



March 5, 2016

## Revance Announces Late-Breaking Podium Presentation of Positive 6-Month Duration Results for BELMONT Phase 2 Active Comparator Study of Injectable RT002 at the 74th Annual Meeting of the American Academy of Dermatology

- Findings confirm statistically significantly greater duration of effect for RT002 compared to BOTOX® Cosmetic -
- 40U dose of RT002 planned to enter pivotal Phase 3 study in the second half of 2016 -

NEWARK, Calif., March 05, 2016 (GLOBE NEWSWIRE) -- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing botulinum toxin products for use in aesthetic and therapeutic indications, today announced that clinical results from the company's BELMONT Phase 2 active comparator study of DaxibotulinumtoxinA for Injection (RT002) were reported in a podium presentation at the American Academy of Dermatology (AAD) annual meeting, which is being held in Washington, DC, March 4-8, 2016. Confirming interim clinical results [previously reported in October 2015](#), all three study dose levels of RT002 achieved the Phase 2 study's primary efficacy measurement demonstrating at least 1-point improvement in frown lines based on the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) scale at 4 weeks. This measurement showed a statistically significantly greater response as compared to placebo for each dose level of RT002 (100% investigator-determined response for all three RT002 dose levels vs. 3% response for placebo). In addition, Revance's study demonstrated a 6-month median duration of effect for RT002 based upon at least 1-point improvement in glabellar lines at maximum frown on the IGA-FWS scale.

- 1 For the mid-dose level of RT002 Injectable 40U, the duration of effect was statistically significantly greater (23.6 weeks) compared to BOTOX® Cosmetic (BOTOX® 20U) (18.8 weeks;  $p=0.02$ ). RT002 40U is the dose Revance intends to bring forward in Phase 3 clinical studies, which are expected to commence in the second half of 2016.
- 1 For RT002 Injectable 40U, investigator assessment of None or Mild wrinkles was statistically superior at the majority of time points when compared to BOTOX® Cosmetic. As an example, at 6 months, 31% of subjects receiving RT002 40U maintained None or Mild wrinkles compared to 12% receiving BOTOX® ( $p < 0.05$ ).

Across all cohorts, RT002 appeared to be generally safe and well-tolerated. Adverse events were predominantly localized, transient, and mild. There were no serious adverse events or evidence of any systemic exposure at any of the three doses evaluated.

Also covered within the presentation was a separate study investigating the impact of dosing of BOTOX® Cosmetic on duration of effect. This prior study showed that increased dosing did not result in meaningfully longer duration, an important finding underscoring the need for an alternative, longer-duration treatment.

**Jean Carruthers, MD, FRCSC, FRC (OPHTH)**, Clinical Professor of Ophthalmology, University of British Columbia where she specializes in facial cosmetic surgery and pioneered the cosmetic use of botulinum toxin, Diplomate of the American Board of Cosmetic Surgery and Fellow of the American Society of Ophthalmic Plastic and Reconstructive Surgery, delivered the Phase 2 findings in a podium presentation titled, "Safety, Efficacy and Duration of Effect of RT002, a Botulinum Toxin Type A for Injection, to Treat Glabellar Lines: The Phase 2 BELMONT Study" (Abstract #3786). The presentation took place in the Late-breaking Research Forums - Procedural Dermatology session during the AAD annual meeting.

Dr. Carruthers commented, "I am delighted that the Phase 2 results from the BELMONT study have been highlighted as a late-breaking presentation at this year's AAD meeting. The findings represent a potentially transformative clinical achievement, demonstrating superior duration of effect in an active comparator study addressing one of the most popular aesthetic procedures."

Dr. Carruthers continued, "What we have demonstrated in this study is the combination of rapid effect, as we saw in the 100 percent achievement of at least a 1-point improvement on the Facial Wrinkle Severity Scale seen as early as two weeks, with a 6-month duration. Offering treatment just two times a year, a schedule that suits other key procedures such as fillers, will make a major difference to many patients. I look forward to the conclusion of this important program and the start of the Phase 3 program later this year."

Added Dan Browne, President and Chief Executive Officer at Revance, "Based on the successful results of the BELMONT study of RT002 injectable, we plan to conduct an End-of-Phase 2 meeting with the FDA before the end of the second quarter in preparation to commence our pivotal Phase 3 studies the second half of 2016. We believe we are well on our way

to supporting a 6-month duration label, assuming our Phase 3 findings are consistent with what we have shown to date. Beyond glabellar lines, prospects of an improved safety profile from less spread, along with a long-lasting duration of effect, could make RT002 an important future treatment option for cervical dystonia and other involuntary muscle movement disorders. From where we stand now, we expect that RT002 could have a significant impact on the estimated \$3 billion global neurotoxin market."

### **BELMONT Phase 2 Study Design**

BELMONT is a Phase 2, randomized, double-blind, dose-ranging, active comparator and placebo-controlled, multi-center study conducted at key sites in Canada. The study has evaluated the safety, efficacy, and duration of three doses of DaxibotulinumtoxinA for Injection (RT002), 20U, 40U or 60U, compared to the labeled dose of the current market leader BOTOX® Cosmetic 20U (or VISTABEL®, as trademarked in Canada) and a placebo control in treating glabellar lines. The BELMONT study enrolled a total of 268 subjects with moderate-to-severe glabellar lines during maximum frown. The primary efficacy measurements for the study, consistent with the BOTOX® Cosmetic label, are the investigator's assessment of glabellar line severity at maximum frown (IGA-FWS) and median duration of effect from the date of treatment to when a subject reverts back to baseline severity. Subjects in the BELMONT study were randomized equally across five study groups receiving one of three doses of RT002, the active comparator, or placebo. All patients were followed for 24 weeks, and the trial was continued to follow a subset of subjects for up to 36 weeks or until return to baseline. Additional information about the trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), Clinical trial identifier NCT02303002.

### **About Glabellar Lines**

The glabella is the skin between the eyebrows and above the nose. Glabellar lines (often called "frown lines") are those 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 towards 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 paralyzing the muscles that cause the frown lines, giving the skin a smoother, more refreshed appearance.

Based on data from UBS Global Research, the global market for aesthetic treatments with neurotoxins represented about a \$1.4 billion market in 2014 and according to the American Society for Aesthetic Plastic Surgery, botulinum toxin treatment is the number one nonsurgical cosmetic procedure in the U.S. and glabellar line treatment represents the largest segment of that market.

### **About RT002 Injectable**

DaxibotulinumtoxinA for Injection (RT002) combines Revance's proprietary, pure 150kD botulinum toxin type A molecule, without any accessory proteins or animal derived components, with Revance's patented TransMTS® peptide technology. RT002 is designed to offer more targeted delivery to the intended treatment sites, while reducing its spread beyond the site of local injection for a long-lasting effect. RT002 is in clinical development for the treatment of glabellar (frown) lines and for cervical dystonia, and has the potential to address additional therapeutic indications in movement disorders, pain, urology, and other potential uses where targeted delivery is required or long duration is desired.

### **About Revance Therapeutics, Inc.**

Revance, a Silicon Valley-based biotechnology company, is committed to the advancement of remarkable science. The company is developing a portfolio of products for aesthetic medicine and underserved therapeutic specialties, including neurology. Revance's trajectory to commercial success begins with the company's novel and proprietary TransMTS® carrier-peptide delivery system, which is uniquely designed to target and transport macromolecules to their desired location.

Revance's journey to market starts with the neurotoxin daxibotulinumtoxinA, the company's highly purified botulinum toxin type A. The TransMTS technology is used in the delivery of botulinum toxin through two novel drug product candidates: DaxibotulinumtoxinA Topical Gel (RT001) that permits needle-free application, and DaxibotulinumtoxinA for Injection (RT002), which is designed to enable targeted administration and long-lasting effect. Revance is developing RT001 and RT002 for a broad spectrum of aesthetic and therapeutic indications, including facial wrinkles, excessive sweating and muscle movement disorders. The company holds worldwide rights for all indications of RT001, RT002 and the TransMTS technology platform. Beyond botulinum toxin, Revance expects the TransMTS technology can be applied to transdermal, mid-dermal or deep tissue delivery of a variety of other macromolecules. More information on Revance can 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 Revance Therapeutics' investigational drug product candidates, including but not limited to statements about our business strategy, clinical development, timeline and other goals and market for our anticipated products, plans and prospects 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, 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 March 4, 2016. 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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