Revance Completes Enrollment in ASPEN-1 Phase 3 Pivotal Trial for Cervical Dystonia

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- DaxibotulinumtoxinA for Injection (DAXI) has potential to be first long-acting neuromodulator for treatment of this debilitating involuntary muscle movement disorder -

- Topline data expected in second half of 2020 -

NEWARK, Calif.--(BUSINESS WIRE)--Nov. 4, 2019-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company pioneering new innovations in neuromodulators for aesthetic and therapeutic indications, today announced it has completed patient enrollment of the company's pivotal ASPEN-1 Phase 3 clinical trial for its investigational drug candidate DaxibotulinumtoxinA for Injection (DAXI) for the treatment of isolated cervical dystonia (CD), a movement disorder affecting the neck. In total, 301 adult patients were enrolled at 60 sites across the U.S., Canada and Europe.

"The completion of patient enrollment in the ASPEN-1 trial marks an important milestone in our development efforts for DAXI and represents the first of many therapeutic indications we plan to pursue for our novel, long-acting neuromodulator," said Mark Foley, President and Chief Executive Officer at Revance. "While our initial regulatory approval for DAXI, expected in 2020, is for the aesthetic indication of glabellar lines, DAXI promises to be a meaningful advancement in the treatment of cervical dystonia, potentially providing a significantly prolonged improvement of symptoms in patients with only twice-a-year administration."

Symptom-relieving treatments for cervical dystonia vary and are often used in combination. These include physical therapy, muscle relaxants and neuromodulator injections. Currently approved neuromodulator formulations only provide relief for about 10-14 weeks.

"Sustained relief is rare with currently-approved treatments for cervical dystonia, and a longer-lasting response would make a significant difference for patients," said Roman Rubio, M.D., Senior Vice President of Clinical Development at Revance. "In our Phase 2 study, treatment with DAXI resulted in clinically meaningful relief from the pain and disability experienced by patients with cervical dystonia for a median duration of 24 weeks."

Revance plans to announce topline results from the ASPEN-1 Phase 3 trial in the second half of 2020, and is currently enrolling patients in a Phase 2 trial for adult upper limb spasticity and a Phase 2 trial for plantar fasciitis.

DAXI is an investigational product and not approved by the FDA.

ASPEN Phase 3 Clinical Program in Cervical Dystonia

The company's ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DaxibotulinumtoxinA for Injection (DAXI) for the treatment of cervical dystonia in adults: 1) ASPEN-1, a randomized, double-blind, placebo-controlled, parallel group trial; and 2) ASPEN-OLS, an open-label, long-term safety trial.

Pivotal Trial (ASPEN-1): Patients were randomized to either a low dose or high dose of DAXI, or placebo treatment. Post-treatment, patients are followed for a maximum of 36 weeks. The primary efficacy endpoint of the trial is the change from baseline in the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) - total score. Key secondary endpoints include the duration of treatment effect, the Clinical and Patient Global Impression of Change, and adverse events. Further, the trial features exploratory efficacy assessments including the Cervical Dystonia Impact Profile (CDIP-58), a disease-specific, patient-rated questionnaire that measures quality of life.

Open-Label Trial (ASPEN-OLS): Patients receive up to four continuous treatment cycles of DAXI over the 52-week observation period. Primary endpoints of the trial are safety and immunogenicity after multiple cycles of treatment with DAXI. Key secondary endpoints are the change from baseline in TWSTRS – total score, and the duration of treatment effect, as well as overall treatment response based on the Clinical and Patient Global Impression of Change. A significant number of patients from the randomized pivotal trial are expected to roll over into the open-label trial, which has plans to enroll a total of 350 patients at sites located in the United States, Canada, and Europe.

Additional information about the ASPEN Phase 3 program is available at www.clinicaltrials.gov.

About Cervical Dystonia

According to the Dystonia Medical Research Foundation, cervical dystonia is a painful condition in which the neck muscles contract involuntarily, causing abnormal movements and awkward posture of the head and neck. The movements may be sustained (tonic), jerky (clonic), or a combination. Cervical dystonia (also referred to as spasmodic torticollis) may be primary (meaning that it is the only apparent neurological disorder, with or without a family history) or may be the results of secondary causes (such as physical trauma).

Treatments for cervical dystonia include oral medications, neuromodulator (botulinum toxin) injections, surgery, and complementary therapies. Neuromodulators block the communication between the nerve and the muscle, relaxing the muscle, which alleviates abnormal involuntary movements and postures. Current neuromodulator treatments for cervical dystonia have a duration of effect of 10-14 weeks. Cervical dystonia can occur at any age, although most individuals first experience symptoms in middle age. The condition affects a few hundred thousand adults and children in the United States alone. Global Industry Analysts, Inc. estimates the global market for treating muscle movement disorders with botulinum toxins, including cervical dystonia, was approximately $1.1 billion in 2018.

About Revance Therapeutics, Inc.

Revance Therapeutics is a Silicon Valley-based biotechnology company, pioneering new innovations in neuromodulators for aesthetic and therapeutic indications. Revance's lead product candidate, DaxibotulinumtoxinA for Injection (DAXI), 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 DAXI in glabellar (frown) lines, delivering unprecedented efficacy and long-lasting duration of effect, and is pursuing U.S. regulatory approval in 2020. Revance is also evaluating DAXI in forehead lines and lateral canthal lines (crow's feet), as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis, with plans to study migraine. Beyond DAXI, Revance has begun development of 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

This press release contains forward-looking statements, including statements related to Revance Therapeutics' 2019 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, enrollment, submission, timing and results of our clinical studies, including the near-term milestone expectations described above; development of a biosimilar to BOTOX®; 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 anticipated BLA submission 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; 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 quarterly report on Form 10-Q filed November 4, 2019. 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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