# Revance Provides Update on DaxibotulinumtoxinA for Injection Pre-Approval Inspection

May 26, 2021

NASHVILLE, Tenn.--(BUSINESS WIRE)--May 26, 2021-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced that the FDA plans to initiate its pre-approval inspection of the company's manufacturing facility for DaxibotulinumtoxinA for Injection by the end of June 2021.

In November 2020, Revance received notification from the FDA that the Agency was deferring a decision on the Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection for the treatment of moderate to severe glabellar (frown) lines because the required pre-approval inspection of the company's manufacturing facility could not be completed due to travel restrictions associated with the COVID-19 pandemic.

**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 statements about our ability to obtain, and the timing relating to regulatory approval with respect to DaxibotulinumtoxinA for Injection in glabellar lines; the timing and outcome of the FDA's inspection of the Northern California manufacturing facility; the commercial launch of DaxibotulinumtoxinA for Injection; and development of a biosimilar to BOTOX® with our partner, Viatris, 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; 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; the rate and degree of economic benefit, the safety, commercial acceptance and the market, competition, size and growth potential of our services and our drug product candidates, if approved; our ability to successfully commercialize our services and our drug product candidates, if approved, and the timing and cost of commercialization activities; our ability to develop 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; and our financial performance, including future revenue, expenses and capital requirements. 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-Q for the quarter ended March 31, 2021, filed with the SEC on May 10, 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.

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