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Revance Therapeutics Announces Positive Results From the RT002 Phase 1/2 Study in Glabellar Frown Lines

Median Duration of 7.3 Months

NEWARK, Calif., April 21, 2014 (GLOBE NEWSWIRE) -- Revance Therapeutics, Inc. (Nasdaq:RVNC), today announced 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. In the study, RT002 met its primary efficacy and safety endpoints. 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 data showed:

- 94% of subjects were rated with None or Mild wrinkle severity at maximum frown 4 weeks post-treatment using the GLSS as assessed by the clinical investigator. 83% of subjects assessed themselves as achieving None or Mild wrinkles at maximum frown at the same time point.
- In the final cohort, the only one where duration of effect was measured, RT002 achieved a median duration of 29.4 weeks or 7.3 months based on both investigator and subject assessments.
- RT002 was well tolerated, and there was no evidence of spread beyond the treatment site at any dose.

Based on the results of this study and previous findings from pre-clinical data, we plan to continue studying RT002 in a Phase 2 active comparator study. Data from the study is anticipated in 2015.

"RT002 was easy to administer and very well received by patients," said Enrique Garcia-Murray, MD lead investigator for the RT002 study. "As the study progressed, we were most impressed by the duration of effect. Patients typically see three to four months of benefit from current botulinum toxin treatments, but we saw an effect that was significantly longer than that. My patients were extremely happy about this increased duration."

"The results of this study are extremely encouraging from both safety and efficacy perspectives," said Jacob Waugh, MD, Chief Scientific Officer and Medical Director. "This data aligns well with previously reported preclinical studies which established less unwanted spread and longer duration. We look forward to expanding our evaluation of RT002 further in Phase 2 studies."

Safety and Tolerability

Across all cohorts, RT002 was shown to be generally safe and well tolerated with minimal adverse events. An independent Data Safety Committee (DSC) composed of experts from neurology, dermatology, and internal medicine, reviewed the data after each cohort and confirmed the safety of dose escalation prior to each successive higher dose. Adverse events were generally mild, localized and transient. The most common adverse events observed were headache and injection site reactions. There was no evidence of spread beyond the treatment site at any dose. There were no serious adverse events or evidence of any systemic exposure based on clinical laboratory results and related evaluations. Adverse event rates did not change in frequency, severity, or type with increasing doses.

Clinical Study Design

RT002-CL001 was a Phase 1/2 dose escalating, open-label study for the treatment of moderate to severe glabellar (frown) lines. The study was conducted in Mexico City and enrolled 48 patients across four dose cohorts, ranging from approximately half the labeled dose to approximately twice the labeled dose of commercially available neurotoxins based on potency assays commonly used in the industry.

The study objective was to establish a safe dose and evaluate safety, efficacy and durability after a single administration of RT002 for the treatment of glabellar (frown) lines. Efficacy was assessed at maximum frown by the investigator and the subjects using the 4-point GLSS at the 2 and 4-week time points for all cohorts. The final cohort, consisting of 10 subjects, was also measured for duration of effect at the six, seven and eight month time points.

About RT002

RT002, an investigational product, is a novel, injectable form of botulinum toxin type A currently under evaluation for the treatment of moderate to severe glabellar (frown) lines. RT002 combines our proprietary, pure 150kD botulinum toxin type A molecule without any accessory proteins or animal derived components with the patented TransMTS® peptide technology. It is designed to be more targeted and longer lasting than currently available botulinum toxin injectable products. It is being developed to treat both aesthetic and therapeutic conditions where deeper, 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 across multiple aesthetic and therapeutic applications. The TransMTS® technology platform is the basis for a suite of novel botulinum toxin products to address many of the shortcomings of currently available neurotoxins. Our lead product is RT001 a topically applied 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) and migraine headache. The Company is leveraging its proprietary portfolio of botulinum toxin compounds combined with its patented delivery system to address unmet needs in the large and growing aesthetic and therapeutic botulinum toxin market.

Forward Looking Statements

This press release contains forward-looking statements, including statements related to the process and timing of anticipated future clinical development of Revance Therapeutics' product candidates, including continued plans to study RT002 in a Phase 2 clinical trial, with anticipated results in 2015; statements about its business strategy and goals; and potential benefits of its product candidates and technologies. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from Revance's expectations. These risks and uncertainties include, but are not limited to: the outcome, cost and timing of its product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design; Revance's ability to obtain and maintain regulatory approval of its product candidates; its ability to obtain funding for its operations; its plans to research, develop and commercialize its product candidates; its ability to achieve market acceptance of its 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 its product candidates; its ability to successfully commercialize its product candidates and the timing of commercialization activities; the rate and degree of market acceptance of its product candidates; its ability to develop sales and marketing capabilities; the accuracy of its estimates regarding expenses, future revenues, capital requirements and needs for financing; its ability to continue obtaining and maintaining intellectual property protection for its product candidates; and other risks detailed in the "Risk Factors" and elsewhere in Revance's U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K filed with the SEC on March 28, 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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