

# REVANCE®

## Revance Announces FDA Approval of DAXXIFY™ (DaxibotulinumtoxinA-lanm) for Injection, the First and Only Peptide-Formulated Neuromodulator With Long-Lasting Results

September 8, 2022

- *Approved label includes full 36-week efficacy data from Phase 3 SAKURA clinical program, positioning DAXXIFY™ as the first and only long-acting neuromodulator that demonstrates a median duration of six months and up to nine months for some patients<sup>1-6\*</sup> ‡*
- *Based on the data from SAKURA, DAXXIFY™ has the ability to deliver year-long results with as few as two treatments per year and has been proven to be effective, generally safe and well tolerated<sup>2-5\*</sup>*
- *DAXXIFY™, powered by Peptide Exchange Technology™, is the first true innovation in neuromodulator product formulation in over 30 years*
- *Conference call and webcast today at 8:00a.m. ET*

NASHVILLE, Tenn.--(BUSINESS WIRE)--Sep. 8, 2022-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved DAXXIFY™ (DaxibotulinumtoxinA-lanm) for injection for the temporary improvement of moderate to severe frown lines (glabellar lines) in adults. DAXXIFY™ is the first and only neuromodulator stabilized with Peptide Exchange Technology™ (PXT) and is free of both human serum albumin and animal-based components.<sup>1-2,7-11</sup> Most importantly, DAXXIFY™ has the ability to address duration of treatment effect, which we believe is the greatest unmet need with existing neuromodulators for both consumers and injectors.<sup>12</sup> The FDA approval, Revance's first, augments the company's innovative aesthetics portfolio and expands the company's access to the growing \$3.2 billion U.S. facial injectables market, further establishing Revance as an innovation leader in the industry and laying the groundwork for potential future therapeutic indications.<sup>13</sup>

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20220908005320/en/>



"The FDA approval of DAXXIFY™ is a foundational achievement for the company as it marks the culmination of years of pioneering research and development made possible by the outstanding execution of our talented team, along with strong support from the medical and investor communities. It has been an incredible and rewarding journey to realize our vision and bring this disruptive innovation to an industry that has remained largely unchanged for over 30 years," said Mark J. Foley, Chief Executive Officer. "Importantly, we are very pleased DAXXIFY™'s label includes data demonstrating the achievement of none or mild wrinkle severity based on investigator and subject assessments, as this provides the foundation for our marketing claims around duration of effect. We look forward to continuing to set new standards in aesthetics and to establishing a new category of long-lasting, peptide-enhanced neuromodulators.<sup>1,11"</sup>

Jeffrey Dover, MD, co-director of SkinCare Physicians of Chestnut Hill, commented, "As a SAKURA investigator, I'm pleased to see DAXXIFY™ now approved as the first and only peptide-formulated, long-acting neuromodulator in the market. Compelling data from the largest Phase 3 clinical program ever conducted for glabellar lines demonstrated that DAXXIFY™ was well tolerated and achieved clinically significant improvement with long-lasting results and high patient satisfaction. Notably, DAXXIFY™ was able to demonstrate a long duration of effect while only utilizing 0.18 ng of core active ingredient in the 40-unit labeled indication for glabellar lines. With today's approval, I look forward to helping patients, who have been accustomed to a 3 to 4-month duration profile with conventional neuromodulators, achieve year-long results with as few as two treatments per year.<sup>2-5 \*</sup>

The U.S. approval of DAXXIFY™ was based on the data generated in the SAKURA Phase 3 clinical trial program (SAKURA [1,2,3](#)), which included more than 2,700 patients and approximately 4,200 treatments. In the pivotal trials:

- 74% of subjects achieved a  $\geq$  two-grade improvement in

Vials of DAXXIFY (Photo: Business Wire)

glabellar lines at week 4 per both investigator and patient assessment<sup>1,4</sup>

- 88% achieved  $\geq$  two-grade improvement at week 4 per investigator assessment<sup>1</sup>
- 98% of subjects achieved none or mild wrinkle severity at week 4 per investigator assessment<sup>4</sup>
- 6-month median duration<sup>3,4\*</sup>
- Some patients maintained treatment results at 9 months<sup>2-4†</sup>
- Results seen as early as one day after treatment, typically seen within two days<sup>14</sup>

DAXXIFY™ is generally safe and well tolerated with no serious treatment-related adverse events reported in the clinical trials and has a safety profile consistent with other currently available neuromodulators in the aesthetics market.<sup>1-5,7-10</sup> The most common treatment-related adverse events with DAXXIFY™ observed in the pivotal trials were headache (6%) followed by eyelid ptosis (2%) and facial paresis, including facial asymmetry (1%).<sup>1</sup>

"With DAXXIFY's innovative and differentiated performance profile, alongside our portfolio that includes the RHA® Collection of dermal fillers and the OPUL® Relational Commerce platform, we have a real opportunity to build on our commercial success while setting a new standard for neuromodulator formulation," said Dustin S. Sjuts, President. "The strong inroads that we have made in the prestige market with our products and services will serve as a solid foundation upon which to launch DAXXIFY™. Consistent with our commercial strategy, DAXXIFY™ will be available through Revance Aesthetics' elite partners, known for delivering exceptional consumer outcomes and experiences. We are excited to be launching DAXXIFY™ shortly with an early training and education program at our world-class headquarters and experience center in Nashville, followed by a broader commercial launch."

Practices interested in receiving more information on DAXXIFY™ may reserve their spot at [RevanceAesthetics.com](https://www.revance.com).

### Conference Call

Revance will host a corresponding conference call and a live webcast today at 5:00 a.m. PT / 8:00 a.m. ET to discuss the FDA approval. Individuals interested in listening to the conference call may do so by registering via the webcast link in the investor relations section of the company's website at: [www.revance.com](https://www.revance.com).

To access the call by phone, please use this [registration link](#), and you will be provided with dial-in details. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time. A webcast replay will be available in the investor relations section on the company's website for 90 days following the completion of the call.

\* At least 50% of patients treated with DAXXIFY™ in SAKURA 1 and 2 had none or mild frown lines per investigator or patient assessments for 24 weeks and 23.9 weeks (6 months) or longer (respectively) after treatment.

† 5% of patients in SAKURA 1 and 3% of patients in SAKURA 2 achieved glabellar line severity of none or mild with DAXXIFY™ at Week 36 (9 months) per investigator's assessment. In SAKURA 1 and 2, and SAKURA 3 Treatments 1 and 2, a total of 7.5%, 5.4%, 17.4%, 11.6% of treated patients had not returned to baseline severity per both investigator and patient assessment at 9 months.

Per pooled data from SAKURA 1 and SAKURA 2.

### INDICATION

DAXXIFY™ (daxibotulinumtoxinA-lanm) for injection is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

### WARNING: DISTANT SPREAD OF TOXIN EFFECT

**The effects of DAXXIFY™ and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. DAXXIFY™ is not approved for the treatment of spasticity or any conditions other than glabellar lines.**

### IMPORTANT SAFETY INFORMATION

#### Contraindications

DAXXIFY™ contraindications include hypersensitivity to any botulinum toxin preparation or any of the components in the formulation and infection at the injection site(s).

#### Warnings and Precautions

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

The potency units of DAXXIFY™ are not interchangeable with other preparations of other botulinum toxin products. Recommended dose and frequency of administration should not be exceeded. Patients should seek immediate medical attention if respiratory, speech or swallowing difficulties occur. Use caution when administering to patients with pre-existing cardiovascular disease. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment.

#### Adverse Reactions

The most commonly observed adverse reactions ( $\geq 1\%$ ) were headache (6%), eyelid ptosis (2%) and facial paresis (1%).

#### Drug Interactions

Co-administration of DAXXIFY™ and aminoglycoside antibiotics, anticholinergic agents or any other agents interfering with neuromuscular transmission or muscle relaxants should only be performed with caution as the effect of DAXXIFY™ may be potentiated. The effect of administering

different botulinum neurotoxins during course of treatment with DAXXIFY™ is unknown.

### Use in Specific Populations

DAXXIFY™ is not recommended for use in children or pregnant women.

Please see DAXXIFY™ full [Prescribing Information, including Boxed Warning and Medication Guide](#).

### About DAXXIFY™

DAXXIFY™ (DaxibotulinumtoxinA-lanm) for injection is the first and only FDA approved long-lasting peptide-formulated neuromodulator product for use in adults for the temporary improvement of moderate to severe frown lines (glabellar lines).<sup>1-2,7-11</sup> DAXXIFY™ has the ability to deliver year-long results for patients with potentially only two treatments per year and has been proven to be effective, and generally safe and well tolerated.<sup>2-5 \*</sup> DAXXIFY™ is powered by a cell-penetrating peptide technology (Peptide Exchange Technology™), Revance's proprietary, synthetic, 35-amino-acid stabilizing excipient with a highly positive charge, and is free of human serum albumin or animal-based components.<sup>1,2,11</sup> Manufactured exclusively in the U.S., DAXXIFY™ is the first true innovation in neuromodulator product formulation in over 30 years.

Revance has evaluated this neuromodulator formulation in other Phase 2 clinical studies in aesthetics, including the full upper face, forehead lines and crow's feet as well as in therapeutic indications, including cervical dystonia and upper limb spasticity. Learn more at [RevanceAesthetics.com](#).

### About Revance

Revance is a commercial stage biotechnology company setting the new standard in healthcare with innovative aesthetic and therapeutic offerings that elevate patient and physician experiences. Revance's aesthetics portfolio of expertly created products and services, including DAXXIFY™ (DaxibotulinumtoxinA-lanm) for injection, the RHA® Collection of dermal fillers, and OPUL®, the first-of-its-kind Relational Commerce platform for aesthetic practices, deliver a differentiated and exclusive offering for the company's elite practice partners and their consumers. Revance has also partnered with Viatrix Inc. to develop a biosimilar to BOTOX®, which will compete in the existing short-acting neuromodulator marketplace. Revance's therapeutics pipeline is currently focused on muscle movement disorders including evaluating DaxibotulinumtoxinA for Injection in two debilitating conditions, cervical dystonia and upper limb spasticity.

Revance is headquartered in Nashville, Tennessee, with additional office locations in Newark, Pleasanton and Irvine, California. Learn more at [www.Revance.com](#) or connect with us on [LinkedIn](#).

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BOTOX® is a registered trademark of Allergan, Inc.

### Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to the rate and degree of commercial acceptance, opportunity and growth potential of DAXXIFY™ and DaxibotulinumtoxinA for Injection in other indications; the growth opportunities available to the company; our ability to set a new standard in aesthetics and healthcare and establish a new category of neuromodulator; the safety, efficacy and duration of DaxibotulinumtoxinA for Injection; development of a biosimilar to BOTOX® with our partner, Viatrix; statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans; the market opportunity for and market impact of DAXXIFY™; the aesthetics industry; patient and physician preferences; the outcomes for and experiences of patients; potential benefits of DAXXIFY™ to patients and physicians; and the extent to which our relationships in the prestige aesthetics market will benefit the commercial launch of DAXXIFY™, 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: our ability to successfully commercialize DAXXIFY™ and to continue to successfully commercialize the RHA® Collection of dermal fillers and OPUL®; the results, timing, costs, and completion of our research and development activities and regulatory approvals; our ability to obtain funding for our operations; the timing of capital expenditures; the accuracy of our estimates regarding expenses, future revenues, capital requirements, our financial performance and the economics of DaxibotulinumtoxinA for Injection, the RHA® Collection of dermal fillers and OPUL®; the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, end user demand for our products and services, the aesthetics market, commercialization efforts, business operations, regulatory meetings, inspections and approvals, clinical trials and other aspects of our business and on the market; our ability and the ability of our partners to manufacture supplies for DAXXIFY™ and our product candidates and to acquire supplies of the RHA® Collection of dermal fillers; the uncertain clinical development process; the risk that clinical trials may not have an effective design or generate positive results or that positive results would assure regulatory approval or commercial success; the applicability of clinical study results to actual outcomes; the rate and degree of economic benefit, safety, efficacy, commercial acceptance, market, competition and/or size and growth potential of the RHA® Collection of dermal fillers, OPUL® and our drug product candidates, if approved; reports of adverse events or safety concerns involving DAXXIFY™ or the RHA® Collection of dermal fillers; the timing and cost of commercialization activities; the proper training and administration of our products by physicians and medical staff; our ability to expand sales and marketing capabilities; the status of commercial collaborations; changes in and failures to comply with privacy and data protection laws; our ability to effectively manage our expanded operations in connection with the acquisition of Hint, Inc; the profitability of and our ability to scale OPUL® and the features and functionalities and benefits to practices and patients of OPUL®; interruptions or performance problems associated with HintMD or OPUL®; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; the cost and our ability to defend ourselves in product liability, intellectual property, class action or other lawsuits; the volatility of our stock price; 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 our periodic filings with the Securities and Exchange Commission (SEC), including factors described in the section entitled "Risks Factors" on our Form 10-K filed with the SEC on February 28, 2022 and including, without limitation, our Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August

9, 2022. 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.

#### SOURCES

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