



FDA Defers Approval of DaxibotulinumtoxinA for Injection in Glabellar Lines Due to COVID-19 Related Travel Restrictions Impacting Manufacturing Site Inspection

November 25, 2020

NEWARK, Calif.--(BUSINESS WIRE)--Nov. 25, 2020-- 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 deferred a decision on the Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection, an investigational neuromodulator product for the treatment of moderate to severe glabellar (frown) lines.

In a communication received on November 24, 2020, the FDA reiterated that an inspection of the company's manufacturing facility is required as part of the BLA approval process. The Agency was unable to conduct a required inspection of the company's Northern California manufacturing facility due to the Agency's travel restrictions associated with the COVID-19 pandemic. Revance confirmed with the FDA that their communication was not a Complete Response Letter.

Though the company's BLA is still under review, the FDA did not indicate there are any other review issues at this time, beyond the on-site inspection. The FDA stated they are actively working to define an approach for scheduling outstanding inspections, once safe travel may resume and based on public health need and other factors.

"We appreciate FDA's engagement on the Chemistry, Manufacturing and Controls (CMC), non-clinical, clinical and labeling sections of our BLA, particularly given the unique and unprecedented situation we are in as a result of the COVID-19 pandemic. We look forward to continued interaction with the Agency and remain ready to support FDA's pre-approval inspection as soon as possible. We are fortunate that we manufacture our product at a single location in the U.S., which should put us at an advantage compared to international manufacturing locations once travel resumes," said Mark J. Foley, President and Chief Executive Officer. "As stated in our third quarter earnings, with the addition of the RHA® Collection of dermal fillers and acquisition of the HintMD fintech platform earlier this year, we believe the company is in an excellent position, both commercially and financially, to weather a change to the timing of this potential approval."

DaxibotulinumtoxinA for Injection is an investigational agent that combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. In the first quarter of 2020, Revance [announced](#) that the BLA for DaxibotulinumtoxinA for Injection had been accepted for review by the FDA and the company had been given a Prescription Drug User Fee Act (PDUFA) target action date of November 25, 2020. The submission was based on results from the largest aesthetic neuromodulator clinical program ever conducted for the treatment of glabellar (frown) lines, including the SAKURA 1, 2 and 3 Phase 3 clinical studies.

About Revance Therapeutics, Inc.

Revance Therapeutics, Inc. 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 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.

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Forward-Looking Statement: Revance Therapeutics

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 and the expected PDUFA date; the inspection by the FDA of our manufacturing facility in connection with the BLA approval process, including the timing and outcome of and factors impacting the inspection; our financial performance; our commercial potential; 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 and timing of our regulatory approvals; delays in the approval of our BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines due to COVID-19-related policies and travel restrictions currently in place at the FDA; 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 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; the applicability of clinical study results to actual outcomes; our ability to obtain regulatory approval of our drug product candidates; whether the HintMD acquisition and Teoxane agreement will provide the anticipated economic and other benefits; the rate and degree of commercial acceptance and the market, size and growth potential of the RHA® Collection of dermal fillers, the HintMD payments platform and our drug product candidates, if approved; our ability to successfully commercialize the RHA® Collection of dermal fillers, the HintMD payments platform 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 filed with the SEC on November 9, 2020. 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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