# Revance Announces Publication of Results on Static Glabellar Lines With Repeated Treatment of DaxibotulinumtoxinA for Injection From the SAKURA Clinical Program in Dermatologic Surgery

September 1, 2021

*- Post-hoc analysis demonstrates sustained improvement of static glabellar lines with repeated treatment of DaxibotulinumtoxinA for Injection*

*- Results suggest that the extended duration of therapeutic benefit with DaxibotulinumtoxinA for Injection can produce dermal remodeling due to the prolonged period of muscle inactivity*

NASHVILLE, Tenn.--(BUSINESS WIRE)--Sep. 1, 2021-- Revance Therapeutics, Inc. (Nasdaq: RVNC) a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced the publication of results from an evaluation of the progressive effects on static or resting glabellar lines with the repeated treatment of DaxibotulinumtoxinA for Injection in *Dermatologic Surgery*, the official journal of the American Society for Dermatologic Surgery (ASDS). The peer-reviewed publication reported efficacy data from a post-hoc analysis of the SAKURA Phase 3 clinical program that demonstrated significant, progressive improvement in static glabellar lines with repeated treatment of DaxibotulinumtoxinA for Injection.

"The data published in *Dermatologic Surgery* showed a substantial reduction in static glabellar lines and, despite subjects being required to return to baseline dynamic line severity between treatments, the improvement in static lines in subjects increased with repeated treatments," said Conor Gallagher, Vice President of Medical Affairs at Revance. "The results seem to indicate that the extended duration of reduction in dynamic glabellar lines following treatment with DaxibotulinumtoxinA for Injection allows greater time for remodeling of static, etched-in lines due to the prolonged period of muscle inactivity."

The post-hoc analysis included 568 subjects with moderate or severe dynamic glabellar lines who were treated with three cycles of 40U of DaxibotulinumtoxinA for Injection in the SAKURA clinical program. Glabellar line severity at rest and at maximum frown was assessed by investigators using the Investigator Global Assessment-Frown Winkle Severity (IGA-FWS) scale and by subjects using the Patient Frown Wrinkle Severity (PFWS) scale. Subjects were required to return to baseline dynamic line severity before each retreatment.

The results showed rapid and sustained improvement in static glabellar line severity following repeated treatment with DaxibotulinumtoxinA for Injection. Improvements in static glabellar lines were achieved within 2 to 4 weeks following the first DaxibotulinumtoxinA for Injection treatment cycle and remained greater than baseline over 24 weeks of follow-up after treatment cycles 1 and 2. Further, amongst all subjects the proportion with no static glabellar lines had increased to more than 70% at 4 weeks after their third treatment cycle of DaxibotulinumtoxinA for Injection.

Additional results included:

- In those subjects with at least mild static lines at baseline, complete elimination of those lines was achieved in 54.4% subjects 4 weeks after the first treatment with DaxibotulinumtoxinA for Injection and further increased to 66.5% and 69.7% 4 weeks after treatment cycle 2 and 3 respectively.
- An incremental improvement in mean resting line severity was observed with each treatment cycle with DaxibotulinumtoxinA for injection, despite a requirement that subjects return to baseline dynamic line severity between treatment cycles.

The SAKURA Phase 3 clinical program is the largest ever Phase 3 clinical program conducted for glabellar lines and included two pivotal trials - SAKURA 1 and SAKURA 2 - and an open-label study, SAKURA 3. The SAKURA clinical program demonstrated that DaxibotulinumtoxinA for Injection was safe, generally well tolerated and achieved clinically significant improvement in glabellar lines with long-lasting results and high patient satisfaction. In patients treated with DaxibotulinumtoxinA for Injection, the median time to return to moderate or severe dynamic glabellar line severity was 24 weeks. The most common treatment- related AEs were headache, injection site pain and injection site erythema. The most common treatment-related adverse events were headache (in 6% of the subjects) followed by eyelid ptosis (2%) and facial paresis (1%).

Revance has evaluated this neuromodulator formulation in other phase 2 clinical studies in aesthetics including the full upper face, forehead lines and crow's feet as well as in therapeutic indications, including cervical dystonia and upper limb spasticity.

**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 HintMD fintech platform, which includes integrated smart payment, subscription and loyalty digital services. 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.

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**Forward-Looking Statements**

Any statements in this press release that are not statements of historical fact, including statements about the results of the post-hoc analysis of the SAKURA Phase 3 clinical program, the effects on static or resting glabellar lines with the repeated treatment of DaxibotulinumtoxinA for Injection, our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates, including with respect to DaxibotulinumtoxinA for Injection in glabellar lines and in therapeutic indications; the rate and degree of commercial acceptance, opportunity and growth potential of our product candidates, if approved; the growth opportunities available to the company; the process and timing of, and ability to complete, the current and anticipated future clinical development of our product candidates; the initiation, design, enrollment, submission, timing and results of our clinical studies, including with respect to the SAKURA Phase 3 clinical program; statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans; and potential benefits of our drug product candidates and our technologies, 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 the continuing delay in the FDA's approval of the BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines; 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; the rate and degree of economic benefit, the safety, commercial acceptance and the market, competition, size and growth potential of the RHA® Collection of dermal fillers, the HintMD fintech platform and our drug product candidates, if approved; our ability to successfully commercialize the RHA® Collection of dermal fillers, the HintMD fintech 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-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.

1. Glogau S, Kontis TC, et al. Progressive Improvement in Static Glabellar Lines Following Repeated Treatment with DaxibotulinumtoxinA for Injection. Derm. Surg. August 16, 2021, Volume - Issue - doi: 10.1097/DSS.0000000000003211

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