Revance Provides Regulatory Update on DaxibotulinumtoxinA for Injection for the Treatment of Moderate to Severe Glabellar (Frown) Lines

October 15, 2021

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 15, 2021-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced that the United States (U.S.) Food and Drug Administration (FDA) has issued a Complete Response Letter, or CRL, regarding the Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection, for the treatment of moderate to severe glabellar (frown) lines.

In a communication received on October 15, the FDA has determined it is unable to approve the BLA in its present form, and indicated that there are deficiencies related to the FDA's onsite inspection at Revance's manufacturing facility. Revance plans to request a Type A meeting with the FDA as soon as possible to address the deficiencies raised. No other deficiencies were identified in the CRL.

"We are very disappointed by this unanticipated response from the FDA and are seeking further clarity from the agency. We remain committed to bringing our next-generation neuromodulator product to market in both aesthetic and therapeutic indications," said Mark Foley, President and Chief Executive Officer.

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 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

This press release contains forward-looking statements, including statements related to statements about our ability to obtain, and the timing relating to the Type A meeting with the FDA with respect to DaxibotulinumtoxinA for Injection; our ability to address the deficiencies raised and obtain approval of and commercialize DaxibotulinumtoxinA for Injection for aesthetic or therapeutic indications; development of a biosimilar to BOTOX®; and statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans, 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 our ability to 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; the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, end user demand for our products, commercialization efforts, business operations, regulatory 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 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, OPUL™, 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; 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; our ability to obtain funding for our operations; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; the accuracy of our estimates regarding expenses, future revenues, capital requirements, our financial performance and the economics of DaxibotulinumtoxinA for Injection; the cost and our ability to defend ourselves in product liability, intellectual property or other lawsuits; 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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