Revance Announces U.S. FDA Acceptance of Biologics License Application (BLA) for DAXI to Treat Glabellar (Frown) Lines

February 6, 2020

- Prescription Drug User Fee Act (PDUFA) target action date of November 25, 2020 -

NEWARK, Calif.--(BUSINESS WIRE)--Feb. 6, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology pioneer focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection (DAXI), today announced that the Biologics License Application (BLA) for DAXI in the treatment of moderate to severe glabellar (frown) lines has been accepted for review by the U.S. Food and Drug Administration (FDA). In its correspondence, FDA stated that no potential filing review issues were identified. The FDA set an action date of November 25, 2020 under the Prescription Drug User Fee Act (PDUFA) VI program. The Agency also indicated in the BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application.

"The FDA's acceptance of our BLA for our next-generation neuromodulator product, DAXI, is a significant achievement for Revance and a crucial step forward as we look to establish a new, premium, long-lasting neuromodulator category," said Mark Foley, President and Chief Executive Officer of Revance. "The patient experience has remained largely unchanged since botulinum toxin type A treatments were first introduced over 30 years ago. If approved, we expect that patients treated with DAXI may achieve lasting, natural-looking frown line correction all year long with as few as two treatments."

DAXI has been evaluated in three Phase 3 trials (SAKURA 1, 2, 3), the largest aesthetic neuromodulator clinical program ever conducted for the treatment of glabellar (frown) lines. In the Phase 3 pivotal program, the median time to loss of none or mild wrinkle severity was 24 weeks and the median time to return to baseline wrinkle severity was approximately 28 weeks. Results from the two pivotal Phase 3 trials, SAKURA 1 and SAKURA 2, were recently presented at the American Society for Dermatologic Surgery (ASDS) 2019 Annual Meeting and published in *Plastic and Reconstructive Surgery* (*PRS*)[1] as well as in the *Journal of the American Academy of Dermatology* (*JAAD*)[2].

The BLA acceptance comes at the beginning of a potentially transformative year for Revance, as the company recently became the exclusive U.S. commercialization partner for TEOXANE SA's innovative Resilient Hyaluronic Acid® (RHA®) dermal fillers, which are highly complementary to DAXI. Counting these two events, Revance has up to twelve significant clinical, regulatory and commercial milestones this year across both aesthetic and therapeutic indications. These include topline results from clinical trials utilizing DAXI for the treatment of forehead lines, lateral canthal lines (crow's feet), full upper facial lines, cervical dystonia and plantar fasciitis, as well as completion of enrollment in an upper limb spasticity clinical study.

About Revance Therapeutics, Inc.
Revance Therapeutics is a Silicon Valley-based biotechnology company, pioneering new innovations in neuromodulators for aesthetic and therapeutic indications. Revance's lead product candidate, DaxibotulinumtoxinA for Injection (DAXI), 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 DAXI in glabellar (frown) lines and is pursuing U.S. regulatory approval in 2020. Revance is also evaluating DAXI in the full upper face, including glabellar lines, forehead lines and crow's feet, as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis. Beyond DAXI, Revance gained exclusive rights to commercialize TEOXANE SA's Resilient Hyaluronic Acid® (RHA®) line of fillers in the U.S., the first and only range of FDA-approved dermal fillers for correction of dynamic facial wrinkles and folds. Revance has also begun development of 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 the, anticipated clinical, development, regulatory and commercial milestones, the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects statements about the timing and our ability to obtain regulatory approval and launch products, including with respect to anticipated approval of DAXI and expected PDUFA date; potential benefits of our drug product candidates and our technologies; complimentary nature of RHA line of fillers; and our ability to compete in the neuromodulator market. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: our ability to obtain and maintain regulatory approval of our drug product candidates, including ability to receive timely approval of DAXI; our ability to realize anticipated synergies and successfully commercialize Teoxane's dermal fillers; the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain funding for our operations and achieve our goals; our plans to research, develop, and commercialize our drug product candidates; our ability to successfully compete with treatments and therapies, our ability to achieve, and the rate and degree of market acceptance and adoption of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; our ability to successfully manufacture and commercialize our drug product candidates and the timing of commercialization activities; our ability to develop sales and marketing capabilities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; 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 Revance's periodic filings with the Securities and Exchange Commission (the "SEC"), including factors described in the section entitled "Risk Factors" of our quarterly report on Form 10-Q filed November 4, 2019. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

[1]Journal of Plastic and Reconstructive Surgery, https://journals.lww.com/plasreconsurg/Abstract/publishahead/_DaxibotulinumtoxinA_in_the_treatment_of_glabellar.97260.aspx

[2] Journal of the American Academy of Dermatology (JAAD), https://www.jaad.org/article/S0190-9622(19)32459-4/fulltext

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