Revance Announces U.S. FDA Acceptance of Supplemental Biologics License Application (sBLA) for DAXXIFY® (DaxibotulinumtoxinA-lanm) for Injection for the Treatment of Cervical Dystonia

January 6, 2023

- Prescription Drug User Fee Act (PDUFA) date of August 19, 2023 -

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jan. 6, 2023-- Revance Therapeutics, Inc. (Nasdaq: RVNC) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental Biologics License Application (sBLA) for DAXXIFY® (DaxibotulinumtoxinA-lanm) for injection for the treatment of cervical dystonia in adults, a chronic and debilitating neurologic condition affecting the muscles of the neck.[1] Revance was provided a Prescription Drug User Fee Act (PDUFA) date of August 19, 2023.

DAXXIFY®, the first and only peptide formulated neuromodulator, which was approved by the FDA for the temporary improvement of moderate to severe glabellar lines in adults, was evaluated in two Phase 3 clinical studies for cervical dystonia: ASPEN-1, a randomized, double-blind, placebo-controlled, parallel group trial, and ASPEN-OLS, an open-label, repeat dose, long-term safety trial.

“Positive results from our ASPEN Phase 3 clinical program demonstrate the potential of DAXXIFY® to bring sustained symptom relief to cervical dystonia patients, along with the potential for reduced frequency of annual injections,” said Mark J. Foley, Chief Executive Officer. “With the FDA’s acceptance of our sBLA and our upcoming PDUFA date in August 2023, we are one step closer to setting a new standard of care for cervical dystonia patients, where botulinum toxins are considered a first line treatment.”

In the pivotal ASPEN clinical program, DAXXIFY® was shown to be effective, generally safe and well tolerated across both dose groups, 125U and 250U, and clinically meaningful improvement was observed by both patients and clinicians, compared to placebo, with a median duration of effect of 24.0 and 20.3 weeks, for the two dose groups respectively. Results from the ASPEN-OLS study reinforced the safety findings reported from ASPEN-1 study, as well as the efficacy of DAXXIFY® with up to four repeat treatments.

“Painful symptom re-emergence is very common for patients with cervical dystonia and up until now physicians have not been able to fully address this issue with existing treatment options,” said Peter McAllister, MD. “As an ASPEN investigator, I am excited about the results of the DAXXIFY® Phase 3 trials, which demonstrate that a long-acting botulinum toxin can help address this significant unmet need in the treatment of cervical dystonia.”

The FDA’s acceptance of the company’s sBLA advances Revance’s opportunity in the nearly $1.0 billion, U.S. muscle movement disorder market, which includes both cervical dystonia and spasticity.[2-3]

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 (≥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). [4-5,10-14] 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.[5-8*] 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. [4,5,14] 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 Cervical Dystonia

According to the Dystonia Medical Research Foundation, 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. Current neuromodulator treatments for cervical dystonia have a duration of effect of approximately three months. Cervical dystonia can occur at any age, although most individuals first experience symptoms in middle age. The condition affects a few hundred thousand adults and children in the United States alone. The U.S. and global market opportunities for cervical dystonia are approximately $325 million and $438 million, respectively as of 2021.[2] The U.S. and global market opportunities for treating muscle movement disorders with botulinum toxins, which include cervical dystonia and spasticity (upper and lower limb), are approximately $929 million and $1.2 billion, respectively as of 2022.[2]

About Revance

Revance is a 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 Viatris 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.

Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to our PDUFA date; our market opportunity; the potential benefits, safety, efficacy and duration of DAXXIFY®; the potential to set a new standard of care; development of a biosimilar to BOTOX® with our partner, Viatris; statements about our business strategy, timeline and other goals, plans and prospects; and the outcomes for and experiences of patients; 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 future expenses, revenues and capital requirements, our financial performance and the economics of DAXXIFY®, 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 DAXXIFY®, 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; our ability to continue obtaining and maintaining intellectual property protection for DAXXIFY® and 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 September 30, 2022, filed with the SEC on November 8, 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

* 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.

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