REVANCE®

U.S. FDA Approves First Therapeutic Indication for Revance's DAXXIFY® (DaxibotulinumtoxinA-lanm) for Injection for the Treatment of Cervical Dystonia

August 14, 2023

- Provides Revance entry into the $2.5 billion U.S. therapeutic neuromodulator market.[1]

- Approval expands the DAXXIFY® label to include efficacy data over the 52-week ASPEN repeat dose clinical study.

- DAXXIFY® for cervical dystonia is the first and only peptide-formulated, long-lasting neuromodulator, designed to meet the needs of patients seeking improved treatment outcomes.[2-5]

- 88% of U.S. cervical dystonia patients experience symptom reemergence eight to 10 weeks after conventional neuromodulator treatment.[6]

NASHVILLE, Tenn.--(BUSINESS WIRE)--Aug. 14, 2023-- Revance Therapeutics, Inc. (Nasdaq: RVNC) today announced that the United States (U.S.) Food and Drug Administration (FDA) has approved the first therapeutic indication for DAXXIFY® (DaxibotulinumtoxinA-lanm) for injection for the treatment of cervical dystonia in adults.[7] DAXXIFY®, powered by Peptide Exchange Technology™, was previously approved by the FDA for the temporary improvement of glabellar lines (frown lines) in adults in September 2022 and is the first true innovation in neuromodulator product formulation in more than 30 years.[8-11]

Cervical dystonia is a chronic, debilitating disease in which the neck muscles contract involuntarily, causing abnormal movements, pain and awkward posture of the head and neck.[12,13] Neuromodulators are considered the first line of treatment for this condition, which effects roughly 60,000 Americans. In 2017, the U.S. FDA granted orphan drug designation to DAXXIFY® for the treatment of cervical dystonia in adults.

"We are very pleased to see the expansion of the DAXXIFY® label to include our first therapeutic indication, unlocking a new market opportunity for DAXXIFY® following the product's recent launch in the aesthetics market. Further, we believe FDA approval represents a significant advancement in the treatment of cervical dystonia," said Chief Executive Officer Mark J. Foley. "DAXXIFY's differentiated efficacy, duration and safety profile can help physicians deliver long-lasting symptom relief to patients suffering from cervical dystonia, while also helping payers address the total cost of care for this population. We look forward to conducting our early experience and education program, PrevU, which will involve a small group of thought leaders, followed by a progressive commercial rollout beginning in 2024. Today's approval is an important milestone for Revance, marking the start to our therapeutics franchise."

Peter McAllister, M.D., ASPEN investigator and co-founder and medical director of the New England Institute for Neurology and Headache, commented: "As an ASPEN investigator, I am excited to see the approval of a new treatment option to address symptom reemergence prior to retreatment, a common issue for cervical dystonia patients. Currently, patients experience painful and life-limiting symptom recurrence as early as eight to 10 weeks in clinical practice but cannot be re-treated until 12 weeks. DAXXIFY® is the first long-acting neuromodulator that has the potential to address this significant unmet need -- demonstrating durable symptom relief between treatment cycles and providing the opportunity to extend treatment intervals."

The U.S. approval of DAXXIFY® for the treatment of cervical dystonia in adults was based on data generated in the Phase 3 clinical program (ASPEN 1, ASPEN OLS), which included 382 patients and 1,240 treatments across up to five injection cycles over an 88-week time span, based on the masked, randomized ASPEN-1 and ASPEN Open Label Study (OLS).[2-5] In the pivotal ASPEN clinical study, DAXXIFY® was shown to be effective, generally safe, and well tolerated across both dose groups, 125U and 250U, with a median duration of effect of 24.0 and 20.3 weeks for the two dose groups respectively.[2-3,14-15*] Based on the ASPEN OLS study, symptoms continued to improve with successive DAXXIFY® treatments at doses up to 300U, while adverse events remained low.[15-16] In particular, dysphagia rates (difficulty swallowing) remained low (2.7% for ASPEN-1 and 4.2% for ASPEN-OLS), further supporting DAXXIFY's safety profile. [15-16]

The total U.S. therapeutic neuromodulator market opportunity for DAXXIFY® is $2.5 billion, which includes the $345 million cervical dystonia market.[1]

Providers and patients interested in receiving more information on DAXXIFY® are encouraged to visit https://www.daxxifytherapy.com/.

*Median duration of effect was defined as time from treatment until loss of ≥80% of the peak effect (change from baseline in TWSTRS total score averaged across weeks four and six).

DAXXIFY® (DaxibotulinumtoxinA-lanm) injection IMPORTANT SAFETY INFORMATION
INDICATIONS
DAXXIFY® (DaxibotulinumtoxinA-lanm) 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 and for the treatment of cervical dystonia in adults.

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 cervical dystonia and 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 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 are:
Glabellar lines (≥1%): headache (6%), eyelid ptosis (2%) and facial paresis (1%).
Cervical dystonia (≥5%): headache (9%), injection site pain (8%), injection site erythema (5%), muscular weakness (5%), and upper respiratory tract infection (5%).

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.

To report side effects associated with DAXXIFY®, please visit safety.revance.com, or call 1-877-373-8669. You may also report side effects to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

[DAXI-004726]

About DAXXIFY®

DAXXIFY® (DaxibotulinumtoxinA-lanm) for injection is the first and only FDA-approved, long-lasting, peptide-formulated neuromodulator product with approved indications in the U.S. for the temporary improvement of glabellar lines (frown lines) and for the treatment of cervical dystonia in adults. DAXXIFY® is powered by Peptide Exchange Technology™, Revance's proprietary, synthetic, 35-amino-acid stabilizing excipient, and is developed free of human serum albumin or animal-based components.[3,4] Manufactured in the U.S., DAXXIFY® is the first true innovation in neuromodulator product formulation in over 30 years.

About Revance

Revance is a biotechnology company setting the new standard in healthcare with innovative aesthetic and therapeutic offerings that enhance patient outcomes and physician experiences. Revance's portfolio includes DAXXIFY® (DaxibotulinumtoxinA-lanm) for injection, the RHA® Collection of dermal fillers in the U.S., and value-added services including the OPUL® Relational Commerce platform for aesthetic practices.

Revance has also partnered with Viatris Inc. to develop a biosimilar to onabotulinumtoxinA for injection and Shanghai Fosun Pharmaceutical to commercialize DAXXIFY® in China.

Revance is headquartered in Nashville, Tenn., with additional office locations in Newark and Irvine, Calif. Learn more at www.Revance.com, www.RevanceAesthetics.com, www.DAXXIFY.com, https://hcp.daxxify.com/, or connect with us on LinkedIn.

About Cervical Dystonia

Cervical dystonia is a painful condition in which the neck muscles contract involuntarily, causing abnormal movements and awkward posture of the head and neck. The movements may be sustained (tonic), jerky (clonic), or a combination. Cervical dystonia (also referred to as spasmodic torticollis) may be primary (meaning that it is the only apparent neurological disorder, with or without a family history) or may be the result of secondary causes (such as physical trauma).

First-line treatment for cervical dystonia is usually neuromodulator (botulinum toxin) injections, but additional treatments can include oral medications, surgery, and complementary therapies. Neuromodulators block the communication between the nerve and the muscle, relaxing the muscle, which alleviates abnormal involuntary movements and postures. Cervical dystonia can occur at any age, although most individuals first experience symptoms in middle age. Roughly 60,000 Americans suffer from this muscle movement disorder.

Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related the rate and degree of commercial acceptance, market opportunity and growth potential of DAXXIFY® in therapeutics and aesthetics; approval of DAXXIFY® for additional therapeutic indications; the extent to which DAXXIFY® will meet patients' needs; the efficacy, duration and safety of DAXXIFY®; the potential to set a new standard of care; development of an onabotulinumtoxinA biosimilar with our partner, Viatris; the commercialization of DAXXIFY® through our Fosun partnership; statements about our business strategy, timeline and other goals, plans and prospects, including our PrevU program and our

commercialization plans; patient and physician preferences, experiences and outcomes, including the reemergence of symptoms prior to retreatment; and potential benefits of DAXXIFY® to patients, physicians and payers, 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 to, but are not limited to: our ability to obtain funding for our operations; the timing of capital expenditures; the accuracy of our estimates regarding expenses, revenues, capital requirements, our financial performance and the economics of DAXXIFY®, the RHA® Collection of dermal fillers and OPUL®; the risk of future goodwill impairment charges; our ability to comply with our debt obligations and draw on our debt; the impact of macroeconomic factors 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 to maintain approval of our products; our ability and the ability of our partners to manufacture supplies for DAXXIFY® and our drug product candidates; our ability to acquire supplies of the RHA® Collection of dermal fillers; the uncertain clinical development process; our ability to obtain, and the timing relating to, regulatory submissions and approvals with respect to our drug product candidates and third-party manufacturers; 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 DAXXIFY®, the RHA® Collection of dermal fillers, and our drug product candidates, if approved; our ability to successfully commercialize DAXXIFY® and to continue to successfully commercialize the RHA® Collection of dermal fillers and OPUL®; 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 laws and regulations; our ability to effectively manage our expanded operations in connection with the acquisition of Hint, Inc.; the rate and degree of commercial acceptance, market, competition and growth potential of OPUL®; the profitability of and our ability to scale OPUL®, the features and functionalities and benefits to practices and patients of OPUL®; interruptions or performance problems associated with 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; our ability to limit or mitigate cybersecurity incidents; 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 "Risk Factors" on our Form 10-K filed with the SEC on February 28, 2023, and including, without limitation, our Form 10-Qs for the quarters ended March 31, 2023 and June 30, 2023, filed with the SEC on May 9, 2023 and August 8, 2023, respectively. 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

1. Market size as of 2022. CAGRs represent projected estimates. Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global 2023.
2. DAXXIFY®. Prescribing Information. Revance Therapeutics, Inc.; 2023.
3. Comella C, Jankovic J, Hauser R, et al. *Efficacy and Safety of DaxibotulinumtoxinA for Injection (DAXI) in Cervical Dystonia: ASPEN-1 Phase 3 Randomized Controlled Trial*. In review.
4. Data on file. ASPEN CSR. Revance. Newark, CA: Revance Therapeutics, Inc., 2018.
5. Data on file. ASPEN OLS CSR. Revance. Newark, CA: Revance Therapeutics, Inc., 2018.
6. Comella C, Ferreira JJ, Pain E, Azoulai M, Om S. Patient perspectives on the therapeutic profile of botulinum neurotoxin type A in cervical dystonia. *J Neurol*. 2021;268(3):903-912.
7. Data on File. DAXXIFY® Package Insert. Newark, CA: Revance Therapeutics, Inc., 2023.
8. Data on File. DAXXIFY® Package Insert. Newark, CA: Revance Therapeutics, Inc., 2022.
9. Botox® Prescribing Information, 2022.
10. Dysport® Prescribing Information, 2020.
11. Xeomin® Prescribing Information, 2021.
12. Dystonia Medical Research Foundation. Website. https://dystonia-foundation.org/what-is-dystonia/types-dystonia/cervical-dystonia/. Accessed 3/20/23.
13. Vu JP, Lee HY, Chen Q, et al. Head tremor and pain in cervical dystonia. *J Neurol*. 2021;268(5):1945-1950.
14. Patel A, McAllister P, Vitarella D, Gallagher C, Gross T. Dose Optimization of DaxibotulinumtoxinA for Injection Through Multiple Cycles of a Phase 3, Open-Label, Multicenter Trial in Adults with Cervical Dystonia. Submitted for American Academy of Physical Medicine and Rehabilitation Annual Meeting, 2023.
15. Comella C, Barbano R, Vasquez A. Efficacy of DaxibotulinumtoxinA for Injection Over Successive Treatments in Adults With Isolated Cervical Dystonia in the Phase 3 ASPEN-1 and ASPEN-OLS Trials. Poster presented at: Association of Academic Physiatrists Annual Meeting; Anaheim, CA; February 21-24, 2023.
16. Data on File. DOF 230401006. Post hoc analysis. Newark, CA: Revance Therapeutics, Inc., 2023.

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