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Revance Plans Phase 3 Program for RT002 Injectable to Treat Cervical Dystonia

- Company completes End-of-Phase 2 Meeting with FDA -

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 the completion of its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) along with receipt of Scientific Advice from the Europe Medicines Agency (EMA) regarding DaxibotulinumtoxinA for Injection (RT002) for the treatment of cervical dystonia, a movement disorder of the neck, in adults. Based on the Phase 2 safety and efficacy results, along with guidance from the FDA and EMA, Revance plans to proceed to a Phase 3 program in cervical dystonia.

Revance's Phase 3 program will be conducted at multiple sites in the U.S., Canada and Europe, and will be designed to fulfill regulatory submission requirements in both the U.S. and Europe. Revance is finalizing the trial protocols for the pivotal program, which is planned to commence in the second quarter of 2018.

In May 2017, the company reported that in a Phase 2 trial, RT002 appeared to be generally safe and well-tolerated, delivered clinically significant improvement in signs and symptoms of cervical dystonia in patients, and demonstrated duration of effect of at least 24 weeks. Earlier this month, the company announced that the FDA granted Orphan Drug Designation for RT002 to treat cervical dystonia.

"Our discussions with the FDA and EMA were very fruitful, directing specific courses of action for our clinical program for RT002 in cervical dystonia," said Dan Browne, President and Chief Executive Officer of Revance. "We are energized by the momentum behind our first potential therapeutic indication and are excited by the prospect of bringing this promising, long-acting therapy to those suffering from this highly debilitating disease."

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. 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 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 to 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.

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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 November 3, 2017. 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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