



Revance to Showcase Phase 3 Results Evaluating DaxibotulinumtoxinA for Injection for the Treatment of Cervical Dystonia at the American Academy of Neurology Annual 2021 Virtual Meeting

April 1, 2021

NASHVILLE, Tenn.--(BUSINESS WIRE)--Apr. 1, 2021-- Revance Therapeutics (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced the company will present an ePoster at the 2021 American Academy of Neurology (AAN) Virtual Annual Meeting taking place from April 17-22, 2021. Revance will present results from its ASPEN-1 Phase 3 clinical trial evaluating the efficacy and safety of DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults.

"We're pleased to present the efficacy and safety findings from the ASPEN-1 Phase 3 clinical trial evaluating DaxibotulinumtoxinA for Injection at this year's 2021 AAN Virtual Meeting, specifically, the median duration of effect of up to 24 weeks, as determined by time to loss of 80% peak treatment benefit, suggested that DaxibotulinumtoxinA for Injection has the potential to reduce frequency of cervical dystonia treatments by up to 50% annually, while being generally safe and well tolerated," said Roman Rubio, Senior Vice President of Clinical Development at Revance. "The findings being presented are part of a growing body of clinical evidence that supports DaxibotulinumtoxinA for Injection's differentiated performance profile and underscores the potential of our therapeutics pipeline for the treatment of muscle movement and pain disorders for patients who suffer from these debilitating conditions."

The abstracts are available online via the AAN website at www.aan.com.

ePoster Presentation:

- **Title:** *A Phase 3 Trial Evaluating the Efficacy, Duration of Effect, and Safety of DaxibotulinumtoxinA for Injection in the Treatment of Cervical Dystonia*
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ASPEN Phase 3 Clinical Program in Cervical Dystonia

In 2017, the U.S. Food and Drug Administration (FDA) granted orphan drug designation for DaxibotulinumtoxinA for Injection to treat cervical dystonia, which provides certain developmental and financial benefits to trial sponsors.

The company's ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DaxibotulinumtoxinA for Injection 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.

Randomized Trial (ASPEN-1): Patients were randomized to a single treatment of either 125 Unit or 250 Unit dose of DaxibotulinumtoxinA for Injection, or placebo. Post-treatment, patients are followed for a maximum of 36 weeks. The primary efficacy endpoint of the trial was the mean change from baseline in the TWSTRS Total Score at the average of Weeks 4 and 6. Key secondary endpoints include the duration of treatment effect, measurement of treatment response on the Clinical and Patient Global Impression of Change assessments, and adverse events. Further, the trial featured exploratory efficacy assessments including the Cervical Dystonia Impact Profile (CDIP-58), a disease-specific, patient-rated questionnaire that measures quality of life.

Open-Label Study (ASPEN-OLS): Patients receive up to four sequential treatment cycles of DaxibotulinumtoxinA for Injection over the 52-week observation period. Primary endpoints of the trial are safety and immunogenicity after multiple cycles of treatment with DaxibotulinumtoxinA for Injection. 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. The ASPEN-OLS trial is fully enrolled with a total of 354 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 and disabling chronic 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 result of secondary causes (such as physical trauma).

First-line treatment for cervical dystonia is usually neuromodulator (botulinum toxin) injections, but additional treatments can include oral medications, 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 approximately three months. 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. The global market opportunity for cervical dystonia was \$390 million in 2020 and is expected to grow to \$587 million by 2025.¹ According to the Decision Resources Group, the global market for treating cervical dystonia

and spasticity muscle movement disorders was approximately \$1.0 billion in 2020.¹

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. 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 two therapeutic indications - cervical dystonia and adult upper limb spasticity. To accompany DaxibotulinumtoxinA for Injection, Revance owns a unique portfolio of premium products and services for U.S. aesthetics practices, including the exclusive U.S. distribution rights to the RHA® Collection of dermal fillers, 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 Viatrix (formerly 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.

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Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to development of a biosimilar to BOTOX®; statements about our business strategy, the market for our anticipated products and plans and prospects, and potential benefits of our drug product candidates, including with respect to cervical dystonia and muscle movement and pain disorders, 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, but are not limited to: the results, timing, costs, and completion of our research and development activities and regulatory approvals, including delays in the approval of our BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines; the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, end user demand for our products, commercialization efforts, business operations, clinical trials and other aspects of our business; our ability to manufacture supplies for our product candidates; the uncertain clinical development process; the risk that clinical trials may not have an effective design or generate positive results; the applicability of clinical study results to actual outcomes; our ability to successfully compete with other treatments and therapies; our ability to achieve, and the rate and degree of commercial acceptance and the market, size and growth potential of our drug product candidates, if approved; our ability to successfully commercialize our drug product candidates, if approved, and the timing and cost of commercialization activities; our ability to obtain and maintain regulatory approval of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; our ability to develop sales and marketing capabilities; the status of commercial collaborations; our ability to obtain funding for our operations; 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 our periodic filings with the Securities and Exchange Commission (SEC), including factors described in the section entitled "Risks Factors" on our Form 10-K filed with the SEC on February 25, 2021. 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.

¹ December 2020 - Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global 2021

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