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Revance Provides Update on Phase 2 Program for RT002 Injectable in the Management of Plantar Fasciitis

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 that it is expanding the Company's Phase 2 program investigating the use of DaxibotulinumtoxinA for Injection (RT002) for the management of plantar fasciitis from a single center to a multi-center study with protocol updates. Revance expects to report topline results from the Phase 2 study in the fourth quarter of 2017.

"We are very excited about the potential use of RT002 to treat plantar fasciitis, which causes severe pain and inflammation along the bottom of the foot, especially in the heel area," said Dan Browne, President and Chief Executive Officer at Revance. "We have moved from a single center to a multi-center study protocol, including Wake Forest Baptist Medical Center and two new non-academic study sites, to help us meet our enrollment goals and report topline safety and efficacy results for the plantar fasciitis program before year-end. The combination of a validated visual analog scale (VAS) for measuring the reduction of pain in the foot as a primary endpoint and the improvement in the American Orthopaedic Foot and Ankle Score (AOFAS) as a secondary endpoint provide for clinically meaningful measurements of RT002's ability to reduce the pain associated with plantar fasciitis. We believe these changes strengthen the Phase 2 program's capacity to assess the use of RT002 to treat plantar fasciitis."

The study protocol has been submitted to the U.S. Food and Drug Administration and is scheduled to post on clintrials.gov this week. Recruitment and screening of patients under the new study protocol is already underway.

Phase 2 Study Design

This Phase 2 prospective, randomized, double-blinded, placebo-controlled, multi-center study will evaluate the safety and efficacy of a single administration of Revance's investigational drug candidate DaxibotulinumtoxinA for Injection (RT002) in reducing the signs and symptoms of plantar fasciitis. This study is expected to enroll approximately 60 subjects across three centers in the United States. The study's primary efficacy endpoint is the reduction in the visual analog scale (VAS) for pain in the foot. Improvement in the American Orthopaedic Foot and Ankle Score (AOFAS) is one of several secondary endpoints. Subjects will be followed for 16 weeks post treatment.

About Plantar Fasciitis

Heel pain is the most common complaint of patients who visit podiatrists and orthopeadic foot and ankle surgeons. Eighty percent of reported heel pain complaints are due to plantar fasciitis, which is caused by inflammation of the connective tissue in the arch of the foot.[1] Plantar fasciitis is estimated to affect 10 to 18 million individuals in the United States annually.[2] Risk factors include age, long distance running, excessive weight, abnormal foot posture, use of poor foot wear, and repetitive trauma.[3]

Treatment options for less severe cases include leg and foot stretching exercises, nonsteroidal anti-inflammatory drugs, shoe inserts, heel pads, and night splints. More severe or refractory cases are currently treated with steroid injections, extracorporeal shock wave therapy, platelet rich plasma injections, and/or surgery.[4]

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 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 annual report on Form 10-K filed February 28, 2017. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

References:

1. Med Clin N America. 2014;98(2): 339-352.
2. Foot & Ankle Int. 2004;25(5):303-310.
3. Foot & Ankle Int. 2008 Mar; 29(3):358-366.
4. J Am Acad Orthop Surg. 2014;22(6):372-380.

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