Revance Announces Positive Results in Two Phase 2a Studies of DaxibotulinumtoxinA For Injection for the Treatment of Forehead Lines and Crow's Feet, Respectively

June 30, 2020

- At least one dose in each study demonstrated a measurable treatment effect in 100% of subjects at 4 weeks, with median duration of 27 weeks in forehead lines and 24 weeks in crow's feet -

- DaxibotulinumtoxinA for Injection was well tolerated across all doses in both indications -

NEWARK, Calif.--(BUSINESS WIRE)--Jun. 30, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection, today announced results for two Phase 2a open-label, dose escalation studies of its investigational drug candidate DaxibotulinumtoxinA for Injection in the treatment of dynamic forehead lines (FHL) following glabellar (frown) line injections and lateral canthal lines (LCL), commonly known as crow's feet. The company announced that both studies demonstrated positive efficacy results and that DaxibotulinumtoxinA for Injection was well tolerated. Additionally, the studies evaluated a range of doses and while not powered to provide clinical significance, they provide directional guidance on the impact of dose on efficacy and duration of effect.

In the forehead lines study, a total of 61 subjects were enrolled into one of four dose groups with each receiving 40 units of DaxibotulinumtoxinA for Injection in the glabellar complex, followed two weeks later by injections of either 12, 16, 24, or 30 units in the forehead for a total study duration of up to 38 weeks. In the crow's feet study, a total of 63 patients were enrolled into one of four dose groups to receive either 12, 24, 36 or 48 units of DaxibotulinumtoxinA for Injection, then followed for up to 36 weeks.

TREATMENT EFFECT
The primary endpoint for efficacy was the proportion of subjects achieving a score of none or mild in wrinkle or line severity at Week 4 either at maximum eyebrow elevation for forehead lines or at maximum smile for crow's feet. The scores were based on the investigator assessment. In the forehead lines study, 100% of subjects achieved a score of none or mild at Week 4 in at least one treatment group. In the crow's feet study, 88% of subjects achieved a score of none or mild at Week 4 in at least one treatment group.

In addition, the proportion of subjects with a measurable treatment effect, as assessed by the investigator, was analyzed. A dose-dependent change in percent of subjects with at least a one-point change from baseline was observed. In both studies, 100% of subjects achieved a score of at least a one-point change from baseline at Week 4 in at least one treatment group.

One of the exploratory endpoints in these studies was duration of effect, defined as the median time to return to baseline wrinkle severity based on both investigator and patient assessment. At least one dose in each study demonstrated a median duration of effect of 27 weeks in the forehead lines study and 24 weeks in the crow's feet study.

SAFETY
In these two Phase 2a studies, DaxibotulinumtoxinA for Injection was well-tolerated at all dose levels. Adverse events were mild, localized and transient as expected and there were no treatment-related serious adverse events, as is common with other approved neuromodulators in the treatment of upper facial lines. The most common treatment-emergent adverse events after forehead line treatment were edema (10%), erythema (6.7%) and headache (5%). There was a single occurrence of mild eyelid ptosis that was fully resolved by Day 9. The most common treatment-emergent adverse events after crow's feet treatment were nasopharyngitis (11.1%), bruising (7.9%) and headache (7.9%). There were no events of ptosis.

ADJACENT STUDIES
Interim Week 4 data from these two Phase 2a studies were used in the final design of Revance's current upper facial lines Phase 2 study (glabellar lines, forehead lines and lateral canthal lines), to optimize dosing and injection patterns. Revance is scheduled to report results from that study in the fourth quarter of 2020. The SAKURA Phase 3 program assessing DaxibotulinumtoxinA for Injection as a potential treatment for moderate to severe glabellar lines yielded positive results, and the subsequent submission for regulatory approval has been given a Prescription Drug User Fee Act (PDUFA) VI program date of November 25, 2020, by the U.S. Food and Drug Administration (FDA).

"We are very encouraged by the results of these two studies, designed to evaluate safety and efficacy, as well as identify safe and effective doses, for DaxibotulinumtoxinA for Injection in the treatment of forehead lines and crow's feet," said Roman Rubio, M.D., Senior Vice President of Clinical Development at Revance. "The finding that at least one dose in each study produced a response rate of 24-weeks duration provides a compelling initial demonstration that DaxibotulinumtoxinA for Injection holds promise for the treatment of forehead lines and crow's feet."

Added Mark Foley, President and Chief Executive Officer, "Exploring DaxibotulinumtoxinA for Injection in other areas of the upper face beyond glabellar lines provides an expanded body of knowledge on the performance of our long-acting, next-generation neuromodulator. Our aim is to provide physicians and patients with a true advancement in the treatment of not only facial wrinkles, but also a number of debilitating muscle movement and pain disorders, which are being addressed through ongoing therapeutic clinical trials."

Phase 2a Clinical Program in Forehead Lines
The company's Phase 2a clinical program was a multicenter, open-label, dose escalation study to evaluate treatment of moderate or severe dynamic forehead lines (FHL) (frontalis) in conjunction with treatment of the glabellar complex. The study was conducted at four sites in the United States and Canada and enrolled 61 male and female patients with moderate to severe FHL, from the ages of 18 to 65 years old. Patients were enrolled sequentially into 1 of 4 treatment cohorts to receive DaxibotulinumtoxinA for Injection at 1 of 4 dose levels, ranging from 12 to 30 units. At the Day 1 study visit, patients received a single 40-unit dose of DaxibotulinumtoxinA for Injection for the treatment of glabellar lines. At the Week 2 study visit,

patients received the assigned dose of DaxibotulinumtoxinA for Injection for the treatment of forehead lines. The total study duration was 38 weeks, plus up to 2 weeks for screening. Patients were then followed for a minimum of 24 weeks.

Phase 2a Clinical Program in Lateral Canthal Lines
The company's Phase 2a clinical program was a multicenter, open-label, dose escalation study that evaluated treatment of moderate or severe lateral canthal lines (LCL) or crow's feet. The study was conducted at three sites in the United States and enrolled 63 male and female patients with moderate to severe lateral canthal lines, from the ages of 18 to 65 years old. Patients were enrolled into the first two treatment cohorts simultaneously, then sequentially into cohorts 3 and 4, to receive DaxibotulinumtoxinA for Injection at doses ranging from 12 to 48 units. The total study duration was up to 36 weeks, plus up to 2 weeks for screening. Patients were then followed for a minimum of 24 weeks.

Additional information about each Phase 2a study can be found at www.clinicaltrials.gov.

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. Beyond DaxibotulinumtoxinA for Injection, Revance has exclusive rights to commercialize TEOXANE SA's Resilient Hyaluronic Acid® (RHA®) Collection of dermal fillers in the U.S., the first and only range of FDA-approved fillers for correction of dynamic facial wrinkles and folds. Revance also has an agreement 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
This press release contains forward-looking statements, including statements related to Revance Therapeutics' 2020 financial outlook, expected cash runway and other financial performance, the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates, the initiation, design, timing and results of our clinical studies, including the SAKURA 3 study of DaxibotulinumtoxinA for Injection, Phase 3 program for treatment of cervical dystonia, Phase 2 and other clinical programs for the management of plantar fasciitis and for the treatment of adult upper limb spasticity, and related results and reporting of such results; 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 pre-commercialization plans and timing of our potential submission of a BLA filing for DaxibotulinumtoxinA for Injection to treat glabellar (frown) lines and potential regulatory approach and product launch; statements about our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates; statements regarding additional milestone payments through our partnerships, and potential benefits of our drug product candidates and our excipient peptide and other 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; 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; 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 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 annual report on Form 10-K filed May 8, 2020. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

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