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Revance Therapeutics Announces Publication of Positive Results From RT002 Phase 1/2 Study

RT002 Achieved Median Duration of 7 Months

Phase 2 Active Comparator Study Underway

NEWARK, Calif., Jan. 8, 2015 (GLOBE NEWSWIRE) -- Revance Therapeutics, Inc. (Nasdaq:RVNC), a specialty biopharmaceutical company developing botulinum toxin products for the use in aesthetic and therapeutic indications, today announced publication in the peer reviewed journal, *Dermatologic Surgery* of positive data from its Phase 1/2 study of RT002 injectable botulinum toxin type A for the treatment of moderate to severe glabellar (frown) lines. RT002 is Revance's proprietary, injectable botulinum toxin investigational product that incorporates the patented TransMTS® technology and is designed to provide a longer lasting duration of effect. Initial results from the study were announced last April and showed RT002 met its efficacy and safety endpoints with an extended duration of action.

The open-label, dose escalating, Phase 1/2 study enrolled 48 adults in four cohorts. All subjects had Severe or Moderate wrinkles at baseline, measured using the 4-point Global Line Severity Scale (GLSS).

In summary, the results were as follows:

- Clinical investigators rated 96% of subjects with None or Mild wrinkle severity at maximum frown 4 weeks post-treatment using the GLSS. At the same time point, 83% of the subjects assessed themselves as achieving None or Mild wrinkles at maximum frown.
- In the final cohort, the only one where duration of effect was measured, RT002 achieved a median duration of 29.4 weeks, or 7 months, based on both investigator and subject assessments.
- In this final cohort, 60% of subjects maintained None or Mild wrinkle severity at 6 months.
- RT002 was well tolerated, and there was no evidence of spread beyond the treatment site at any dose; additionally, adverse event rates did not change in frequency, severity, or type with increasing doses.

Based on the results of this study and previous findings from pre-clinical data, Revance initiated BELMONT, a Phase 2 active comparator study. BELMONT is a double-blind, dose ranging, active and placebo controlled multi-center study. Top-line data is expected in late 2015.

"BELMONT compares injectable RT002 and placebo with the current industry standard and this makes it a unique study," said Alastair Carruthers, MD, editor of the current special issue of Dermatologic Surgery focused on Botulinum Toxin. An investigator in the BELMONT trial, he added "In 2015 we will know how RT002 compares with BOTOX® Cosmetic and a placebo control, especially with regard to duration of effect and complications. If results are in line with previous data, use of RT002 could extend well beyond aesthetic applications."

"Publication of our RT002 data in this peer-reviewed journal is a significant contribution to the published literature on the use of botulinum toxin," said Dan Browne, Revance co-founder, President and CEO. "The study showed that RT002 reduced glabellar lines in nearly all of the 48 patients treated. Even more significant, patients in the final cohort enjoyed benefit almost twice as long as what the literature has shown with conventional botulinum toxin injections. We believe that such duration of effect could have significant positive implications for the botulinum toxin market."

About RT002

RT002, an investigational product, is a novel, injectable form of botulinum toxin type A. 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. RT002 is in clinical development for the treatment of glabellar (frown) lines and has the potential to address additional therapeutic indications in movement disorders, pain, urology, ophthalmology and other potential uses where more targeted delivery is required or longer duration is desired.

About Revance Therapeutics, Inc.

Revance is a specialty biopharmaceutical company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic applications. Revance is leveraging its proprietary portfolio of botulinum toxin compounds combined with its patented TransMTS® peptide delivery system to address unmet needs in the large and growing aesthetic and therapeutic botulinum toxin market. Revance's proprietary TransMTS® technology enables transcutaneous delivery of botulinum toxin A eliminating the need for injections. Revance's lead product candidate, RT001, is a topical formulation of botulinum toxin type A, which has the potential to be the first commercially-available non-injectable dose form. RT001 is being evaluated in a broad clinical program that includes aesthetic indications such as crow's feet lines (wrinkles around the eyes) and therapeutic indications such as hyperhidrosis (excessive sweating). Revance's second product candidate is RT002, a novel injectable formulation of botulinum toxin type A designed to be more targeted and longer lasting than currently available botulinum toxin injectable products.

For more information, please visit: www.revance.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements about our RT002 product candidate, including but not limited to statements regarding the process and timing of, and ability to complete, current clinical studies and anticipated future clinical development, the initiation and design of clinical studies for current and future indications, related results and reporting of such results; statements about our business strategy, goals, applications and market for our anticipated products, plans and prospects; statements about potential benefits of our product candidates and our technologies; and statements about future performance.

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 product candidates; our ability to obtain funding for our operations; our plans to research, develop and commercialize our product candidates; our ability to achieve market acceptance of our 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 product candidates; our ability to successfully commercialize our product candidates and the timing of commercialization activities; the rate and degree of market acceptance of our 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 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 described in the "Risk Factors" section of our quarterly report on Form 10-Q filed November 13, 2014. 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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