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Revance Therapeutics Announces Initiation of BELMONT Phase 2 Active Comparator Trial of Injectable RT002

BELMONT Designed to Investigate the Efficacy, Safety and Duration of RT002 Botulinum Toxin Type A Compared to the Market Leader for the Treatment of Glabellar (Frown) Lines

NEWARK, Calif., Jan. 5, 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 initiation of the BELMONT trial, a Phase 2, Randomized, Double-**B**lind, Dos**E** Ranging, Active and P**L**acebo Controlled, **M**ulti-Center Study to Evaluate the Safety and Efficacy and Duration **O**f Effect of RT002, a Botuli**N**um Toxin **T**ype A for Injection, to Treat Glabellar Lines, more commonly known as frown lines. RT002, incorporating Revance's patented TransMTS® delivery technology, is an investigational product designed to offer more targeted delivery of botulinum toxin to intended treatment sites with reduced spread beyond the site of local injection. Last April, Revance reported the results of a Phase1/2 study which showed median duration of 29.4 weeks, which exceeds the labeled duration of currently marketed botulinum toxin products for the treatment of glabellar lines.

"We are very excited about the potential for RT002; our previous dose escalation study for the treatment of glabellar lines showed compelling safety, efficacy and duration of effect," said Dan Browne, co-founder, President and Chief Executive Officer at Revance. "The opportunity for a longer-lasting, more targeted neurotoxin is tremendous as it offers the potential for improved patient satisfaction and safety with longer-lasting results." Mr. Browne added, "Based on the current progress of our program, we expect to report top-line data from this Phase 2 study in late 2015, as previously disclosed."

"A product that could last roughly double the duration of commercially available neurotoxins for the treatment of frown lines, could be a 'game changer' for not only the cosmetic market, but potentially for other applications as well," commented Jean Carruthers, MD, Clinical Professor in the Department of Ophthalmology at the University of British Columbia in Vancouver, an investigator in the BELMONT trial and leading expert on botulinum toxin who has participated in clinical trials for over 30 years.

BELMONT Study Design

The BELMONT study will evaluate the safety, efficacy and duration of three doses of RT002, the labeled dose of the current market leader BOTOX® Cosmetic and a placebo control. BELMONT is expected to enroll approximately 250 subjects at up to 10 sites in Canada. The primary endpoints for the study are the investigator's assessment of glabellar line severity at maximum frown at Week 24 and median duration of effect from the date of treatment back to baseline severity. Patients in the BELMONT study will be randomized one-to-one across five study arms receiving one of three doses of RT002, an active comparator (BOTOX® Cosmetic) or placebo. The RT002 doses will be equal to or greater than the labeled doses of commercially available products. Previous RT002 clinical data showed a similar safety profile across escalating doses. Additional information about the trial, including eligiblity criteria, can be found at www.clinicaltrials.gov. (Clinical trial identifier NCT02303002).

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.

In a Phase 1/2 open-label study of RT002 for the treatment of moderate to severe glabellar lines, RT002 met its efficacy endpoint, demonstrating high response rates across all doses. Further, RT002 was well-tolerated with no safety concerns and minimal adverse events which included headache and itching or burning at the injection site; all events were considered mild or moderate and transient. There was no evidence of spread beyond the treatment site. In the final cohort that

measured duration, RT002 achieved a median duration of 29.4 weeks based on both investigator and patient assessments.

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

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**BOTOX ® is a registered trademark of Allergan, Inc.*

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 and market for our anticipated products, plans and prospects; statements about our ability to obtain regulatory approval; statements about potential benefits of our product candidates and our technologies; and statements about future financial 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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