



## Revance Continues to Anticipate FDA Approval of DaxibotulinumtoxinA for Injection for the Treatment of Glabellar Lines in 2021

October 12, 2021

*- BLA for DaxibotulinumtoxinA for Injection remains under FDA review -*

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 12, 2021-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, responds to the public disclosure of its Form 483 pursuant to a Freedom of Information Act (FOIA) request that was directed to the FDA. The Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection remains under FDA review and the company continues to anticipate FDA approval of DaxibotulinumtoxinA for Injection for the treatment of glabellar lines in 2021.

Revance notes that the issuance of a Form 483 following the conclusion of an on-site inspection is not uncommon. A Form 483 lists observations made by FDA representatives during the inspection of a facility. A Form 483 does not constitute a final agency determination.

Revance provided its response to the Form 483 in July 2021 following a pre-approval inspection and is currently awaiting the FDA's decision on its BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines. The company remains confident in the quality of its BLA submission and continues to anticipate FDA approval in 2021.

### 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 OPUL™ Relational Commerce Platform. 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](http://www.revance.com).

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Resilient Hyaluronic Acid® and RHA® are trademarks of TEOXANE SA.

BOTOX® is a registered trademark of Allergan, Inc.

### Forward Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to our ability to obtain and the timing relating to FDA approval of our BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines; our confidence in the quality of our BLA submission; the status of our BLA submission; the outcome of the FDA's inspection of the company's Northern California manufacturing facility and development of a biosimilar to BOTOX® with our partner, Viatrix; 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 OPUL™, the RHA® Collection of dermal fillers and our drug product candidates, if approved; our ability to continue to successfully commercialize the RHA® Collection of dermal fillers and OPUL™ 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; the cost and our ability to defend ourselves in product liability, intellectual property and other lawsuits; 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.

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