Revance Highlights Recent Regulatory Progress and Provides Anticipated 2019 Milestones

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- Completes Type B Pre-BLA meeting with U.S. FDA for glabellar lines indication and remains on track to submit application in first half of 2019 -

- Initiates Phase 2 trials for RT002 in both plantar fasciitis and adult upper limb spasticity -

NEWARK, Calif.--(BUSINESS WIRE)--Jan. 7, 2019-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing next-generation neuromodulators for use in treating aesthetic and therapeutic conditions, today announced updates on meetings with the U.S. Food and Drug Administration (FDA), the initiation of two new Phase 2 clinical trials for DaxibotulinumtoxinA for Injection (RT002) in therapeutic indications, commercial collaborations, and details on certain anticipated clinical and regulatory milestones in 2019.

“Revance is entering 2019 with tremendous momentum on multiple fronts,” said Dan Browne, president and chief executive officer at Revance. “We have an exciting ensemble of late-stage clinical trials underway for our next-generation neuromodulator and are operating a U.S.-based, commercial-scale drug substance and drug product facility to manufacture a broad range of proprietary neuromodulation formulations. We also have an active collaboration for the introduction of RT002 in China and another to develop a biosimilar to BOTOX®. Strategically, as we anticipate entering the market with RT002 in 2020, we intend to set a new standard in neuromodulators, focused on providing patients with the ability to safely alleviate the appearance of frown lines with just two or fewer treatments per year.”

REGULATORY UPDATE AND MILESTONES

In December of 2018, the company completed its pre-Biologics Licensing Application (BLA) meeting with the FDA for its submission of DaxibotulinumtoxinA for Injection (RT002) in the treatment of glabellar (frown) lines. According to Browne, “With the unprecedented SAKURA 3 Phase 3 open-label clinical program in glabellar lines successfully concluded, we have completed all the necessary clinical trials for our long-lasting neuromodulator RT002 and we are busy finalizing steps to submit our application to the FDA for regulatory approval. We remain confident in our ability to gain approval with a differentiated label and to build a meaningful neuromodulator business based on innovation, best-in-class performance, and improved patient outcomes.”

In February of 2018, Revance announced a collaboration and license agreement with Mylan N.V. on a biosimilar to BOTOX®. Revance has since performed detailed analytical (structural and functional) characterization and comparability testing of its product to the reference product for the Biosimilar Initial Advisory Meeting (BIAM). In concert with Mylan, Revance submitted its BIAM briefing package to the FDA to develop the biosimilar to BOTOX® under a 351(k)-development pathway, and was granted a face-to-face meeting in the first quarter of 2019.

“We have a strong conviction in our ability to create a biosimilar to BOTOX ® under the 351(k) pathway,” said Abhay Joshi, PhD, Revance’s chief operating officer. “Pending FDA agreement on a biosimilar development path, we expect to work with Mylan to continue the analytical similarity program and conduct clinical trials necessary for approval.”

RT002 INJECTABLE 2019 CLINICAL MILESTONES

“In 2019, we will have an extensive and active clinical pipeline – a total of six programs for RT002 injectable that address over half of the current $4 billion global neuromodulation market,” said Browne. “In aesthetics, while we pursue a U.S. regulatory approval in glabellar lines, we plan to initiate a study in the first quarter for forehead lines in conjunction with treatment of the glabellar complex, followed mid-year with a study in lateral canthal lines, also known as crow’s feet. These trials will help determine the injection pattern and dosage for treatment of the upper face. In therapeutics, we have done a major expansion into neuroscience indications. We are pleased to announce that in late December we dosed the first patients in Phase 2 clinical trials for RT002 in both plantar fasciitis and adult upper limb spasticity. We now have clinical programs in three therapeutic areas actively recruiting patients.”

ASPEN Phase 3 Program for Treatment of Cervical Dystonia – Enrollment progressing to plan

The company initiated a Phase 3 program for patients with cervical dystonia in the second quarter of 2018. Patients with cervical dystonia suffer from painful, embarrassing twisting movements of the neck, often impairing their ability to work, drive and perform activities of daily living. The program consists of two trials. First, a randomized, double-blind trial, with a high dose, low dose and placebo group. Post-treatment, patients will be followed for a maximum of 36 weeks. Second, an open-label, long-term safety trial, with patients receiving up to four treatment cycles of RT002 injectable over a 52-week observation period. Each trial, conducted at multiple sites in the United States, Canada, and Europe, is expected to enroll a total of approximately 300 patients, with a majority of patients expected to roll-over from the pivotal into the long-term safety trial. Treatment using neuromodulators for cervical dystonia was estimated in 2017 to be a $200 million global opportunity. The company expects to complete enrollment by early 2020.

Phase 2 Trial for Treatment of Plantar Fasciitis – Trial initiated, with first patient dosed at end of 2018

Revance has initiated patient dosing in a Phase 2 clinical trial for RT002 for the management of plantar fasciitis. The plantar fascia is the foot’s shock absorber. Repeated pressure on this tissue, whether from sport activities, aging, or obesity, can result in plantar fasciitis, characterized by inflammation accompanied by sharp, constant pain in the heel that can become highly debilitating. There are currently no FDA-approved drugs to treat plantar fasciitis. Estimates suggest that 20 million people suffer from plantar fasciitis in the U.S. annually and more than two million patients per year receive treatment. Revance expects to complete enrollment in this Phase 2 trial during the second half of 2019.

Trial Design - The Phase 2 prospective, randomized, double-blind, multi-center, placebo-controlled study will evaluate the safety and efficacy of two doses of 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 150 adult patients with unilateral plantar fasciitis, from approximately 20 study centers in

the United States. Patients will be randomized (1:1:1) to receive an injection of a low dose, high dose or placebo. The study's primary efficacy endpoint is the change from baseline in Numeric Pain Rating Scale (NPRS) score at Week 8. Patients will be followed for up to 24 weeks post treatment to assess treatment response, tolerability and safety.

Additional information, including patient eligibility criteria, will be posted shortly at www.clinicaltrials.gov.

JUNIPER Phase 2 Trial for Treatment of Adult Upper Limb Spasticity–Trial now underway, with first patient dosed in late December 2018

Today, Revance announced it dosed the first patient in the JUNIPER Phase 2 clinical trial for RT002 in the treatment of upper limb spasticity. Upper limb spasticity is a form of movement disorder that presents as increased tone or stiffness of the muscles affecting a patient's ability to produce or control voluntary movement in the arms and hands. Treatment using neuromodulators for upper limb spasticity was estimated in 2017 to be more than a $200 million global opportunity, with the muscle movement market exceeding $1 billion globally. The company expects to complete enrollment in the second half of 2019.

Trial Design - The company's JUNIPER Phase 2 clinical trial of upper limb spasticity is a randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of RT002 injectable at three dose levels versus placebo in reducing muscle tone of adult patients with upper limb spasticity due to stroke or traumatic brain injury over 36 weeks. The program is expected to enroll a total of approximately 128 patients, 18-70 years of age, at 25 sites in the United States.

Patients will be randomized to one of three active treatment groups of RT002 or placebo. Post-treatment, patients will be followed for a maximum of 36 weeks. The co-primary efficacy endpoints of the trial will be the mean change from baseline in muscle tone using the Modified Ashworth Score (MAS) scale in the suprahypertonic muscle group (SMG – highest degree for muscle tone) of the elbow, wrist, or finger flexors at Week 6, and the mean score on the Physician Global Impression of Change (PGIC) scale at Week 6.

Additional information, including patient eligibility criteria, will be posted shortly at www.clinicaltrials.gov.

About Revance Therapeutics, Inc.

Revance Therapeutics is an emerging Silicon Valley biotechnology leader developing neuromodulators for the treatment of aesthetic and therapeutic conditions. Revance uses a unique proprietary, peptide excipient technology to create development for a broad range of aesthetic and therapeutic indications, including glabellar lines, cervical dystonia, plantar fasciitis, upper limb spasticity and chronic migraine. RT002 has the potential to be the first long-acting neuromodulator. The company is advancing a robust pipeline of 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 the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates, the initiation, enrollment, design, timing and results of our clinical studies, including the SAKURA Phase 3, ASPEN Phase 3, JUNIPER Phase 2 and other clinicalprograms relating to RT002, and related results and reporting of such results; and statements about our anticipated 2019 objectives, our commercial collaborations, our ability to obtain, and timing relating to, regulatory approval with respect to our drug candidates; and potential market form andbenefits 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 quarterly report on Form 10-Q filed November 2, 2018. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

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