Revance to Present New Data on DAXXIFY® (DaxibotulinumtoxinA-lanm) for Injection for the Treatment of Cervical Dystonia at the Association of Academic Physiatrists Annual Meeting

February 23, 2023

- New data demonstrate duration of efficacy up to 26-weeks and favorable safety profile with up to 5 injection cycles for Cervical Dystonia -

NASHVILLE, Tenn.--(BUSINESS WIRE)--Feb. 23, 2023-- Revance Therapeutics, Inc. (RVNC) today announced that new data on DAXXIFY® will be presented at the annual meeting of Association of Academic Physiatrists (AAP), taking place in Anaheim, California, February 21-24, 2023. The supplemental biologics license agreement for DAXXIFY® for the treatment of cervical dystonia is currently under regulatory review with the Food and Drug Administration.

A poster by Dr. Cynthia Comella and colleagues reports on 382 patients receiving 1,240 DAXXIFY® treatments across up to five injection cycles over an 88-week time span, based on the masked, randomized ASPEN-1 pivotal trial and subsequent ASPEN Open Label Study (OLS). The findings reinforce the extended duration of efficacy and favorable safety profile of DAXXIFY®. Notably the duration of effect, as measured by an ≥80% loss of peak Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) benefit, was maintained for approximately 20 to 26 weeks across the evaluable injection cycles. Dysphagia rates (difficulty swallowing) were low (2.7% for ASPEN-1 and 4.2% for ASPEN-OLS), further supporting DAXXIFY's safety profile.

A second poster, by Dr. Peter McAllister and colleagues, focuses on the 357 patients in the ASPEN OLS study in which physicians began dosing at either 125 or 250 U and were then permitted to refine dosing based on the clinical response. Symptoms continued to improve with successive DAXXIFY® treatments. The average dose at the last visit was 243 U, with 37% of patients receiving up to 300 U during the study. The rate of adverse events remained low with repeated dosing and at increasing dosing levels.

"These analyses demonstrate that DAXXIFY's extended duration of effect is sustained across multiple injection cycles." said David A. Hollander, MD, MBA, Chief Medical Officer. "The low rate of adverse events with repeated treatments and as doses were increased on an individual patient basis lends even further support that DAXXIFY® can offer a new and differentiated treatment option for patients with cervical dystonia."

Poster Details:

Title: Efficacy of DaxibotulinumtoxinA for Injection Over Successive Treatments in Adults with Isolated Cervical Dystonia in the Phase 3 ASPEN-1 and ASPEN-OLS Trials

Authors and Affiliation: Cynthia Comella, Richard Barbano, Alberto Vasquez, Todd Gross, Roman Rubio, Kristie Kooken, Domenico Vitarella; Rush University Medical Center, New Philadelphia, Ohio, USA; University of Rochester, Rochester, New York, USA; Suncoast Neuroscience Associates, St. Petersburg, Florida, USA; Revance Therapeutics, Inc., Nashville, Tennessee, USA; Blue Obsidian Consulting, LLC, Redwood City, California, USA; Revance Therapeutics, Inc, Nashville, Tennessee, USA

The above poster is available on the conference website. Please visit www.physiatry.org for the latest information.

Title: A Phase 3, Open-Label, Multi-Center Trial to Evaluate the Long-Term Safety and Efficacy of Repeat Treatments of DaxibotulinumtoxinA for Injection in Adults with Isolated Cervical Dystonia

Authors and Affiliation: Peter McAllister, Jaroslaw Slawek, Sebastian Paus, Daniel Truong, Todd M. Gross, Roman G. Rubio, Pat Kesslak, Domenico Vitarella; New England Institute for Neurology and Headache, Stamford, Connecticut, USA; Medical University of Gdańsk and St. Adalbert Hospital, Gdansk, Pomorskie, Poland; University of Bonn and GFO Kliniken Troisdorf, Bonn, Rheinland-Pfalz, Germany; University of California and the Parkinson's & Movement Disorder Institute, Riverside, California, USA; Blue Obsidian Consulting, LLC, Redwood City, California, USA; Revance Therapeutics, Inc., Nashville, Tennessee, USA

The above poster is available on the conference website. Please visit www.physiatry.org for the latest information.

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). [1-7] 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.[2,8-10]* 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. [1,2,7] Manufactured exclusively in the U.S., DAXXIFY® is the first true innovation in neuromodulator product formulation in over 30 years. Learn more at DAXXIFY.com.

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.

* 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.

Please see DAXXIFY® important safety information below and full Prescribing Information, including Boxed Warning and Medication Guide.

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 onabotulinumtoxinA for injection, which will compete in the existing short-acting neuromodulator marketplace. Revance's therapeutics pipeline is currently focused on muscle movement disorders including evaluating DAXXIFY® 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, www.RevanceAesthetics.com, www.DAXXIFY.com or connect with us on LinkedIn.

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Resilient Hyaluronic Acid® and RHA® are trademarks of TEOXANE SA.

Forward-Looking Statements

Any statements in this press release that are not statements of historical fact, including statements related to the approval of DAXXIFY® for the

treatment of cervical dystonia; our market opportunity; the potential benefits, safety, efficacy and duration of DAXXIFY®; our opportunity in therapeutics; 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 and other 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 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, and our drug product candidates, if approved; the rate and degree of commercial acceptance, market, competition and growth potential of OPUL® ; 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

1. Data on File. Draft DAXXIFY® Package Insert. Newark, CA: Revance Therapeutics, Inc, 2022.
2. Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global 2021.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230223005449/en/

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