Revance Submits Biologics License Application (BLA) to the FDA for DAXI to Treat Glabellar (Frown) Lines

November 25, 2019

NEWARK, Calif.--(BUSINESS WIRE)--Nov. 25, 2019-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company pioneering new innovations in neuromodulator products for aesthetic and therapeutic indications, today announced the Company has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for DaxibotulinumtoxinA for Injection (DAXI) in the treatment of moderate to severe glabellar (frown) lines. The submission includes results from the SAKURA Phase 3 trials, which is the largest aesthetic neuromodulator clinical program ever conducted for the treatment of glabellar frown lines.

“The submission of our BLA represents a significant milestone in the Company’s history and initiates our transition from a development company to a commercial organization. I’m incredibly excited about the opportunity to introduce the first truly novel advancement in neuromodulator products in over 30 years. We believe that a long-acting neuromodulator product will fill a significant, unmet need in both aesthetics and therapeutics and that the market is hungry for innovation,” said Mark Foley, President and Chief Executive Officer of Revance. “As we manufacture our own product in the United States, the BLA filing represents a monumental achievement for a company of our size, which was only made possible through the incredible dedication and commitment of our employees. I would like to sincerely thank all of those involved for their tireless efforts.” Foley further commented, “Based on the SAKURA trial results, DAXI has the potential to provide patients with lasting, natural-looking frown line correction all year long with just two treatments. Following this submission, Revance enters a catalyst-rich calendar year of significant clinical trial readouts and meaningful Company milestones, which we believe will culminate in the approval and launch of DAXI in the aesthetic marketplace.”

DAXI has been evaluated in three Phase 3 trials (SAKURA 1, 2, 3). Both SAKURA 1 and SAKURA 2 demonstrated that half of the patients treated maintained none or only mild frown lines for at least 24 weeks (approximately 6 months), after a single treatment. Additionally, frown lines did not return to their pre-treatment severity for at least 26–28 weeks for half of the patients treated. 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 accepted for future publication in the *Journal of the American Academy of Dermatology* (*JAAD*).

Under the current Prescription Drug User Fee Agreement (PDUFA VI), the FDA has agreed to file acceptable applications within 60 days of receipt and to review the majority of BLAs within 10 months following the Day 60 filing date. Based on that timeline, Revance anticipates potential product approval in the second half of 2020.

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 forehead lines and lateral canthal lines (crow’s feet), as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis, with plans to study migraine. Beyond DAXI, Revance has 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 process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates, including but not limited to initiation and design of clinical studies for current and future indications, related results and reporting of such results; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects; including our pre-commercialization plans; and statements about the timing and our ability to obtain regulatory approval and launch products, including with respect to DAXI for Injection to treat glabellar (frown) lines; and potential benefits of our drug product candidates and our technologies. 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: 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 and maintain regulatory approval of our drug product candidates; 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

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