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Revance Announces Interim Phase 2a Results for RT002 in Treating Plantar Fasciitis

NEWARK, Calif.--(BUSINESS WIRE)-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing neuromodulators for use in treating aesthetic and underserved therapeutic conditions, today announced interim 8-week Phase 2a results for its next-generation neuromodulator DaxibotulinumtoxinA for Injection (RT002) in treating plantar fasciitis, a common debilitating form of foot pain.

The trial's primary endpoint, the reduction in the patient-reported visual analog scale (VAS) for pain at Week 8, showed a robust impact on pain, with a greater than 50% reduction for patients treated with RT002. In the intent-to-treat population, a mean reduction in the VAS score of 54.2% from baseline was achieved with RT002, compared with a 42.6% reduction in the placebo group, which upon further subgroup analysis, was driven primarily by a strong placebo response in the control group at two of the five study sites. While not statistically significant (p=0.39), RT002 did outperform placebo, providing patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints.

RT002 appeared to be generally safe and well-tolerated through Week 8. The majority of adverse events in both treatment groups were mild in severity. There were no treatment-related serious adverse events. The most common treatment-related adverse events for RT002 and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity.

"This initial proof-of-concept study demonstrates that RT002 may have a positive impact on the severe heal pain caused by plantar fasciitis," said Dan Browne, Co-Founder, President and Chief Executive Officer of Revance. "The substantial reduction in the VAS with RT002 at Week 8 is consistent with prior neuromodulator studies in plantar fasciitis. This data provides a rich resource to understand plantar fasciitis and how to best treat the pain associated with this condition using a neuromodulator. We plan to complete this study and review the full data set. Further, before moving to a Phase 2b trial later this year as previously planned, we now expect to conduct another Phase 2a trial with a modified design to demonstrate the ability of RT002 to treat plantar fasciitis."

Phase 2a Study Design

This Phase 2a prospective, randomized, double-blind, placebo-controlled, multi-center study conducted at five centers in the U.S. is evaluating the safety and efficacy of a single administration of 240 units of DaxibotulinumtoxinA for Injection (RT002) in reducing the signs and symptoms of plantar fasciitis. The trial enrolled a total of 59 male or female subjects, 18 to 65 years of age, with diagnosis of unilateral plantar fasciitis by physical examination and/or ultrasonography. The study's primary efficacy endpoint is the reduction in the visual analog scale (VAS) for pain in the foot evaluated at Week 8. The secondary endpoints include American Orthopaedic Foot and Ankle Score (AOFAS), Foot and Ankle Disability Index (FADI), and Patient Reported Outcome Measurement Information System (PROMIS). An exploratory efficacy evaluation is the Improvement in the Plantar Fasciitis Pain and Disability Scale (PFPS). Subjects will be followed for a total of 16 weeks post-treatment.

About Plantar Fasciitis

Heel pain is the most common complaint of patients who visit podiatrists and orthopaedic foot and ankle surgeons. Eighty percent of reported heel pain complaints are due to plantar fasciitis, which is caused by tears in the fascia that in turn lead to inflammation of the connective tissue in the arch of the foot.[1] The fascia is a sheet or band of fibrous connective tissue under the skin that covers a surface of underlying tissues. Fascia surrounds each of the muscles that move the skeleton. When the fascia is inflamed, the condition is referred to as "fasciitis."[2]

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.[4]

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.[5]

About RT002

DaxibotulinumtoxinA for Injection (RT002) is an investigational product. It is a novel, next-generation neuromodulator in development for the treatment of aesthetic and therapeutic conditions, including glabellar lines, cervical dystonia and plantar fasciitis. Created using Revance's proprietary peptide technology, RT002 has the potential to become the first neuromodulator with long-acting duration of six months for the treatment of glabellar lines. This proprietary, stabilizing excipient peptide technology eliminates the need for human- and animal-based components, which carry a potential risk of transmitting pathogens.

Revance has two other active clinical programs for RT002 injectable under way. In December of 2017, Revance announced positive SAKURA 1 and SAKURA 2 Phase 3 pivotal trials to treat glabellar lines. With the SAKURA 3 open-label, long-term safety study fully enrolled, the company plans to complete the safety study in the second half of 2018 and file its biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) in the first half of 2019. For the treatment of cervical dystonia, the company was recently granted orphan drug designation and plans to initiate a Phase 3 program in the second quarter of 2018.

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 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 our business strategy, timeline and other goals and market for our anticipated products, plans and prospects; statements about our ability to obtain regulatory approval; 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; 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.

References:

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INVESTORS
Revance Therapeutics, Inc.:
Jeanie Herbert, 714-325-3584
jherbert@revance.com
or
Burns McClellan, Inc.:
Ami Bavishi, 212-213-0006
abavishi@burnsmc.com
or
MEDIA
General Media:
TOGORUN:
Mariann Caprino, 917-242-1087
m.caprino@togorun.com
or
Trade Media:
Nadine Tosk, 504-453-8344
nadinepr@gmail.com

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