017 was estimated to be more than $1 billion. The company plans to initiate a Phase 2 program in upper limb spasticity, the largest indication in the muscle movement segment, later this year.

ASPEN Phase 3 Clinical Program in Cervical Dystonia

The company's ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of RT002 injectable for the treatment of cervical dystonia in adults: 1) a randomized, double-blind, placebo-controlled, parallel group trial, and 2) an open-label, long-term safety trial. The program is expected to enroll a total of approximately 300 patients at multiple sites in the United States, Canada, and Europe.

Randomized Trial: Patients will be randomized to either a low dose or high dose of RT002 injectable or placebo treatment. Post-treatment, patients will be followed for a maximum of 36 weeks. The primary efficacy endpoint of the trial will be the change from baseline in the TWSTRS – Total score. Key secondary endpoints include the duration of treatment effect, the Clinical and Patient Global Impression of Changes, and adverse events. Further, the trial features exploratory efficacy assessments, including the Cervical Dystonia Impact Profile (CDIP)-58, a disease-specific, patient-rated questionnaire that measures quality of life.

Open-Label Trial: Patients will receive up to four continuous treatment cycles of RT002 injectable over the 52-week observation period. Primary endpoints of the trial are safety and immunogenicity after multiple cycles of treatment with RT002. Key secondary endpoints are the change from baseline in TWSTRS – Total score, and the duration of treatment effect, as well as overall treatment response based on the Clinical and Patient Global Impression of Change.

Additional information about the ASPEN Phase 3 program, including patient eligibility criteria, will be posted shortly 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 results of secondary causes (such as physical trauma) and can cause considerable pain and discomfort.

Treatments for cervical dystonia include oral medications, neuromodulator (botulinum toxin) injections, surgery, and complementary therapies. Neuromodulators blocks the communication between the nerve and the muscle, relaxing the muscle, which alleviates abnormal involuntary movements and postures. Current neuromodulator 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. Global Industry Analysts, Inc. 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 underserved 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.

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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