Revance Receives Clarity on Path to Resubmission of the BLA for DaxibotulinumtoxinA for Injection Following Type A Meeting with FDA

January 18, 2022

- *Complete response requires qualification of new working cell bank (WCB), which is in progress*
- *The FDA stated that a reinspection of the company's manufacturing facility will be necessary prior to approval*

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jan. 18, 2022-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a commercial stage biotechnology company focused on innovative aesthetic and therapeutic offerings, announced today that it has received the official Type A meeting minutes from the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) received for DaxibotulinumtoxinA for Injection for glabellar lines. The Type A meeting was held on December 15, 2021.

Based on the meeting minutes, a complete response to address the outstanding observations related to the WCB and the drug substance manufacturing process will require Revance to qualify its new WCB by producing three consecutive drug substance lots and one drug product lot. The qualification of the new WCB has been underway and Revance plans to submit the new WCB qualification package as part of its biologics license application (BLA) resubmission as soon as possible. The FDA stated that a reinspection of Revance's manufacturing facility will be necessary once the resubmission is accepted by the FDA. Based on FDA regulations, once the resubmission is accepted by the FDA, the agency has up to 6 months to complete its reinspection and review.

"We believe we have a clear path to resubmission of the BLA for DaxibotulinumtoxinA for Injection for glabellar lines following our Type A meeting with the FDA," said Mark J. Foley, Chief Executive Officer of Revance. "As we have noted previously and as confirmed by the FDA during the meeting, the CRL was related to the onsite inspection of our manufacturing facility and not the safety and efficacy of our drug product. The qualification of our new WCB is in progress and we look forward to resubmitting the BLA as soon as possible."

About Revance

Revance is a commercial stage 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 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 the requirements, timing and path for the resubmission of the BLA and FDA reinspection of our manufacturing facility and related regulatory process for DaxibotulinumtoxinA for Injection in glabellar lines; our ability to adequately address the FDA's observations from the manufacturing site inspection and submit a complete response; the FDA's acceptance and review of the resubmission; and development of a biosimilar to BOTOX®, 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; our ability to remediate deficiencies identified by the FDA and obtain FDA 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; our ability to obtain funding for our operations; the timing of capital expenditures; the accuracy of our estimates regarding future expenses, future revenues, capital requirements, our financial performance and the economics of DaxibotulinumtoxinA for Injection, the RHA® Collection of dermal fillers and OPUL™; the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, end user demand for our products and services, commercialization efforts, business operations, regulatory meetings, inspections and approvals, clinical trials and other aspects of our business and on the market; our ability and the ability of our partners to manufacture supplies for our product candidates and our ability 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, safety, efficacy, commercial acceptance, market, competition and/or size and growth potential of the RHA® Collection of dermal fillers, OPUL™ and our drug product candidates, if approved; our ability to successfully commercialize the RHA®

Collection of dermal fillers, OPUL™ and DaxibotulinumtoxinA for Injection, if approved, and the timing and cost of commercialization activities; the proper training and administration of our products by physicians and medical staff, including the RHA® Collection of dermal fillers; our ability to execute our sales and marketing strategy; the status of commercial collaborations; changes in and failures to comply with privacy and data protection laws; our ability to effectively manage our expanded operations in connection with the acquisition of Hint, Inc; the profitability of and our ability to scale OPUL™; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; the cost and our ability to defend ourselves in product liability, intellectual property, class action or other lawsuits; the volatility of our stock price; 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 September 30, 2021, filed with the SEC on November 9, 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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