Revance Announces Results of Phase 2 Trial of DaxibotulinumtoxinA for Injection in Plantar Fasciitis

November 9, 2020

- Patients reported significant pain reduction that was numerically greater than placebo, however, the primary efficacy endpoint was not met –

NEWARK, Calif.--(BUSINESS WIRE)--Nov. 9, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced results from its Phase 2 clinical trial of investigational drug candidate DaxibotulinumtoxinA for Injection for the management of plantar fasciitis, a painful affliction caused by inflammation of the ligament running along the bottom of the foot (the plantar fascia), the most common cause of heel pain.[1]

This Phase 2 prospective, randomized, double-blind, multi-center, placebo-controlled trial evaluated the safety and efficacy of two doses of DaxibotulinumtoxinA for Injection in reducing the signs and symptoms of plantar fasciitis. The trial enrolled 155 adult patients with unilateral plantar fasciitis, 18 to 65 years of age, at 17 study centers in the United States. Patients were randomized (1:1:1) to receive an injection of DAXI 80 U, DAXI 120 U or placebo. The study's primary efficacy endpoint was the change from baseline on the 10-point Numeric Pain Rating Scale (NPRS) score averaged over five days at Week 8. Patients were followed for up to 24 weeks post treatment to assess treatment response, tolerability and safety.

In the trial, both doses of DaxibotulinumtoxinA for Injection resulted in significant, measurable pain relief after treatment that was numerically greater than placebo. However, neither dose met the primary efficacy endpoint of statistically significant improvement from baseline in the NPRS for foot pain at Week 8, compared to placebo. Subjects treated with DaxibotulinumtoxinA for Injection showed an average reduction from baseline of 3.29 on the NPRS (a 54.6% reduction) at 80U (p=0.2135 vs. placebo) and 3.25 on the NPRS (a 50.1% reduction) at 120U (p=0.2205 vs. placebo, p=0.9207 vs. 80U), compared to placebo subjects at 2.75 on the NPRS (a 45.1% reduction).

DaxibotulinumtoxinA for Injection was found to be safe and well-tolerated at both doses through Week 24. There were no serious treatment-related adverse events and no dose dependent increase in adverse events was observed. Treatment-related adverse events were generally transient and mild to moderate in severity. The two most common treatment-related adverse events were (for 80 Units, 120 Units and placebo, respectively) injection site pain (6.1%, 5.6%, 5.8%) and injection site erythema (2.0%, 1.9%, 1.9%).

"While we are disappointed with these Phase 2 results, it's important to note that no other neuromodulator has been approved for the treatment of plantar fasciitis, which is a new therapeutic category with an underlying physiology that is different from currently approved indications for muscle movement and pain disorders that utilize neuromodulators," said Mark Foley, President and Chief Executive Officer of Revance. "Though we plan to further analyze the plantar fasciitis data, we will primarily focus our therapeutic efforts on established neuromodulator indications, including muscle movement disorders where our positive ASPEN-1 Phase 3 cervical dystonia results are a source of confidence. Consequently, we look forward to announcing the topline results from our JUNIPER Phase 2 upper limb spasticity trial in the first quarter of 2021."

About Revance Therapeutics, Inc.

Revance Therapeutics, Inc. is a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection. DaxibotulinumtoxinA for Injection combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. Revance has successfully completed a Phase 3 program for DaxibotulinumtoxinA for Injection in glabellar (frown) lines and is pursuing U.S. regulatory approval in 2020. Revance is also evaluating DaxibotulinumtoxinA for Injection in the full upper face, including glabellar lines, forehead lines and crow's feet, as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis. To accompany DaxibotulinumtoxinA for Injection, Revance has built a unique portfolio of premium products and services for U.S. aesthetics practices, including the RHA® Collection of dermal fillers in the U.S., the first and only range of FDA-approved fillers for correction of dynamic facial wrinkles and folds, and the HintMD fintech platform, which includes integrated smart payment, subscription and loyalty digital services. Revance has also partnered with Mylan N.V. to develop a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. Revance is dedicated to making a difference by transforming patient experiences. For more information or to join our team visit us at www.revance.com.

Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements about our analysis of the plantar fasciitis data; the therapeutic and commercial potential of DaxibotulinumtoxinA for Injection; the potential value of DaxibotulinumtoxinA for Injection in established neuromodulator indications, including muscle movement disorders; the process and timing of, and ability to complete, of current and anticipated future clinical development of our investigational drug product candidates; our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates, including with respect to the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines and the expected Prescription Drug User Fee Act (PDUFA) action date of November 25, 2020; the initiation, design, enrollment, submission, timing and results of our clinical studies, including the near-term milestone expectations described above; development of a biosimilar to BOTOX®; our business strategy, timeline and other goals for our anticipated products, plans and prospects, including our commercialization plans; and potential benefits of our drug product candidates, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties relate to, but are not limited to: the results, timing, costs, and completion of our research and development activities; the uncertain clinical development process, including the risk that the top-line results from the ASPEN-1 trial evaluating DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia are based on our preliminary analysis of key efficacy and safety data, the fact that such data may change following a more comprehensive review of the data related to the clinical trial and such top-line data may not accurately reflect the complete results of the trial, and the FDA may not agree with our interpretation of such results; clinical trials may not have an effective design or generate positive results; our plans to research, develop, and commercialize our drug product candidates; the applicability of clinical study results to actual outcomes; our ability to obtain regulatory approval of our drug product candidates, including with respect to a potential delay in the anticipated PDUFA target action date for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines due to COVID-19-related policies and travel restrictions currently in place at the FDA; our ability to successfully commercialize our drug product candidates, if approved, and the timing and cost of commercialization activities; our ability to obtain funding for our operations; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; our financial performance, including future revenue, expenses and capital requirements; and the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, business operations, clinical trials and other aspects of our business. 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 our periodic filings with the Securities and Exchange Commission (SEC), including factors described in the section entitled "Risks Factors" on our Form 10-Q filed with the SEC on August 6, 2020 and in our future filings with the SEC, including, without limitation, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, expected to be filed with the SEC on November 9, 2020. The forward-looking statements in this press release speak only as of the date hereof. We disclaim any obligation to update these forward-looking statements.

References:

1. Med Clin N America. 2014;98(2): 339-352.
Source: Revance Therapeutics, Inc.

View source version on businesswire.com: https://www.businesswire.com/news/home/20201109005928/en/

Investors
Revance Therapeutics, Inc.:
Jeanie Herbert, 714-325-3584
jherbert@revance.com
or
Gilmartin Group, LLC.:
Laurence Watts, 619-916-7620
laurence@gilmartinir.com

Media
Revance Therapeutics, Inc.:
Sara Fahy, 949-887-4476
sfahy@revance.com
or
General Media:
Goodfuse:
Jenifer Slaw, 347-971-0906
jenifer.slaw@YR.com
or
Trade Media:
Nadine Tosk, 504-453-8344
nadinepr@gmail.com

Source: Revance Therapeutics, Inc.