# Revance to Showcase Data from Phase 3 ASPEN-1 Clinical Trial Evaluating Efficacy, Duration of Effect and Safety of DaxibotulinumtoxinA for Injection for Cervical Dystonia at International Parkinson and Movement Disorder Society Virtual Congress 2021

September 16, 2021

*- ePoster and video presentation showcasing Phase 3 data to be shared -*

NASHVILLE, Tenn.--(BUSINESS WIRE)--Sep. 16, 2021-- Revance Therapeutics, Inc. (Nasdaq: RVNC) a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced that it will present an ePoster with a video poster presentation by Dr. Joseph Jankovic at the International Parkinson and Movement Disorder Society (MDS) Virtual Congress 2021 taking place from September 17-22, 2021. Revance will present results from its ASPEN-1 Phase 3 clinical trial evaluating the efficacy, duration of effect and safety of DaxibotulinumtoxinA for Injection, for the treatment of cervical dystonia in adults, showing a meaningful reduction in signs and symptoms associated with cervical dystonia.

"Data from the ASPEN-1 clinical trial continues to highlight DaxibotulinumtoxinA for Injection's long duration of effect and encouraging safety profile for the treatment of cervical dystonia, reinforcing the drug product's differentiated performance profile," said Roman Rubio, Senior Vice President of Clinical Development at Revance. "We look forward to filing a Supplemental Biologics License Application, which may bring us one step closer to helping patients with this debilitating condition achieve long-lasting symptom relief."

The following ePoster and video presentation is available online via the MDS website at MDSCongress.org.

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 the following two trials to evaluate the safety and efficacy of DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults:

- **Randomized Controlled 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 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 with patients experiencing symptom re-emergence within approximately 10.5 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. The global market opportunity for cervical dystonia was $436 million in 2021 and is expected to grow to $624 million by 2026.[1] According to the Decision Resources Group, the global market for treating cervical dystonia and spasticity muscle movement disorders was approximately $1.2 billion in 2021.[1]

**About Revance**

Revance 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 Viatris (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.



**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®; the potential benefits of DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia; the differentiated performance profile of DaxibotulinumtoxinA for Injection; the filing of an sBLA; and statements about our strategy, plans and prospects, 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 the continuing delay in the FDA's approval of the BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines, including as a result of observations made by the FDA during the site inspection or other reasons; 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 and on the market; our ability to manufacture supplies for our product candidates and to acquire supplies of the RHA® Collection of dermal fillers; the uncertain clinical development process; the risk that clinical trials may not have an effective design or generate positive results or that positive results would assure regulatory approval or commercial success; the applicability of clinical study results to actual outcomes; the rate and degree of economic benefit, the safety, efficacy, commercial acceptance and the market, competition, size and growth potential of the RHA® Collection of dermal fillers and our dug product candidates, if approved; our ability to continue to successfully commercialize the RHA® Collection of dermal fillers and fintech platform and our ability to successfully commercialize DaxibotulinumtoxinA for Injection, if approved, and the timing and cost of commercialization activities; our ability to expand sales and marketing capabilities; the status of commercial collaborations; our ability to obtain funding for our operations; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; our financial performance, including future revenue, expenses and capital requirements; 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 and including, without limitation, our Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 5, 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.

SOURCES

1. Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global 2021
2. Carruthers JD, Fagien S, et al. DaxibotulinumtoxinA for Injection for the treatment of glabellar lines: results from each of two multicenter, randomized, double-blind, placebo-controlled, phase 3 studies (SAKURA 1 and SAKURA 2). Plast Reconstr Surg. 2020;145(1):45-58.
3. Fabi SG, Cohen JL, et al. DaxibotulinumtoxinA for Injection for the treatment of glabellar lines: efficacy results from SAKURA 3, a large, open-label, phase 3 safety study. Dermatol Surg. 2020. doi:10.1097/DSS.0000000000002531
4. Waugh JM, Lee J, Dake MD, Browne D. Nonclinical and clinical experiences with CPP-based self-assembling peptide systems in topical drug development. Methods Mol Biol. 2011;683:553-572.

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Source: Revance Therapeutics, Inc.