



## Revance's RT002 Meets Primary and All Secondary Endpoints, Achieves 6-Month Duration in Pivotal SAKURA Phase 3 Trials for Glabellar Lines

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- Highly statistically significant results on primary composite endpoint achieved at Week 4 -
- RT002 delivered highly statistically significant reduction in severity of glabellar lines at Week 24 -
- If approved, RT002 could represent a new, next-generation, long-acting neuromodulator -
- Revance to host conference call at 8:00 am ET today -

NEWARK, Calif.--(BUSINESS WIRE)-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing neuromodulators for use in treating aesthetic and underserved therapeutic conditions, today announced its next-generation neuromodulator DaxibotulinumtoxinA for Injection (RT002) delivered positive top-line results in alleviating moderate-to-severe glabellar lines in two pivotal SAKURA Phase 3 trials. RT002 appeared generally safe and well-tolerated in both studies.

If approved by the U.S. Food and Drug Administration (FDA), Revance believes RT002 would be the first neuromodulator with a long-acting duration of six months. Marketed neuromodulators have demonstrated duration of three to four months in treating glabellar lines.

Both SAKURA 1 and SAKURA 2 met the primary composite endpoint by delivering highly statistically significant improvement against placebo in reducing the severity of glabellar lines, i.e., the frown lines or wrinkles between the brows. The percent of RT002-treated patients who had none or mild wrinkles and achieved at least a two-point improvement from baseline on both validated physician and patient assessments were 73.6 percent in SAKURA 1 and 74.0 percent in SAKURA 2 compared to placebo (p <math>\leq 0.0001</math>) at Week 4. Also at that time point, 88 percent of RT002-treated patients in SAKURA 1 and 91 percent of RT002 patients in SAKURA 2 said they were very satisfied or satisfied with their treatment experience.

All secondary endpoints measuring reduction in severity of glabellar lines with RT002 compared to placebo were highly statistically significant at every time point evaluated to 24 weeks. On an additional key secondary endpoint, median duration for patients treated with RT002 to return to baseline wrinkle severity was nearly 27 weeks (SAKURA 1: 27.7 weeks and SAKURA 2: 26.0 weeks) as assessed by both physicians and patients.

"We are extremely pleased with these positive SAKURA top-line results, which reinforce the findings from the BELMONT Phase 2 active-comparator study. These results demonstrate it is scientifically and clinically possible to create a significantly longer-acting neuromodulator with a duration of six months, compared to three to four months observed with currently available products," said Dan Browne, Co-Founder, President and Chief Executive Officer of Revance Therapeutics. "We look forward to providing patients and healthcare professionals with what we believe is a new, next-generation, long-acting neuromodulator for the treatment of glabellar lines."

In addition to SAKURA 1 and SAKURA 2, a long-term safety trial, SAKURA 3, is fully enrolled and is expected to be completed in the second half of 2018. Assuming successful completion of SAKURA 3, the company plans to submit a Biologics License Application in the first half of 2019 and, pending approval by the FDA, launch RT002 in the U.S. in 2020.

"Both SAKURA 1 and SAKURA 2 show RT002 delivers consistent long-acting performance, which is unprecedented for a neuromodulator given what we have seen over the last 30 years," said Jean D. Carruthers, M.D., a SAKURA lead investigator and pioneer in the use of botulinum toxin for both aesthetic and therapeutic conditions, and Clinical Professor, University of British Columbia. "The data confirm the enhanced effect of this new neuromodulator both in its longevity and patient response. With just two treatments a year, RT002 has the potential to change the landscape in neuromodulator therapy."

Treatment of glabellar lines is the most popular aesthetic procedure for an injectable neuromodulator, accounting for nearly a third of the \$3.6 billion in global neuromodulator sales in 2016. Patients and physicians alike identify duration as the most important attribute of an injectable aesthetic treatment, market research shows. <sup>1</sup>

"Patients in my practice are very savvy - not only do they want their neuromodulator treatment to give them great results, they also want the look to last as long as possible," said Joely Kaufman-Janette, M.D., Skin Associates of South Florida, and a SAKURA investigator. "I am very excited about the results of the SAKURA trials since RT002 appears to provide the look my patients desire over a six-month period, which is remarkable and will fulfill a significant need among my patients."

### TOP-LINE 36-WEEK RESULTS

#### PRIMARY ENDPOINT

The primary efficacy measurement was a composite of the proportion of patients who achieved a score of 0 or 1 (none or mild) and at least a two-point improvement from baseline at maximum contraction (frown) in glabellar line severity on both the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) and Patient Facial Wrinkle Severity (PFWS) scales at Week 4.

- Percent of patients who achieved the primary composite endpoint:
  - SAKURA 1: 73.6 percent of patients vs. 0 percent for placebo (p <math>\leq 0.0001</math>)
  - SAKURA 2: 74.0 percent vs. 1.0 percent for placebo (p <math>\leq 0.0001</math>)

## SECONDARY DURATION ENDPOINTS

There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-FWS and PFWS.

- The percent of patients treated with RT002 who achieved a none or mild response on IGA-FWS at Week 24:
  - SAKURA 1: 35.3 percent vs. 2.0 percent for placebo (p &#60 0.0001)
  - SAKURA 2: 29.4 percent vs. 2.0 percent for placebo (p &#60 0.0001)
- Median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS for patients treated with RT002:
  - SAKURA 1: 24.0 weeks
  - SAKURA 2: 23.9 weeks
- Median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS for patients treated with RT002:
  - SAKURA 1: 27.7 weeks
  - SAKURA 2: 26.0 weeks

For comparison, an additional exploratory duration endpoint was evaluated, which mirrors the duration measure used in the BELMONT Phase 2 study.

- Median duration of  $\geq 1$  point improvement from baseline on IGA-FWS for patients treated with RT002:
  - SAKURA 1: 24.1 weeks
  - SAKURA 2: 24.1 weeks
  - BELMONT: 23.6 weeks<sup>2</sup>

## SAFETY

RT002 appeared to be generally safe and well-tolerated through the end of study at Week 36. Adverse events were mild, localized and transient. There were no treatment-related serious adverse events. The most common adverse events for RT002 in both studies combined were headache (6.4 percent) and injection site pain (3.7 percent). The incidence of eyelid ptosis and brow ptosis were 2.2 percent and 0.7 percent, respectively.

### About SAKURA Phase 3 Clinical Program

The SAKURA clinical program includes 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. The SAKURA 1 and SAKURA 2 trials enrolled a total of 609 patients at 30 sites in the U.S. and Canada. In both trials, patients were randomized 2:1 to receive either RT002 (40U) or placebo. Post-treatment, patients were followed for at least 24 weeks and up to 36 weeks.

The primary efficacy endpoint was the composite of the proportion of patients who achieved a score of 0 or 1 (none or mild) and at least two-point improvement from baseline in glabellar line severity on both the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) and Patient Facial Wrinkle Severity (PFWS) scales, at maximum contraction (frown), at Week 4. Duration of the reduction of severity of glabellar lines was assessed as secondary efficacy endpoints.

The program also includes an open-label trial designed to evaluate the long-term safety of RT002 in glabellar lines following both single and repeat treatment administration. The long-term safety trial enrolled more than 2,500 patients at 66 sites in the U.S. and Canada and is expected to be completed in the second half of 2018.

### About Glabellar Lines

The glabella is the skin 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 and may also appear angled toward the inner corners of the eyebrows. When you frown, the muscles of the lower forehead contract in a downward direction, causing the skin between the eyebrows to crease. Lines are formed by the repeated action of frowning due to the lack of elasticity in the skin. Age, sun exposure, and genetics are contributing factors. Botulinum toxin is used to block the nerve impulses, temporarily 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. It is a novel, next-generation neuromodulator in development for the treatment of aesthetic and therapeutic conditions, including glabellar lines, cervical dystonia and plantar fasciitis. Created using Revance's proprietary peptide technology, RT002 has the potential to become the first neuromodulator with long-acting duration of six months. This proprietary, stabilizing excipient peptide technology eliminates the need for human- and animal-based components, which carry a potential risk of transmitting pathogens.

Revance has three active clinical programs for RT002 injectable under way. With the SAKURA 1 and SAKURA 2 Phase 3 pivotal trials to treat glabellar

lines now completed, Revance plans to complete the SAKURA 3 open-label, long-term safety study in the second half of 2018. For cervical dystonia, the company was recently granted orphan drug designation and plans to initiate a Phase 3 program in 2018. A Phase 2 trial for RT002 for the management of plantar fasciitis is fully enrolled, and the company plans to share results by year end 2017.

#### Conference Call

Individuals interested in listening to the conference call today, December 5, at 5:00am PT/8:00am ET, may do so by dialing (855) 453-3827 for domestic callers, or (484) 756-4301 for international callers and reference conference ID: 9076999; or from the webcast link in the investor relations section of the Company's website at: <http://investors.revance.com/index.cfm>.

A replay of the call will be available beginning today at 8:00am PT/11:00am ET through 8:00am PT/11:00am ET on December 6, 2017. To access the replay, dial (855) 859-2056 or (404) 537-3406 and reference conference ID: 9076999. 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 a biotechnology company developing neuromodulators for use in treating aesthetic and underserved therapeutic conditions, including muscle movement disorders and pain. The company's lead drug candidate, DaxibotulinumtoxinA for Injection (RT002), is currently in development for the treatment of glabellar lines, cervical dystonia and plantar fasciitis, with the potential to be the first long-acting neuromodulator. Revance has developed a proprietary, stabilizing excipient peptide technology designed to create novel, differentiated therapies. The company has a comprehensive pipeline based upon its peptide technology, including injectable and topical formulations of daxibotulinumtoxinA. More information on Revance may be found at [www.revance.com](http://www.revance.com).

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#### Forward-Looking Statements

*This press release contains forward-looking statements, including statements related to our business strategy, timeline and other goals and market for our anticipated products, plans and prospects; statements about our ability to obtain regulatory approval; and statements about 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; 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 3, 2017. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.*

#### References:

1. Data on file
2. Carruthers, J., et al. Injectable DaxibotulinumtoxinA for the Treatment of Glabellar Lines: A Phase 2, Randomized, Dose-Ranging, Double-Blind, Multicenter Comparison with OnabotulinumtoxinA and Placebo. *Dermatol. Surg.* 2017; 43: 1321 - 1331

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#### INVESTORS

Revance Therapeutics, Inc.  
Jeanie Herbert, 714-325-3584  
[jherbert@revance.com](mailto:jherbert@revance.com)

or

Burns McClellan, Inc.  
Ami Bavishi, 212-213-0006  
[abavishi@burnsmc.com](mailto:abavishi@burnsmc.com)

or

#### MEDIA

General Media:  
TOGORUN  
Mariann Caprino, 917-242-1087  
[m.caprino@togorun.com](mailto:m.caprino@togorun.com)

or

Trade Media:  
Nadine Tosk, 504-453-8344  
[nadinepr@gmail.com](mailto:nadinepr@gmail.com)

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