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Revance Announces Completion of Pre-Phase 3 Meeting with FDA for RT002 Injectable to Treat Glabellar Lines

- Company plans to initiate global Phase 3 program in the second half of 2016 -

NEWARK, Calif.--(BUSINESS WIRE)-- Revance Therapeutics, Inc. (NASDAQ:RVNC), a biotechnology company developing botulinum toxin products for use in aesthetic and therapeutic indications, today announced the completion of its Type B / pre-IND / pre-Phase 3 meeting with the U.S. Food and Drug Administration (FDA) regarding DaxibotulinumtoxinA for Injection (RT002) for the treatment of glabellar (frown) lines. Based upon the discussion with the FDA and the minutes received following the meeting, Revance is moving forward with an Investigational New Drug (IND) submission for the Phase 3 clinical program for RT002 in glabellar lines and other supportive studies required for Biologics License Application (BLA) filing. Revance expects to initiate its Phase 3 clinical trials in the second half of 2016.

The company's Phase 3 program will include two placebo-controlled pivotal studies conducted at multiple sites in the US and Canada. The primary endpoint of these studies will be a composite of the proportion of subjects who achieve a score of 0 or 1 (*none or mild*) and a two-point improvement from baseline in glabellar line severity on investigator assessment (IGS-FWS) and patient assessment (PFWS) scales, at maximum contraction (frown), at Week 4. Duration of the reduction of severity of the glabellar lines will be assessed as a secondary endpoint in the Phase 3 pivotal studies. In addition, the Phase 3 program will include a long-term, open-label safety study. Revance plans to announce additional details on the study designs when the company begins dosing patients.

"We have been very pleased by the informative and productive discussions with the FDA and our ability to reach agreement on appropriate next steps for our pivotal frown line program," said Dan Browne, President and Chief Executive Officer of Revance. "The design of our Phase 3 program is consistent with the FDA 'Draft Guidance for Industry: Upper Facial Lines'. We are finalizing the IND submission for the glabellar line program and have already begun study start-up activities."

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 United States. Glabellar line treatment represents the largest segment of that market.

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 dermatology and neurology. Revance's trajectory to commercial success begins with the company's novel and proprietary TransMTS® carrier-peptide delivery system applied to botulinum toxin.

Revance is developing daxibotulinumtoxinA, the company's highly purified botulinum toxin, for a broad spectrum of aesthetic and therapeutic indications, including facial wrinkles and muscle movement disorders.

The company holds worldwide rights for all indications of DaxibotulinumtoxinA Topical Gel (RT001), DaxibotulinumtoxinA for Injection (RT002) and the TransMTS technology platform. Beyond botulinum toxin, Revance believes 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.

"Revance Therapeutics", TransMTS®, "Remarkable Science Changes Everything", and the Revance logo are registered trademarks of Revance Therapeutics, Inc.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to: statements about our investigational drug product candidates and planned studies and related activities, expected efficacy of our drug product candidates, 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 quarterly report on Form 10-Q filed on May 10, 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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