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Revance Announces Initiation of Phase 2 Trial of RT002 Injectable to Treat Plantar Fasciitis

- Topline Results Expected in 2017 -

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 initiation of a Phase 2 placebo-controlled trial of its investigational drug candidate DaxibotulinumtoxinA for Injection (RT002) for the management of plantar fasciitis. This painful affliction, caused by inflammation of the ligament running along the bottom of the foot, is the most common cause of heel pain. Topline clinical results from the Phase 2 trial are expected in 2017.

"The plantar fascia is the foot's shock absorber. Repeated pressure on this tissue, whether from sport activities, aging, or obesity, can create small tears in or overstretch the fascia. The result is inflammation accompanied by sharp, constant pain that often gets worse over time and can become highly debilitating," said Clinical Investigator L. Andrew Koman, MD, Professor and Chair of the Department of Orthopaedic Surgery and Executive Director Musculoskeletal Service Line, Wake Forest School of Medicine. "Preclinical and clinical research suggests a neurotoxin candidate such as RT002 may provide patients with sustained relief from chronic heel pain and support healing of the plantar fascia without the risks of plantar fascia rupture or atrophy of the fat pad that can occur with corticosteroid injections.[1]"

An estimated one in 10 people will develop plantar fasciitis during their lifetime. Symptoms can last six months or more, sometimes requiring surgery.[2] In the United States alone, more than two million patients undergo treatment for plantar fasciitis each year.[3]

"This Phase 2 study for plantar fasciitis will advance a whole new treatment area for botulinum toxin that addresses pain and muscle tightness. Revance has the opportunity to be a first mover for this indication and other musculoskeletal disorders," said Dan Browne, President and Chief Executive Officer at Revance. "No botulinum toxin is approved for treating plantar fasciitis; however, the clinical endpoints are well validated. Published estimates place the annual U.S. evaluation and treatment market for plantar fasciitis at more than $250 million, and we believe the market could grow significantly larger if patients had a compelling neurotoxin treatment option."

Phase 2 Study Design

This Phase 2 prospective, randomized, double-blinded, placebo-controlled 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. The study is expected to enroll approximately 60 subjects in the United States. The study's primary efficacy endpoint is the improvement in the American Orthopaedic Foot and Ankle Score (AOFAS). 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.[4] Plantar fasciitis is estimated to affect 10 to 18 million individuals in the United States annually.[3] Risk factors include age, long distance running, excessive weight, abnormal foot posture, use of poor foot wear, and repetitive trauma.[5]

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.[6]

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 and neurology. Revance's science is based upon a proprietary TransMTS® 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, and has the potential to be the first long-acting neurotoxin. The company holds worldwide rights for all indications of RT002 injectable and RT001 topical and the pharmaceutical uses of the TransMTS technology platform. More information on Revance may be found at www.revance.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to: statements about our business strategy, our investigational drug product candidates, expected efficacy of our drug product candidates, clinical development, timeline and other goals and market for our anticipated products, plans and prospects and statements about 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 on August 5, 2016. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

References:

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3. Foot & Ankle Int. 2004;25(5):303-310.

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