Revance Reports Positive Results from ASPEN-1 Phase 3 Trial of DaxibotulinumtoxinA for Injection in Cervical Dystonia

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- Trial met primary and all secondary endpoints for both 125- and 250-Unit doses with high statistical significance -

- DaxibotulinumtoxinA for Injection was effective and generally well-tolerated in reducing the signs and symptoms for cervical dystonia, delivering up to a median duration of 24 weeks -

- Results suggest DaxibotulinumtoxinA for Injection has the potential to reduce frequency of cervical dystonia treatments by up to 50% annually -

- Global market opportunity for cervical dystonia is $340M[1] -

- Conference call today at 8:30 a.m. ET -

Infographic 1 - Phase 3 Cervical Dystonia Presentation October 2020

Infographic 2 - Phase 3 Cervical Dystonia Presentation October 2020

NEWARK, Calif.--(BUSINESS WIRE)--Oct. 14, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced positive topline results from its ASPEN-1 Phase 3 randomized, double-blind, placebo-controlled, parallel group clinical trial for its investigational drug candidate DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia, a chronic and debilitating neurologic condition affecting the muscles of the neck.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20201014005360/en/

This pivotal study enrolled a total of 301 subjects at 60 sites in the U.S., Canada and Europe. Subjects were randomized 3:3:1 to receive a single treatment of either 125 Units or 250 Units of DaxibotulinumtoxinA for Injection, or placebo and were followed for up to 36 weeks. The drug was generally safe and well-tolerated at both doses, with an encouraging safety profile.

The study met its primary efficacy endpoint at both doses, demonstrating a clinically meaningful improvement in the signs and symptoms of cervical dystonia at the average of Weeks 4 and 6. Compared to placebo, subjects treated with either 125 Units or 250 Units showed a statistically significant greater change from baseline (12.7 and 10.9 respectively vs. 4.3, p<0.0001 and p=0.0006) as measured on the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) Total Score.

Median duration of effect was 24.0 and 20.3 weeks, for the 125 Unit and 250 Unit dose groups respectively, based on the median time to loss of 80% of the peak treatment effect.

“I was delighted to see both the degree and duration of relief that DaxibotulinumtoxinA for Injection provided trial subjects in ASPEN-1. Currently, most patients with cervical dystonia visit their physician 3 to 4 times a year for injections, which places a heavy burden on patients’ time and schedule. Often, the treatment effect wears off between injections, significantly impacting the quality of their work and personal lives,” said trial investigator Dr. Joseph Jankovic, Professor of Neurology, Distinguished Chair in Movement Disorders, Founder and Director, The Parkinson's Disease Center and Movement Disorders Clinic at Baylor College of Medicine, Houston, Texas. “If a treatment could offer longer duration of effect, thus requiring fewer trips each year for reinjection, I imagine patients would find this quite beneficial.”

“We are very pleased to report these positive results from the ASPEN-1 Phase 3 trial, as this is the company’s second successful Phase 3 program demonstrating DaxibotulinumtoxinA for Injection’s extended duration profile, now across two different treatment categories – aesthetics and therapeutics. In addition to laying the foundation for our therapeutics franchise, these results reinforce its potential in other muscle movement and pain disorders,” said Mark Foley, President and Chief Executive Officer at Revance. “A cervical dystonia treatment option with a longer duration of effect has the ability to offer patients a meaningful extension of symptom relief while also providing a compelling pharmacoeconomic profile. We look forward to continuing to leverage the differentiated performance profile of DaxibotulinumtoxinA for Injection across the $5.1B global neuromodulator market.”

The company expects results from the companion ASPEN-OLS Phase 3 open-label, long-term safety trial, which enrolled 354 subjects, in 2021.

EFFICACY RESULTS:

Positive efficacy results were seen with both DaxibotulinumtoxinA for Injection dose groups studied. The trial’s primary efficacy measurements were based on the average of the change from baseline in TWSTRS Total Score at Weeks 4 and 6. TWSTRS Total Score is a composite score evaluating features of the cervical dystonia condition, including severity, disability and pain:

	125 Unit Dose	250 Unit Dose	Placebo
Average Reduction from Baseline in TWSTRS Total Score (% change from baseline, p-value vs. placebo)	12.7 (31%, p<0.0001)	10.9 (27%, p=0.0006)	4.3 (12%)

The median duration of effect was 24.0 weeks for the 125 Unit dose, and 20.3 weeks for the 250 Unit dose, as measured by the time to loss of 80% of the peak treatment effect.

Two of the secondary endpoints measured the percentage of responders showing improvement with at least a 2-point improvement based on the Clinical Global Impression of Change (CGIC) and Patient Global Impression of Change (PGIC) at Week 4 or 6. Both the clinician and patient results were consistent and showed a statistically significant improvement greater than placebo ($p<0.001$).

SAFETY RESULTS: In both dose groups, DaxibotulinumtoxinA for Injection appeared to be generally safe and well-tolerated through Week 36. 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, with one case of neck pain reported as severe, which resolved two days after onset. The three most common treatment-related adverse events were (for 125 Units and 250 Units):

- Injection site pain (7.9%, 4.7%)
- Headache (4.7%, 4.7%)
- Injection site erythema (4.7%, 2.3%)

The incidence of dysphagia (difficulty swallowing) and muscle weakness, which are considered adverse events of particular interest with botulinum toxin treatments for cervical dystonia, was encouragingly low: dysphagia (1.6%, 3.9%) and muscular weakness (4.7%, 2.3%).

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 Week 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 enrollment 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 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 is $340 million[1]. 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.

Conference Call

The company plans to host a conference call to discuss the results today at 8:30 am ET. A PDF of a slide deck covering the trial design and results will be posted to the company website at 8:05 am ET to accompany the commentary on the conference call. They can be found on the Revance website at www.revance.com within *Presentations and Corporate Materials* under the Events & Webcast tab. We encourage you to download the PDF prior to the call.

Individuals interested in listening to the conference call may do so by dialing 1(855)453-3827 for domestic callers, or (484) 756-4301 for international callers and reference conference ID: 1987683; or from the webcast link in the investor relations section of the company's website at: www.revance.com. A replay of the call will be available beginning October 14, 2020 at 8:30 a.m. PT/12:30 a.m. ET to October 16, 2020 at 8:30 a.m. PT/12:30 a.m. ET. To access the replay, dial (855) 859-2056 or (404) 537-3406 and reference conference ID: 1987683.

The live webcast can be accessed here and will be available in the investor relations section on the company's website for 30 days following the completion of the call. In light of reduced call center resources during this time of required social-distancing, Revance requests that listeners who do not plan on participating in the question and answer session listen to the live webcast rather than dialing in by phone.

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 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 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 DaxibotulinumtoxinA potential for the treatment of cervical dystonia; its therapeutic and commercial potential; the timing and results of the ASPEN Phase 3 clinical program; potential value for DaxibotulinumtoxinA in other muscle movement and pain disorders; 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®; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects, including our commercialization plans; statements about 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 expected PDUFA date; and potential benefits of our drug product candidates and our technologies, including with respect to the RHA® line of dermal fillers and HintMD fintech platform, constitute forward-looking statements.

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 the top-line results from the ASPEN-1 trial 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 ability to obtain and maintain regulatory approval of our drug product candidates, including our ability to receive timely approval of DaxibotulinumtoxinA for Injection; our ability to obtain funding for our operations; our plans to research, develop, and commercialize our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; our reliance on third-party manufacturers; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; the proper training and administration of our products by physicians and medical staff; our ability to successfully commercialize our drug product candidates and the timing of commercialization activities and anticipated product launches; 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 the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, business operations, commercialization efforts, end user demand for our products, 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 (the "SEC"), including factors described in the section entitled "Risks Factors" on our Form 10-Q filed with the SEC on August 6, 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.

1. SOURCE: Global Industry Analytics Inc. Botulinum Toxin Global Market Trajectory & Analytics; September 2020

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