Revance Announces Two Peer-Reviewed Publications Reporting Safety and Efficacy Results from the SAKURA 3 Open-Label Safety Study in Dermatologic Surgery

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- The SAKURA 3 safety and efficacy results are consistent with those observed in SAKURA 1 and SAKURA 2 studies for DaxibotulinumtoxinA for Injection in the treatment of glabellar (frown) lines –

NEWARK, Calif.--(BUSINESS WIRE)--Aug. 11, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its investigational neuromodulator product, DaxibotulinumtoxinA for Injection, today announced the publication of two separate peer-reviewed articles in *Dermatologic Surgery,* the official journal of the American Society for Dermatologic Surgery (ASDS). The two peer-reviewed publications reported efficacy data as well as detailed safety results from the SAKURA 3 Phase 3 open-label, long-term safety study. The SAKURA 3 study is part of the largest Phase 3 clinical development program for a neuromodulator in the treatment of glabellar lines.

The Phase 3, open-label, multicenter trial evaluated single and repeat treatments in subjects receiving DaxibotulinumtoxinA for Injection for the treatment of moderate or severe glabellar lines. The study was conducted at 65 centers and with a total of 2,691 enrolled subjects who received one to three doses of DaxibotulinumtoxinA for Injection for a total of 3,830 treatments.

In the first paper, the efficacy of DaxibotulinumtoxinA for Injection was not only highly consistent across successive treatment cycles and multiple end points evaluating response rates and duration of effect, but also confirmed results seen in the pivotal Phase 3 trials.[1]

Results that were found to be complementary to SAKURA 1 and 2 included:

- Median duration for return to moderate or severe wrinkle severity was 24 weeks; and
- Median time to return to baseline severity was 28 weeks.

Additional results include high (>96%) response rates (based on the proportion of patients achieving none or mild severity) on the Investigator Global Assessment–Frown Wrinkle Severity (IGA-FWS) scale seen after each of the three treatments.

“The data published in *Dermatologic Surgery* replicate the previously reported safety and efficacy results observed in the two pivotal SAKURA studies with DaxibotulinumtoxinA for Injection in a substantially larger sample size of almost 2700 subjects at 65 clinical sites in the US and Canada,” said Roman Rubio, Senior Vice President of Clinical Development at Revance. “The publication of these results further demonstrates the consistency of DaxibotulinumtoxinA for Injection to offer a long duration of response in the treatment of glabellar lines while being generally well-tolerated.”

The second data set, published in the same journal, showed that the safety profile of DaxibotulinumtoxinA for Injection was consistent within the pivotal SAKURA 1 and 2 studies, as well as with what was observed in other FDA-approved botulinum toxin products for glabellar lines[1]. Adverse events (AEs) were consistent across treatments and no new safety signals were observed. Treatment-related AEs occurred in 17.8% of subjects and were generally mild in severity. As previously reported, no serious AEs were treatment-related, and AEs reported were comparable with those in Phase 3 trials of other botulinum toxin type A products for treatment of glabellar lines. Headache was the most frequently reported AE in this trial (5.9%) and eyelid ptosis occurred in 0.9% of treatments.

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 in 2020. 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 three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis. 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 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 Statement: Revance Therapeutics

This press release contains forward-looking statements, including statements related to Revance’s financial outlook, milestone expectations, expected cash runway and financial performance; the planned commercial launch of our RHA® Collection of dermal fillers and the HintMD fintech platform, the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates; the initiation, design, enrollment, submission, timing and results of our clinical studies, including the near-term milestone expectations described above; development of a biosimilar to BOTOX®; results of our non-clinical programs; statements about our business strategy, timeline and other goals and

market for our anticipated products, plans and prospects, including our commercialization plans; statements about our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates, including with respect to the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines and expected PDUFA date; and potential benefits of our drug product candidates and our technologies, including with respect to the RHA® line of dermal fillers and HintMD fintech platform.

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, including our ability to receive timely approval of DaxibotulinumtoxinA for Injection; our ability to obtain funding for our operations; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance 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 commercialize our drug product candidates and the timing of commercialization activities and anticipated product launches; the rate and degree of market acceptance of our drug product candidates; 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 the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, business operations, commercialization efforts, end user demand for our products, clinical trials and other aspects of our business. 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 "Risks Factors" in the Registration Statement on Form S-4/A filed with the SEC on June 23, 2020. The forward-looking statements in this press release speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

SOURCES:

1. *Carruthers JD, Fagien S, Joseph JH, Humphrey SD, et al. DaxibotulinumtoxinA in the treatment of glabellar lines: results from each of two multicenter, randomized, double-blind, placebo-controlled phase 3 studies (SAKURA 1 and SAKURA 2). Plast Reconstr Surg 2020;145:45–58.*

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