Revance Announces Last Patient Enrolled in Modified JUNIPER Phase 2 Upper Limb Spasticity Trial of DaxibotulinumtoxinA for Injection

June 30, 2020

- Enrollment closed with at least 76 subjects; study protocol modified in light of ongoing COVID-19 pandemic -

- Revance now expects to report topline results from JUNIPER trial in early 2021 -

NEWARK, Calif.--(BUSINESS WIRE)--Jun. 30, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection, today announced a decision to complete enrollment in its JUNIPER Phase 2 trial of DaxibotulinumtoxinA for Injection for the treatment of upper limb spasticity in adults after stroke or traumatic brain injury. Due to ongoing COVID-19 concerns related to subject enrollment and scheduling in-person study visits, the company has chosen to end screening and complete the study with 76 subjects enrolled, along with a few subjects currently being evaluated for participation in the study. The 73 subjects dosed before enrollment was paused in March due to COVID-19 will be followed for up to 36 weeks; subjects enrolled after this will be followed to Week 12. Revance now expects to announce topline data from the JUNIPER Phase 2 trial in early 2021.

“In announcing the close of enrollment for our JUNIPER Phase 2 trial, we are taking a pragmatic approach and making a proactive decision in light of the ongoing COVID-19 pandemic,” said Roman Rubio, M.D., Senior Vice President of Clinical Development at Revance. “Fortunately, we have enrolled approximately two-thirds of the initial target subjects, which will produce phase 2 trial data that provides adequate information to advance our clinical program in upper limb spasticity.”

Added Mark Foley, President and Chief Executive Officer, “While the vast majority of our clinical development programs for DaxibotulinumtoxinA for Injection have been unaffected by the coronavirus pandemic, the one exception has been our JUNIPER trial, as previously communicated. We announced a pause in enrollment due to challenges in ongoing recruitment and subject monitoring due to social distancing. As COVID-related concerns have continued, we reassessed our assumptions and timeline, concluding that truncating the Phase 2 trial now could potentially allow us to move into the pivotal Phase 3 upper limb spasticity trials earlier than originally planned, while also avoiding patient enrollment during this challenging time.”

Today’s announcement means Revance’s therapeutic programs for DaxibotulinumtoxinA for Injection will generate three topline clinical results near term: A Phase 3 pivotal trial in cervical dystonia; a Phase 2 trial in plantar fasciitis; and a Phase 2 trial in upper limb spasticity. Concluded Foley, “We believe this enrollment decision is optimal for Revance’s upper limb spasticity program, as well as for the patients we hope to treat, and we look forward to announcing the readouts in three therapeutic indications in the coming months.”

About JUNIPER Phase 2 Study

The company’s JUNIPER study is a Phase 2, randomized, double-blind, placebo-controlled, parallel group, dose-ranging, multi-center trial to evaluate the efficacy and safety of DaxibotulinumtoxinA for Injection for the treatment of upper limb spasticity in adults following stroke or traumatic brain injury. The study is being conducted at 28 sites in the United States and has enrolled male and female patients between the age of 18 to 75 years old. Patients have been randomized into one of four treatment groups: low dose, medium doses, high dose and a placebo. The study was designed to run for up to 36 weeks, with two primary outcome measures: change from baseline in muscle group most severely affected by spasticity score at Week 6; and change from Baseline Physician Global Impression of Change score at Week 6. Five secondary outcome measures are also included in the study to assess muscle tone improvement and duration of effect.

Additional information about the JUNIPER Phase 2 study can be found at www.clinicaltrials.gov using the identifier NCT03821402.

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. Beyond DaxibotulinumtoxinA for Injection, Revance has exclusive rights to commercialize TEOXANE SA’s Resilient Hyaluronic Acid® (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. Revance also has an agreement 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 Statement

This press release contains forward-looking statements, including statements related to Revance Therapeutics' 2020 financial outlook, expected cash runway and other financial performance, the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates, the initiation, design, timing and results of our clinical studies, including the SAKURA 3 study of

DaxibotulinumtoxinA for Injection, Phase 3 program for treatment of cervical dystonia, Phase 2 and other clinical programs for the management of plantar fasciitis and for the treatment of adult upper limb spasticity, and related results and reporting of such results; results of our non-clinical programs; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects; including our pre-commercialization plans and timing of our potential submission of a BLA filing for DaxibotulinumtoxinA for Injection to treat glabellar (frown) lines and potential regulatory approach and product launch; statements about our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates; statements regarding additional milestone payments through our partnerships, and potential benefits of our drug product candidates and our excipient peptide and other 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 May 8, 2020. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200630005831/en/

Media
Revance Therapeutics, Inc.:
Sara Fahy, 949-887-4476
sfahy@revance.com

or

General Media:
Y&R:
Jenifer Slaw, 347-971-0906
jenifer.slaw@YR.com

or
Trade Media:
Nadine Tosk, 504-453-8344
nadinepr@gmail.com

Investors
Revance Therapeutics, Inc.:
Jeanie Herbert, 714-325-3584
jherbert@revance.com

or

Gilmartin Group, LLC.:
Laurence Watts, 619-916-7620
laurence@gilmartinir.com

Source: Revance Therapeutics, Inc.