Revance's RT002 Demonstrates Unprecedented Efficacy and Duration In Largest-Ever Aesthetic Neuromodulator Clinical Program

December 4, 2018

– In SAKURA 3, RT002 was well-tolerated across over 3,800 treatmentsin glabellar (frown) lines –

– The median time to return to baseline glabellar line severity was 28 weeks –

– RT002 represents the first long-acting neuromodulator, allowing for two or fewer treatments per year –

– Revance announces new trials in forehead lines and lateral canthal lines (crow's feet) –

– Revance to host conference call at 8:30 am ET today –

NEWARK, Calif.--(BUSINESS WIRE)--Dec. 4, 2018-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing next-generation neuromodulators for use in treating aesthetic and therapeutic conditions, today announced its long-acting neuromodulator DaxibotulinumtoxinA for Injection (RT002) with its proprietary stabilizing excipient peptide technology delivered positive top-line results in alleviating moderate-to-severe glabellar (frown) lines in the SAKURA 3 Phase 3 open-label, long-term safety study. Completion of this study paves the way for Revance to submit a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA), which is on-track for the first half of 2019.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20181204005591/en/

As a component of the largest clinical program of an aesthetic neuromodulator, the SAKURA 3 study included nearly 2,700 patients and more than 3,800 treatments. Patients received up to three treatments of RT002 and were followed for over a year and a half. Overall, the safety findings were consistent with the known safety profiles for currently available neuromodulators in aesthetics. Importantly, the rate of treatment-related adverse events decreased over successive treatments. For efficacy, based on investigator assessment, more than 95% of patients achieved a score of none or mild glabellar lines at maximum frown at Week 4 after each of three treatments. Measuring duration of effect, the median time to return to baseline glabellar line severity was 28 weeks. The median time to loss of none or mild wrinkle severity was 24 weeks. The SAKURA 3 results were consistent with those in the Phase 3 pivotal trials, SAKURA 1 and SAKURA 2.

"The results of this trial are exceptional since they demonstrate that RT002 has consistently and predictably produced long duration and high response rates and was well tolerated over successive treatments," said SAKURA investigator Jean D. Carruthers, M.D., who has served as an investigator for multiple FDA-approved neuromodulators, and is a clinical professor at the University of British Columbia. "My study patients were thrilled with their appearance and the longevity RT002 delivered, and they can't wait for this treatment option. I look forward to the possibility of providing my patients a new, unique neuromodulator that needs just two or fewer treatments a year."

Dan Browne, co-founder, president and chief executive officer of Revance said, "We are very excited by these compelling new data, which support RT002 as a next-generation neuromodulator with highly differentiated characteristics. We look forward to working closely with the FDA to bring this important treatment to patients as soon as possible. The success of the SAKURA aesthetic trials, combined with our ongoing therapeutic studies in multiple neuroscience indications, drive our mission to become the leading innovator in neuromodulators."

Following these results, Revance today announced it will begin studies in 2019 in forehead and lateral canthal lines (crow's feet) to explore the use and dosage of RT002 in the upper face.

"The long-term results in these studies, which are consistent and predictable across age groups and prior toxin experience, are extremely impressive," said SAKURA investigator Steven Fagien, M.D., FACS, Aesthetic Eyelid Plastic Surgery, Boca Raton, Florida, and one of the world's foremost experts in injectable neuromodulators. "The SAKURA data demonstrate RT002 provides a trifecta of results – a reassuring safety profile, high patient response rates, and long-lasting results. RT002 has the potential to raise the bar of expectations for neuromodulators in the injectable facial aesthetic landscape."

Global sales of neuromodulators totaled $4 billion in 2017 and are estimated to nearly double by 2025. Despite this, market penetration has remained below 10 percent for decades, at least in part because currently available short-acting neuromodulators do not address the number one desire of patients and physicians for longer-lasting results.

According to findings from a proprietary landmark survey of more than 2,000 women aged 25-70 conducted on behalf of Revance by The Harris Poll,* facial lines and wrinkles are the most concerning visible sign of aging among women in this age range. Still, only seven percent of women said they have used a neuromodulator in the past five years. In addition, the survey also included 246 dermatologists and plastic surgeons who see at least 15 patients a week who receive neuromodulator treatments. Among this group of physicians, 86 percent wish there was a neuromodulator that offered longer-lasting results than what is currently available.

SAKURA 3 TOP-LINE RESULTS

The SAKURA program targeted enrollment of at least 2,600 patients to receive at least one treatment and 500 to receive three treatments with RT002. The topline results include data from 2,691 subjects with moderate-to-severe glabellar lines who were treated with RT002 (40U); 2,380 patients received Treatment #1, 882 patients received Treatment #2, and 568 patients received all three treatments. In general, results across safety, efficacy and duration measures were consistent and predictable across age groups and prior toxin experience.

SAFETY

RT002 appeared to be generally well-tolerated, with no new tolerability or safety concerns reported. As was seen in the SAKURA 1 and SAKURA 2

pivotal trials, adverse events were mild, localized and transient. The rate of treatment-related adverse events decreased over successive treatments. The most common treatment-related adverse events per treatment of RT002 were headache (3.3 percent of treatments), injection site pain (2.7 percent) and injection site erythema (2.5 percent). There were no treatment-related serious adverse events. Eyelid ptosis was reported in 0.9 percent of treatments, decreased in frequency with successive treatments and was substantially lower than the rate observed in SAKURA 1 and SAKURA 2 (2.2 percent). The majority of ptosis events were characterized as mild in severity (85 percent) and transient.

EFFICACY

A high degree of efficacy was seen consistently across all three treatment cycles. Results were consistent with SAKURA 1 and SAKURA 2 based on the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) and Patient Facial Wrinkle Severity (PFWS) scales. As early as Week 1, over 90 percent of subjects across all three treatments had none or mild wrinkles.

At Week 4, the none or mild response rates as assessed by IGA-FWS were:

- SAKURA 3: First treatment 95.8 percent; second treatment 96.6 percent; third treatment 97.7 percent
- SAKURA 1: 97.5 percent
- SAKURA 2: 97.5 percent

On the more stringent 2-point composite endpoint, which was the primary efficacy endpoint in SAKURA 1 and 2, efficacy improved with successive treatment cycles:

- SAKURA 3: First treatment 73.2 percent; second treatment 77.7 percent; third treatment 79.6 percent
- SAKURA 1: 73.6 percent
- SAKURA 2: 74.0 percent

DURATION

As in the SAKURA 1 and SAKURA 2 pivotal trials, there were several secondary endpoints used to evaluate duration of effect, including median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS. Duration was evaluated in the first two 36-week treatment cycles; the third treatment cycle was not evaluated for duration as the observation period ended at twelve weeks for the purpose of this study.

Median time to return to baseline wrinkle severity on both IGA-FWS and PFWS:

- SAKURA 3: First treatment 28.0 weeks; second treatment 28.1 weeks
- SAKURA 1: 27.7 weeks
- SAKURA 2: 26.0 weeks

Median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS:

- SAKURA 3: First treatment 24.0 weeks; second treatment 24.1 weeks
- SAKURA 1: 24.0 weeks
- SAKURA 2: 23.9 weeks

About SAKURA Phase 3 Clinical Program

The SAKURA Phase 3 clinical program is the largest-ever aesthetic neuromodulator clinical program, including nearly 2,800 patients who received, in total, more than 4,200 treatments with RT002.

The SAKURA program included SAKURA 1 and SAKURA 2 – two randomized, double-blind, placebo-controlled pivotal trials that were identical in design to evaluate the safety and efficacy of a single administration of RT002 for the treatment of moderate-to-severe glabellar lines in adults from 18 to 75 years of age --and SAKURA 3, an open-label trial designed to evaluate the long-term safety of RT002 in glabellar lines following both single and repeat treatment administration in adults 18 years and older. The SAKURA 1 and SAKURA 2 trials enrolled a total of 609 patients at 30 sites in the U.S. and Canada. In these trials, patients were randomized 2:1 to receive either RT002 (40U) or placebo. Post-treatment, patients were followed for at least 24 weeks, at which time they were eligible to roll-over into SAKURA 3.

The SAKURA 3 long-term safety trial enrolled 2,691 patients at 66 sites in the U.S. and Canada. In SAKURA 3, patients were eligible to receive up to three treatments and were followed for up to 84 weeks. Subjects were eligible to be followed for up to 36 weeks after both treatments 1 and 2 and for up to 12 weeks after treatment 3.

About Glabellar Lines

The glabella is the area between the eyebrows and above the nose. Glabellar lines, often called “frown lines,” are vertical lines that develop between the eyebrows and may appear as a single vertical line or as two or more lines. When you frown, the muscles of the glabella contract causing vertical creases to form between the eyebrows. Botulinum toxin is used to temporarily block the ability of nerves to trigger contraction of injected muscle, inhibiting movement of the muscles that cause the frown lines, giving the skin a smoother, more refreshed appearance.

Based on data from Global Industry Analysts, Inc., the global market for aesthetic treatments with neuromodulators represented about $1.6 billion in revenue in 2016, and according to the American Society for Aesthetic Plastic Surgery, botulinum toxin treatment is the No.1 nonsurgical cosmetic procedure in the U.S. Management estimates glabellar line treatment represents nearly $1 billion of the global market.

About RT002

DaxibotulinumtoxinA for Injection (RT002) is an investigational product and the first neuromodulator with long-lasting duration. It is a novel, next-generation neuromodulator in development for the treatment of aesthetic indications and a number of potential therapeutic conditions, including movement disorders, pain and other neuroscience-based targets. RT002 is the only neuromodulator using a Revance proprietary stabilizing excipient peptide technology in its formulation, which results in high efficacy, long duration and provides two-year product stability requiring no refrigeration. RT002 is the first and only botulinum toxin product sourced, processed and manufactured in the U.S. and formulated without human blood-derived products or manufactured using animal-derived proteins.

Revance has four active clinical programs for RT002 injectable under way. The SAKURA 1, SAKURA 2 and SAKURA 3 trials to treat glabellar lines are complete. For cervical dystonia, the company was granted orphan drug designation from the FDA and initiated a Phase 3 program in mid-2018. The company plans to announce first patient dosing for Phase 2 trials for RT002 for the management of plantar fasciitis and for adult upper limb spasticity before year-end 2018.

Conference Call

Individuals interested in listening to the conference call may do so by dialing (855) 453-3827 for domestic callers, or (484) 756-4301 for international callers and reference conference ID: 2281019; or from the webcast link in the investor relations section of the company's website at: www.revance.com.

A replay of the call will be available beginning December 4, 2018 at 8:30am PT/11:30am ET to December 5, 2018 at 8:30am PT/11:30am ET. To access the replay, dial (855) 859-2056 or (404) 537-3406 and reference conference ID: 2281019. The webcast will be available in the investor relations section on the company's website for 30 days following the completion of the call.

About Revance Therapeutics, Inc.

Revance Therapeutics is an emerging Silicon Valley biotechnology leader developing neuromodulators for the treatment of aesthetic and therapeutic conditions. Revance uses a unique proprietary, stabilizing excipient peptide technology to create novel, differentiated therapies. The company's lead compound, DaxibotulinumtoxinA for Injection (RT002), is in clinical development for a broad range of aesthetic and therapeutic indications, including glabellar lines, cervical dystonia, plantar fasciitis, upper limb spasticity and chronic migraine. RT002 has the potential to be the first long-acting neuromodulator. The company is advancing a robust pipeline of injectable and topical formulations of daxibotulinumtoxinA. More information on Revance may be found at www.revance.com.

*Method Statement -This survey was conducted online by The Harris Poll on behalf of Revance among women aged 25-70 and Dermatologists and Plastic Surgeons who see patients who receive neuromodulator treatments in the United States. The consumer survey was conducted July 11 through July 30, 2018 among 1,004 women ages 25-70 who have used a Neuromodulator in the past 5 years and 1,005 women ages 25-70 who have either never used a Neuromodulator, or have used one 5+ years ago. Figures for age by gender, education, income, race/ethnicity, region, size of household, marital status, and employment status were weighted where necessary to bring them into line with their actual proportions in the population. The healthcare professional survey was conducted July 31 through August 29, 2018 among 141 Dermatologists and 105 Plastic Surgeons who see at least 15 patients per week who receive a Neuromodulator treatment. Results were weighted for gender by years in practice and region where necessary to bring them into line with their actual proportions in the population.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to Revance Therapeutics' current and anticipated future clinical development of our investigational drug product candidates, theinitiation, design, timing and results of our clinical studies, including the SAKURA 3 study of RT002, and related reporting of such results; the timing for the Phase 2 trials for RT002 for the management of plantar fasciitis and for adult upper limb spasticity; 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 BLA submission for RT002 to treat glabellar (frown) lines *and commercial potential of our client candidates; and statements about our ability to obtain regulatory approval with respect to our drug; 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, or that positive results would assure regulatory approval or commercial success of our product candidates; 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 quarterly report on Form 10-Q filed November 2, 2018. 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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Source: Revance Therapeutics, Inc.

INVESTORS

Revance Therapeutics, Inc.:
Jeanie Herbert
714-325-3584
jherbert@revance.com

Burns McClellan, Inc.:
Ami Bavishi
212-213-0006
abavishi@burnsmc.com

MEDIA
General Media:
TOGORUN:
Mariann Caprino
917-242-1087
m.caprino@togorun.com

Trade Media:
Nadine Tosk
504-453-8344
nadinepr@gmail.com