



June 5, 2017

Revance Reports Additional Positive Week 24 Efficacy Results from RT002 Injectable Phase 2 Cervical Dystonia Trial

- Poster on display today to be presented during late-breaking session on June 7, 2017, at 21st International Congress of Parkinson's Disease and Movement Disorders -

NEWARK, Calif.--(BUSINESS WIRE)-- Revance Therapeutics, Inc. (NASDAQ: RVNC), a biotechnology company developing botulinum toxin products for use in treating aesthetic and therapeutic conditions, today announced additional clinical 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, a movement disorder of the neck, in adults. A late-breaking poster including these data was displayed today and will be presented on Wednesday, June 7, 2017, at 1:15 pm PT in Vancouver, Canada, by study investigator Cynthia L. Comella, MD, Professor in the Department of Neurological Sciences at Rush University Medical Center, Chicago, Illinois.

These results are in addition to findings reported on May 18, 2017, which showed RT002 injectable to be generally safe and well-tolerated. The previously reported findings also demonstrated duration of effect of at least 24 weeks and that RT002 injectable delivered clinically significant improvement in signs and symptoms of cervical dystonia as determined by reduction of the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)-Total score from baseline.

KEY NEW 24-WEEK FINDINGS

- **DURATION OF EFFECT AT LEAST 24 WEEKS BY DOSE GROUP:** The study researchers analyzed efficacy results in two dose groups: Dose Group A (N=21), individuals who received 100 to 240 units of RT002 injectable, and Dose Group B (N=16), receiving 300 to 450 units. Median duration of effect, defined as the number of weeks subjects maintained at least 20% of the treatment benefit achieved at Week 4 (Target TWSTRS Score), was greater than 24 weeks for both dose groups, consistent with the \geq 24-week duration of effect previously reported in each of the trial's three pre-specified patient cohorts.
- **TWSTRS-TOTAL AND SUBSCALE SCORES:** RT002 injectable showed a clinically significant mean reduction of the TWSTRS-Total score from baseline at Week 4 - the primary efficacy endpoint - in both Group A (37%) and Group B (39%), 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% of subjects at Week 6 experiencing a reduction of at least 20% from baseline in TWSTRS-Total Score, and 68% of subjects at week 24 observed to maintain this treatment benefit at Week 24. In addition, a mean reduction of 37% from baseline in the Cervical Dystonia Impact Profile (CDIP-58) score was observed at Week 6 for all subjects, 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 evaluated. 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, with one case of neck pain reported as severe (day 10 onset, duration of 2 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 3 month intervals in order to maintain benefit," said trial investigator Cynthia Comella, MD, Professor of Neurological Sciences, Rush University Medical Center. "The data from the RT002 study indicate 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 twice as long as the toxins currently available. Overall, I believe RT002 holds tremendous promise to provide cervical dystonia patients a significant and longer-lasting improvement of their symptoms."

Additional data at 21st International Congress of Parkinson's Disease and Movement Disorders

In addition to the late-breaking poster, a regular session poster with guided tour is scheduled for Thursday, June 8, 2017, at 1:15 pm PT presented by study investigator Atul Patel, MD, MHSA, Physical Medicine and Rehabilitation Physician at Kansas City Bone & Joint.

Once the posters are displayed at the congress, the company plans to add a slide presentation of the poster contents to its website under the *THERAPEUTICS* tab in the section entitled *Presentations and Publications*.

Based on these Phase 2 results, the company expects to discuss next steps in this clinical program with the US and EU regulatory agencies later this year.

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 moderate-to-severe cervical dystonia were enrolled at multiple sites in the United States. 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 of 13 subjects 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 covers different features of the cervical dystonia condition. The first part of the scale evaluates severity of the condition based on the physical findings of dystonia, the second part rates the patient's perceived level of disability, and the third part rates pain associated with the condition. The study protocol also features a number of secondary efficacy endpoints.

All subjects were followed for up to a total of 24 weeks after treatment, or until return of symptoms that warrant treatment, at which time subjects could complete the study. Due to the long duration of effect seen in the first cohort, subjects in the second and third cohorts were given the option to continue. Several patients elected to remain in the study and will be followed for up to 36 weeks.

About Cervical Dystonia

According to the Dystonia Medical Research Foundation, whose mission is to advance research, promote awareness and education, and support the needs of 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 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 neuromodulator. The company holds worldwide rights for all indications of RT002 injectable and RT001 topical and the pharmaceutical uses of its proprietary peptide technology platform. More information on Revance may be found at www.revance.com.

"Revance Therapeutics" and the Revance logo are registered trademarks of Revance Therapeutics, Inc.

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 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, 2017. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

View source version on [businesswire.com](http://www.businesswire.com/news/home/20170605005865/en/): <http://www.businesswire.com/news/home/20170605005865/en/>

Investors:

Revance Therapeutics
Jeanie Herbert, 714-325-3584
jherbert@revance.com

or

Burns McClellan
Ami Bavishi, 212-213-0006
abavishi@burnsmc.com

or

Trade Media:
Nadine Tosk, 504-453-8344
nadinepr@gmail.com

Source: Revance Therapeutics, Inc.

News Provided by Acquire Media