



Revance Reports Positive Efficacy and Duration Results from Phase 2 Upper Facial Lines Study

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- Open-label study of DaxibotulinumtoxinA for Injection in the combined treatment of glabellar lines, forehead lines and crow's feet lines showed efficacy of none or mild wrinkle severity in at least 92 percent of subjects at Week 4 –
- Median time to return to baseline wrinkle severity was at least 33 weeks (7.6 months) –
- Treatment with DaxibotulinumtoxinA for Injection was well tolerated across upper facial regions –

NEWARK, Calif.--(BUSINESS WIRE)--Dec. 17, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced positive topline efficacy and safety results from its Phase 2 multicenter, open-label study of investigational drug candidate DaxibotulinumtoxinA for Injection for the combined treatment of upper facial lines, which are comprised of glabellar (frown) lines (GL), dynamic forehead lines (FHL) and lateral canthal lines (LCL), commonly known as crow's feet lines.

In the Phase 2 study, 48 subjects were enrolled to receive a single treatment of DaxibotulinumtoxinA for Injection with a total study duration of 36 weeks. Subjects received 40, 32, and 48 units of DaxibotulinumtoxinA for Injection respectively in the glabellar complex, forehead and lateral canthal areas.

TREATMENT EFFECT

The key endpoints for efficacy were the proportion of subjects achieving a score of none or mild wrinkle severity at maximum contraction (maximum frown, eyebrow elevation, and smile effort) at Week 4, as assessed on the Investigator Global Assessment Frown Wrinkle Severity (IGA-FWS), Investigator Global Assessment Forehead Wrinkle Severity (IGA-FHWS), and Investigator Global Assessment Lateral Canthal Wrinkle Severity (IGA-LCWS), respectively.

	<u>Proportion of subjects achieving a score of none or mild at Week 4</u>
Glabellar lines	95.8 percent
Forehead lines	95.8 percent
Lateral canthal lines	91.7 percent

The study measured duration of effect in responders (those who achieved a score of none or mild at Week 4). These duration measures were defined as the median time to return to baseline wrinkle severity or the time to loss of none or mild wrinkle severity, both based on investigator and subject assessments.

	<u>Median time to return to baseline</u>	<u>Median time to loss of none or mild</u>
Glabellar lines	33.3 weeks	25.0 weeks
Forehead lines	35.3 weeks	24.0 weeks
Lateral canthal lines	35.2 weeks	28.1 weeks

SAFETY RESULTS

DaxibotulinumtoxinA for Injection was generally safe and well tolerated when all three facial areas were injected simultaneously. There were no treatment-related serious adverse events (SAEs). The most common adverse events (AEs) were injection site erythema (6.3 percent), facial discomfort (4.2 percent) and headache (2.1 percent). No eyelid or brow ptosis was reported.

PATIENT SATISFACTION RESULTS

Participants used a 7-point Subject Global Satisfaction with Treatment Questionnaire to rate their satisfaction with treatment of DaxibotulinumtoxinA for Injection. At Week 4, 100 percent of participants reported being at least "Somewhat Satisfied" with the treatment in all three areas, and 83.0 percent, 78.7 percent, and 80.9 percent reported being "Very Satisfied" with the treatment of their glabellar lines, forehead lines, and crow's feet, respectively.

"The positive results reported today are reflective of the real-world applications of neuromodulators in the upper face and provide an enhanced understanding of the safety and efficacy of DaxibotulinumtoxinA for Injection in the combined treatment of glabellar lines, forehead lines and lateral canthal lines," said Roman Rubio, M.D., Senior Vice President of Clinical Development at Revance. "This full upper face data complements our already reported results from individual dose-ranging studies, and further expands the body of knowledge on our next-generation neuromodulator. As we saw in our other aesthetic and therapeutic clinical trials, DaxibotulinumtoxinA for Injection delivered a meaningful duration of effect, ranging from 24 to 35 weeks, depending on the measure used and indication studied, while being generally well tolerated by patients."

"Many of my patients are looking for a more enduring treatment of their upper facial lines and wrinkles, as currently available neuromodulators typically only last 10 to 16 weeks, depending on the location within the face," said study investigator Jeffrey S. Dover, MD, FRCPC, co-director of SkinCare Physicians in Chestnut Hill, MA. "I am pleased to see the high patient satisfaction scores for DaxibotulinumtoxinA for Injection and expect a treatment regimen of just two times a year could be a welcome benefit to patients looking for long-lasting treatment."

Phase 2 Clinical Program in Upper Facial Lines

Revance's Phase 2, multicenter, open-label study to evaluate the efficacy and safety of DaxibotulinumtoxinA for Injection for the combined treatment of upper facial lines - glabellar (frown) lines, dynamic forehead lines, and lateral canthal lines, or crow's feet - was conducted at eight sites in the United States and Canada and enrolled 48 subjects, 18 years of age and above. Patients received a single DaxibotulinumtoxinA for Injection treatment of 40 units in five sites of the glabella, 32 units in four sites of the forehead and 48 units in six sites (three on each side) of the lateral canthus. After treatment on Day 1, subjects were followed for a minimum of 24 weeks and up to 36 weeks.

This trial was undertaken in addition to two Phase 2a open-label, dose escalation studies of DaxibotulinumtoxinA for Injection in the treatment of forehead lines following glabellar line injections and crow's feet lines injections. Revance [announced](#) positive results from the Phase 2a studies in June 2020. Interim Week 4 data from the Phase 2a studies in forehead lines and crow's feet were used in the final design of this upper facial lines Phase 2 study to optimize dosing and injection patterns.

In December of 2018, Revance completed a successful SAKURA Phase 3 program for DaxibotulinumtoxinA for Injection in the treatment of glabellar lines, reporting high response rates and 24-weeks duration of effect, based on a median time to loss of none or mild of wrinkle severity. Revance is currently awaiting a decision on the approval of DaxibotulinumtoxinA for Injection for the treatment of glabellar lines by the U.S. Food and Drug Administration, pending a manufacturing site inspection, which was delayed due to COVID-19 travel restrictions.

More information about the Phase 2 study can be found at www.clinicaltrials.gov.

About Revance Therapeutics, Inc.

Revance Therapeutics, Inc. is a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection. DaxibotulinumtoxinA for Injection combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. Revance has successfully completed a Phase 3 program for DaxibotulinumtoxinA for Injection in glabellar (frown) lines and is pursuing U.S. regulatory approval. Revance is also evaluating DaxibotulinumtoxinA for Injection in the full upper face, including glabellar lines, forehead lines and crow's feet, as well as in two therapeutic indications - cervical dystonia and adult upper limb spasticity. To accompany DaxibotulinumtoxinA for Injection, Revance owns a unique portfolio of premium products and services for U.S. aesthetics practices, including the exclusive U.S. distribution rights to the RHA® Collection of dermal fillers, the first and only range of FDA-approved fillers for correction of dynamic facial wrinkles and folds, and the HintMD fintech platform, which includes integrated smart payment, subscription and loyalty digital services. Revance has also partnered with Viatrix (formerly Mylan N.V.) to develop a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. Revance is dedicated to making a difference by transforming patient experiences. For more information or to join our team visit us at www.revance.com.

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Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements about the commercial potential of DaxibotulinumtoxinA for Injection; the potential value and application of DaxibotulinumtoxinA for Injection in neuromodulator indications; the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates; our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates, including with respect to the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines; the rate and degree of commercial interest and acceptance; development of a biosimilar to BOTOX®; our business strategy, timeline and other goals for our anticipated products, plans and prospects, including our commercialization plans; and potential benefits of our drug product candidates, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties relate, but are not limited to: the uncertain clinical development process; the risk that clinical trials may not have an effective design or generate positive results; the applicability of clinical study results to actual outcomes; the rate and degree of commercial acceptance and our ability to successfully commercialize DaxibotulinumtoxinA for Injection, if approved, and the timing and cost of commercialization activities; the status of commercial collaborations; the results and timing of our regulatory approvals; delays in the approval of our BLA for DaxibotulinumtoxinA for Injection for the treatment of glabellar lines due to COVID-19-related policies and travel restrictions currently in place at the FDA; the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, end user demand for our products, commercialization efforts, business operations, clinical trials and other aspects of our business; our ability to obtain funding for our operations; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and our financial performance, including future revenue, expenses and capital requirements. 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 our periodic filings with the Securities and Exchange Commission (SEC), including factors described in the section entitled "Risks Factors" on our Form 10-Q filed with the SEC on November 9, 2020. The forward-looking statements in this press release speak only as of the date hereof. We disclaim any obligation to update these forward-looking statements.

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